

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 20-F**

(Mark One)

☐ REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2018

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

OR

☐ SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of event requiring this shell company report _____

Commission file number 001-38097

ARGENX SE

(Exact name of registrant as specified in its charter and translation of Registrant's name into English)

The Netherlands

(Jurisdiction of incorporation or organization)

Willemstraat 5

4811 AH, Breda, the Netherlands

(Address of principal executive offices)

Tim Van Hauwermeiren

argenx BVBA

Industriepark Zwijnaarde 7,

Building C

9052 Zwijnaarde (Ghent)

Belgium

+32 9 310 34 00

TVanHauwermeiren@argenx.com

(Name, telephone, e-mail and/or facsimile number and address of company contact person)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class:

American Depositary Shares, each representing one ordinary share with a nominal value of €0.10 per share

Ordinary shares with a nominal value of €0.10 per share *

Name of each exchange on which registered:

Nasdaq Global Select Market

Nasdaq Global Select Market*

* Not for trading, but only in connection with the registration of the American Depositary Shares.

Securities registered or to be registered pursuant to Section 12(g) of the Act: None.

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: None.

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report:

As of December 31, 2018 35,975,312 ordinary shares were outstanding, including ordinary shares represented by American Depositary Shares.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes X No ☐

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

Yes ☐ No X ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days:

Yes X No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files):

Yes X No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer X

Accelerated filer ☐

Non-accelerated filer ☐

Emerging growth company ☐

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 13(a) of the Exchange Act.

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☐

International Financial Reporting Standards as issued by the International Accounting Standards Board X

Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.

Item 17 ☐ Item 18 ☐

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No X ☒

TABLE OF CONTENTS

	<u>Page</u>
<u>PART I</u>	1
<u>ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS</u>	1
<u>ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE</u>	1
<u>ITEM 3. KEY INFORMATION</u>	1
<u>3.A. SELECTED FINANCIAL DATA</u>	1
<u>3.B. CAPITALIZATION AND INDEBTEDNESS</u>	2
<u>3.C. REASONS FOR THE OFFER AND USE OF PROCEEDS</u>	2
<u>3.D. RISK FACTORS</u>	2
<u>ITEM 4. INFORMATION ON THE COMPANY</u>	62
<u>4.A. HISTORY AND DEVELOPMENT OF THE COMPANY</u>	62
<u>4.B. BUSINESS OVERVIEW</u>	65
<u>4.C. ORGANIZATIONAL STRUCTURE</u>	129
<u>4.D. PROPERTY, PLANTS AND EQUIPMENT</u>	130
<u>ITEM 4A. UNRESOLVED STAFF COMMENTS</u>	130
<u>ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS</u>	130
<u>5.A. OPERATING RESULTS</u>	130
<u>5.B. LIQUIDITY AND CAPITAL RESOURCES</u>	148
<u>5.C. RESEARCH AND DEVELOPMENT, PATENTS AND LICENSES</u>	152
<u>5.D. TREND INFORMATION</u>	152
<u>5.E. OFF-BALANCE SHEET ARRANGEMENTS</u>	152
<u>5.F. TABULAR DISCLOSURE OF CONTRACTUAL OBLIGATIONS</u>	152
<u>5.G. SAFE HARBOR</u>	153
<u>ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES</u>	153
<u>6.A. DIRECTORS AND SENIOR MANAGEMENT</u>	153
<u>6.B. COMPENSATION</u>	158
<u>6.C. BOARD PRACTICES</u>	168
<u>6.D. EMPLOYEES</u>	173
<u>6.E. SHARE OWNERSHIP</u>	173
<u>ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS</u>	173
<u>7.A. MAJOR SHAREHOLDERS</u>	173
<u>7.B. RELATED PARTY TRANSACTIONS</u>	177
<u>7.C. INTERESTS OF EXPERTS AND COUNSEL</u>	179
<u>ITEM 8. FINANCIAL INFORMATION</u>	179
<u>8.A. CONSOLIDATED STATEMENTS AND OTHER FINANCIAL INFORMATION</u>	179
<u>8.B. SIGNIFICANT CHANGES</u>	179
<u>ITEM 9. THE OFFER AND LISTING</u>	180
<u>9.A. OFFER AND LISTING DETAILS</u>	180
<u>9.B. PLAN OF DISTRIBUTION</u>	180
<u>9.C. MARKETS</u>	180
<u>9.D. SELLING SHAREHOLDERS</u>	180
<u>9.E. DILUTION</u>	180
<u>9.F. EXPENSES OF THE ISSUE</u>	180
<u>ITEM 10. ADDITIONAL INFORMATION</u>	180
<u>10.A. SHARE CAPITAL</u>	180
<u>10.B. MEMORANDUM AND ARTICLES OF ASSOCIATION</u>	181
<u>10.C. MATERIAL CONTRACTS</u>	181
<u>10.D. EXCHANGE CONTROLS</u>	181

10.E.	TAXATION	181
10.F.	DIVIDENDS AND PAYING AGENTS	214
10.G.	STATEMENT BY EXPERTS	214
10.H.	DOCUMENTS ON DISPLAY	214
10.I.	SUBSIDIARY INFORMATION	214
ITEM 11.	QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	214
ITEM 12.	DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES	215
12.A.	DEBT SECURITIES	215
12.B.	WARRANTS AND RIGHTS	215
12.C.	OTHER SECURITIES	215
12.D.	AMERICAN DEPOSITARY SHARES	215
	PART II	218
ITEM 13.	DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES	218
ITEM 14.	MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS	218
ITEM 15.	CONTROLS AND PROCEDURES	218
ITEM 16.	[RESERVED]	220
ITEM 16A.	AUDIT COMMITTEE FINANCIAL EXPERT	221
ITEM 16B.	CODE OF ETHICS	221
ITEM 16C.	PRINCIPAL ACCOUNTANT FEES AND SERVICES	221
ITEM 16D.	EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES	222
ITEM 16E.	PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS	222
ITEM 16F.	CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT	222
ITEM 16G.	CORPORATE GOVERNANCE	222
ITEM 16H.	MINE SAFETY DISCLOSURE	223
	PART III	224
ITEM 17.	FINANCIAL STATEMENTS	224
ITEM 18.	FINANCIAL STATEMENTS	224
ITEM 19.	EXHIBITS	224

Cautionary Statement with Respect to Forward-Looking Statements

This annual report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are based on our management's beliefs and assumptions and on information currently available to our management. All statements other than present and historical facts and conditions contained in this annual report, including statements regarding our future results of operations and financial positions, business strategy, plans and our objectives for future operations, are forward-looking statements. When used in this annual report, the words "anticipate," "believe," "can," "could," "estimate," "expect," "intend," "is designed to," "may," "might," "will," "plan," "potential," "predict," "objective," "should," or the negative of these and similar expressions identify forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- the initiation, timing, progress and results of clinical trials of our product candidates, including statements regarding when results of the trials will be made public;
- the potential attributes and benefits of our product candidates and their competitive position with respect to other alternative treatments;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- our plans related to the commercialization of our product candidates, if approved;
- the anticipated pricing and reimbursement of our product candidates, if approved;
- the timing or likelihood of regulatory filings and approvals for any product candidates;
- our ability to establish sales, marketing and distribution capabilities for any of our product candidates that achieve regulatory approval;
- our regulatory strategy and our ability to establish and maintain manufacturing arrangements for our product candidates;
- the scope and duration of protection we are able to establish and maintain for intellectual property rights covering our product candidates, platform and technology;
- our plans regarding, and consequences of, our restructuring and possible redomiciliation;
- our estimates regarding expenses, future revenues, capital requirements and our needs for additional financing;
- the rate and degree of market acceptance of our product candidates, if approved;
- the potential benefits of our current collaborations;
- our plans and ability to enter into collaborations for additional programs or product candidates; and
- the impact of government laws and regulations on our business.

You should refer to the section of this annual report titled "Item 3.D.—Risk Factors" for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this annual report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these

statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

You should read this annual report and the documents that we reference in this annual report and have filed as exhibits to the annual report completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

Information regarding market and industry statistics contained in this annual report is included based on information available to us that we believe is accurate. Forecasts and other forward looking information obtained from this available information is subject to the same qualifications and the additional uncertainties accompanying any estimates of future market size, revenue and market acceptance of products and services.

PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

A. SELECTED FINANCIAL DATA

Our consolidated audited financial statements have been prepared in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB. We derived the selected consolidated statements of profit and loss and other comprehensive income, selected condensed consolidated statements of financial position and selected condensed consolidated statements of cash flow as of December 31, 2018, 2017 and 2016 and for the years ended December 31, 2018, 2017 and 2016 from our consolidated audited financial statements, included herein. Our selected consolidated statement of profit and loss and other comprehensive income, selected condensed consolidated statement of financial position and selected condensed consolidated statement of cash flow as of December 31, 2015 and for the year ended December 31, 2015 have been extracted from our audited consolidated financial statements, which are not included herein. Our selected consolidated statement of profit and loss and other comprehensive income, selected condensed consolidated statement of financial position and selected condensed consolidated statement of cash flow as of December 31, 2014 and for the year ended December 31, 2014 have been extracted from our unaudited consolidated financial statements, which are not included herein. This data should be read together with, and is qualified in its entirety by reference to, “Item 5—Operating and Financial Review and Prospects” as well as our financial statements and notes thereto appearing elsewhere in this report. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

	Year ended December 31,				
	2018	2017	2016	2015	2014
	(In thousands, except share and per share data)				
Consolidated statement of profit and loss and other comprehensive income:					
Revenue	€ 21,482	€ 36,415	€ 14,713	€ 6,854	€ 3,756
Other operating income	7,749	4,841	2,439	3,101	1,621
Research and development expenses	(83,609)	(51,740)	(31,557)	(20,635)	(12,641)
Selling, general and administrative expenses	(27,471)	(12,448)	(7,011)	(4,925)	(3,479)
Operating loss	(81,849)	(22,932)	(21,416)	(15,605)	(10,743)
Financial income	3,694	1,250	73	112	137
Financial expenses	—	—	—	—	(3)
Exchange gains/(losses)	12,308	(5,797)	(31)	181	295
Loss before taxes	(65,847)	(27,479)	(21,374)	(15,312)	(10,314)
Income tax expense	(794)	(597)	—	—	—
Loss for the year and total comprehensive loss	€ (66,641)	€ (28,076)	€ (21,374)	€ (15,312)	€ (10,314)
Weighted average number of shares outstanding	33,419,356	24,609,536	18,820,612	15,734,007	7,551,576
Basic and diluted loss per share	€ (1.99)	€ (1.14)	€ (1.14)	€ (0.97)	€ (1.37)

	As of December 31,				
	2018	2017	2016	2015	2014
	(In thousands)				
Condensed consolidated statement of financial position:					
Cash, cash equivalents and current financial assets	€ 564,569	€ 359,775	€ 96,728	€ 42,327	€ 55,973
Total assets	578,458	370,908	105,772	45,962	58,510
Deferred revenue — current and non-current	2,161	10,070	30,206	4,141	3,451
Total liabilities	40,063	25,977	42,398	8,684	8,428
Share capital	3,597	3,217	2,012	1,580	1,571
Share premium	673,454	430,518	126,358	82,169	81,940
Total equity	538,395	344,931	63,374	37,278	50,082

	As of December 31,				
	2018	2017	2016	2015	2014
	(In thousands)				
Condensed consolidated statement of cash flows:					
Cash and cash equivalents at beginning of the period	€ 190,867	€ 89,897	€ 35,514	€ 32,180	€ 22,720
Net cash flows (used in) / from operating activities	(53,839)	(36,546)	10,599	(13,897)	(5,235)
Net cash flows (used in) / from investing activities	(107,542)	(162,052)	(806)	16,812	(23,341)
Net cash flows (used in) / from financing activities	244,671	305,365	44,621	238	37,741
Effect of exchange rate differences on cash and cash equivalents	6,883	(5,797)	(31)	181	295
Cash and cash equivalents at end of the period	€ 281,040	€ 190,867	€ 89,897	€ 35,514	€ 32,180

B. CAPITALIZATION AND INDEBTEDNESS

Not applicable.

C. REASONS FOR THE OFFER AND USE OF PROCEEDS

Not applicable.

D. RISK FACTORS

Our business faces significant risks. You should carefully consider all of the information set forth in this annual report and in our other filings with the U.S. Securities and Exchange Commission, or the SEC, including the following risk factors which we face and which are faced by our industry. Our business, financial condition or results of operations could be materially and adversely affected if any of these risks occurs. This report also contains forward-looking statements that involve risks and uncertainties. See “Cautionary Statement with Respect to Forward-Looking Statements.” Our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain factors including the risks described below and elsewhere in this annual report and our other SEC filings. See “Cautionary Statement with Respect to Forward-Looking Statements” above.

Risks Related to Our Financial Position and Need for Additional Capital

We are a clinical-stage biopharmaceutical company and have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

We are a clinical-stage biopharmaceutical company with a limited operating history. Since our inception, we have incurred significant operating losses. We incurred losses for the year and total comprehensive losses of €28.1 million and €66.6 million for the years ended December 31, 2017 and 2018, respectively. As of December 31, 2018, we had accumulated losses of €169.6 million. Our losses resulted principally from costs incurred in research and development, preclinical testing, clinical development of our product candidates as well as costs incurred for research programs and from general and administrative costs associated with our operations. In addition, we expect to continue to incur significant costs associated with our listings in the United States and in

Europe. In the future, we intend to continue to conduct research and development, preclinical testing, clinical trials and regulatory compliance activities, and we intend to establish a sales, marketing and distribution infrastructure. These expenses, together with anticipated general and administrative expenses, will result in incurring further significant losses for the next several years. Our losses, among other things, will continue to cause our working capital and shareholders' equity to decrease. We anticipate that our expenses will increase substantially if and as we:

- execute the Phase 3 clinical trials of efgartigimod (ARGX-113) in myasthenia gravis, or MG, and, potentially, primary immune thrombocytopenia, or ITP, and pemphigus vulgaris, or PV;
- complete the Phase 2 clinical trials of efgartigimod in ITP and PV and launch a Phase 2 clinical trial in chronic inflammatory demyelinating polyneuropathy, or CIDP;
- complete the Phase 2 clinical trials in acute myeloid leukemia, or AML and high-risk myelodysplastic syndrome, or MDS;
- execute a Phase 2 clinical trial in ITP with the subcutaneous formulation of efgartigimod;
- continue the research and development of our other clinical- and preclinical-stage product candidates and discovery stage programs;
- seek to enhance our technology platform and discover and develop additional product candidates;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize any product candidates for which we may obtain regulatory approval;
- maintain, expand and protect our intellectual property portfolio, including litigation costs associated with defending against alleged patent infringement claims;
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts; and
- experience any delays or encounter any issues relating to any of the above, including failed studies, ambiguous trial results, safety issues or other regulatory challenges.

Since our inception in 2008, we have invested most of our resources in developing our product candidates, building our intellectual property portfolio, developing our supply chain, conducting business planning, raising capital and providing general and administrative support for these operations. We do not currently have any approved products and have never generated any revenue from product sales. To date, we have funded our operations through public and private placements of equity securities, upfront, milestone and expense reimbursement payments received from our collaborators, funding from governmental bodies and interest income from the investment of our cash, cash equivalents and financial assets.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, discovering and developing additional product candidates, obtaining regulatory approval for any product candidates that successfully complete clinical trials, establishing manufacturing and marketing capabilities and ultimately selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities. We may

never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with pharmaceutical and biological product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or EMA, or other comparable foreign authorities to perform studies in addition to those we currently anticipate, or if there are any delays in completing our clinical trials or the development of any of our product candidates, our expenses could increase and revenue could be further delayed.

Even if we do generate product royalties or product sales, we may never achieve or sustain profitability on a quarterly or annual basis. Our failure to sustain profitability would depress the market price of the ADSs and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. A decline in the market price of the ADSs also could cause you to lose all or a part of your investment.

We may need substantial additional funding in order to complete the development and commercialization of our product candidates. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate certain of our product development or research operations.

To date, we have funded our operations through public and private placements of equity securities, upfront, milestone and expense reimbursement payments received from our collaborators, funding from governmental bodies and interest income from the investment of our cash, cash equivalents and financial assets. We expect to require additional funding in the future to sufficiently finance our operations and advance development of our product candidates.

Our future capital requirements for efgartigimod, cusatuzumab (ARGX-110) or our preclinical programs will depend on many factors, including:

- the progress, timing and completion of preclinical testing and clinical trials for our current or any future product candidates;
- the number of potential new product candidates we identify and decide to develop;
- the costs involved in growing our organization to the size needed to allow for the research, development and potential commercialization of our current or any future product candidates;
- the costs involved in filing patent applications and maintaining and enforcing patents or defending against claims or infringements raised by third parties;
- the maintenance of our existing collaboration agreements and the entry into new collaboration agreements;
- the time and costs involved in obtaining regulatory approval for our product candidates and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to any of our product candidates;
- selling and marketing activities undertaken in connection with the potential commercialization of our current or any future product candidates, if approved, and costs involved in the creation of an effective sales and marketing organization; and
- the amount of revenues, if any, we may derive either directly or in the form of royalty payments from future sales of our product candidates, if approved.

We expect that the costs of development and commercialization will significantly increase due to the extended product development roadmap for cusatuzumab as part of our collaboration with Janssen Pharmaceuticals, Inc., or Janssen. Although this collaboration agreement provides a joint decision process to approve the development plan as well as the budget, we will not control the actual amounts spent within such approved budget and we cannot control or guarantee that these funds are spent in the most efficient way.

Our ability to raise additional funds will depend on financial, economic and market conditions and other factors, over which we may have no or limited control. As a result, we will need additional financing to support our continuing operations. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity or debt financings or other sources, which may include collaborations with third parties. Adequate additional financing may not be available to us on acceptable terms, or at all. Our ability to raise additional funds will depend on financial, economic and market conditions and other factors, over which we may have no or limited control. The inability for us to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. As a result, we may be forced to delay, reduce or terminate the development or commercialization of all or part of our research programs or product candidates or we may be unable to take advantage of future business opportunities.

Raising additional capital may cause dilution to holders of our ordinary shares or ADSs restrict our operations or require us to relinquish rights to our technologies or product candidates.

In order to further advance development of our product candidates, discover additional product candidates and pursue our other business objectives, we will need to seek additional funds.

We cannot guarantee that future financing will be available in sufficient amounts or on commercially reasonable terms, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of holders of our ordinary shares or the ADSs and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of the ADSs to decline. The sale of additional equity or convertible securities would dilute all of our existing shareholders and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of ADSs. The incurrence of indebtedness could result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. Further, any additional fundraising efforts may divert our management from its day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any of our product candidates, or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

Since our inception in 2008, we have invested most of our resources in developing our product candidates, building our intellectual property portfolio, developing our supply chain, conducting business planning, raising capital and providing general and administrative support for these operations. Our most advanced candidate, efgartigimod, completed a Phase 2 clinical trial for the treatment of MG and ITP. In September 2018, we launched our first Phase 3 clinical trial in MG. We also have a third ongoing Phase 2 clinical trial of efgartigimod for the treatment of PV and announced the analysis of efgartigimod in a fourth indication, CIDP. We also concluded a

Phase 1 clinical trial of a subcutaneous formulation of efgartigimod for the treatment of chronic autoimmune diseases. We have not yet demonstrated an ability to obtain regulatory approvals, manufacture a commercial-scale product or conduct sales and marketing activities necessary for successful product commercialization. In addition, given our limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors in achieving our business objectives. If we are successful at completing the approval process for one of our product candidates, we may consider transitioning from our current research and development focus to focusing on commercializing our products. We may not be successful in such a transition or may incur greater costs than expected, which would materially adversely affect our business, prospects, financial condition and results of operation. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or more experience developing and commercializing antibody-based drugs.

Risks Related to the Development and Clinical Testing of Our Product Candidates

All of our product candidates are in preclinical or early-stage clinical development. Clinical drug development is a lengthy and expensive process with uncertain timelines and uncertain outcomes. If clinical trials of our product candidates, particularly efgartigimod and cusatuzumab, are prolonged or delayed, we or our collaborators may be unable to obtain required regulatory approvals, and therefore will be unable to commercialize our product candidates on a timely basis or at all, which will adversely affect our business.

To obtain the requisite regulatory approvals to market and sell any of our product candidates, we or our collaborator for such candidates must demonstrate through extensive preclinical studies and clinical trials that our products are safe, pure and potent or effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process and our future clinical trial results may not be successful.

We may experience delays in our ongoing clinical trials and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all.

Clinical trials can be delayed, suspended, or terminated for a variety of reasons, including the following:

- delays in or failure to obtain regulatory approval to commence a trial, including as a result of circumstances beyond our control, such as the partial shutdown of operations at U.S. governmental agencies involved in granting necessary approvals;
- delays in or failure to reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in or failure to obtain institutional review board, or IRB, or ethics committee approval at each site;
- delays in or failure to recruit suitable patients to participate in a trial;
- failure to have patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- adding new clinical trial sites;
- manufacturing sufficient quantities of product candidate for use in clinical trials;

- third-party actions claiming infringement by our product candidates in clinical trials and obtaining injunctions interfering with our progress;
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires;
- safety or tolerability concerns could cause us or our collaborators, as applicable, to suspend or terminate a trial if we or our collaborators find that the participants are being exposed to unacceptable health risks;
- changes in regulatory requirements, policies and guidelines;
- lower than anticipated retention rates of patients and volunteers in clinical trials;
- our third-party research contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- delays in establishing the appropriate dosage levels in clinical trials;
- the difficulty in certain countries in identifying the sub-populations that we are trying to treat in a particular trial, which may delay enrollment and reduce the power of a clinical trial to detect statistically significant results; and
- the quality or stability of the product candidate falling below acceptable standards.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted or ethics committees, by the Data Review Committee, or DRC, or Data Safety Monitoring Board, or DSMB, for such trial or by the EMA, the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the EMA, the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, including those relating to the class to which our product candidates belong, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates and impair our ability to commercialize our product candidates and may harm our business and results of operations.

Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates or result in the development of our product candidates being stopped early.

Clinical trials must be conducted in accordance with the FDA, the EMA and other applicable regulatory authorities' legal requirements and regulations, and are subject to oversight by these governmental agencies and IRBs at the medical institutions where the clinical trials are conducted or ethics committees. In addition, clinical trials must be conducted with supplies of our product candidates produced under current good manufacturing practices, or cGMP, requirements and other regulations. Furthermore, we rely on CROs and clinical trial sites to

ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance. We depend on our collaborators and on medical institutions and CROs to conduct our clinical trials in compliance with Good Clinical Practice, or GCP, requirements. To the extent our collaborators or the CROs or investigators fail to enroll participants for our clinical trials, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays or both, which may harm our business. In addition, clinical trials that are conducted in countries outside the European Union and the United States may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non-European Union and non-U.S. CROs, as well as expose us to risks associated with clinical investigators who are unknown to the FDA or the EMA, and different standards of diagnosis, screening and medical care.

Preclinical drug development is uncertain. Some or all of our preclinical programs, such as ARGX-116 and ARGX-117, may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these product candidates on a timely basis or at all, which would have an adverse effect on our business.

In order to obtain FDA or EMA approval to market a new biological product we must demonstrate proof of safety, purity and potency or efficacy in humans. To meet these requirements we will have to conduct adequate and well-controlled clinical trials. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned Investigational New Drug application, or IND, in the United States, or a Clinical Trial Authorization Application, or CTA, in Europe. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA or EMA will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of these product candidates. Thus, we cannot be sure that we will be able to submit INDs or CTAs for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or CTAs will result in the FDA or EMA allowing clinical trials to begin.

Conducting preclinical testing is a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity, novelty and intended use of the product candidate, and often can be several years or more per product candidate. Delays associated with product candidates for which we are directly conducting preclinical testing and studies may cause us to incur additional operating expenses. Moreover, we may continue to be affected by delays associated with the preclinical testing and studies of certain product candidates conducted by our potential partners over which we have no control. The commencement and rate of completion of preclinical studies and studies for a product candidate may be delayed by many factors, including, for example:

- the inability to generate sufficient preclinical or other in vivo or in vitro data to support the initiation of clinical studies;
- delays in reaching a consensus with regulatory agencies on study design; and
- the FDA or EMA not allowing us to rely on previous findings of safety and efficacy for other similar but approved products and published scientific literature.

Moreover, even if clinical trials do begin for these preclinical programs, our development efforts may not be successful, and clinical trials that we conduct or that third parties conduct on our behalf may not demonstrate sufficient safety, purity and potency or efficacy to obtain the requisite regulatory approvals for any of our product candidates or product candidates employing our technology. Even if we obtain positive results from preclinical studies or initial clinical trials, we may not achieve the same success in future trials.

The results of preclinical studies and early-stage clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Initial success in our ongoing clinical trials may not be indicative of results obtained when these trials are completed or in later stage trials.

Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Furthermore, there can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development of any of our product candidates. There is a high failure rate for drugs and biologics proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies, and any such setbacks in our clinical development could have a material adverse effect on our business and operating results.

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim, topline or preliminary data from our clinical trials. Preliminary and interim data from our clinical trials may change as more patient data become available. Preliminary or interim data from our clinical trials are not necessarily predictive of final results. Preliminary and interim data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues, more patient data become available and we issue our final clinical trial report. Interim, topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, preliminary and interim data should be viewed with caution until the final data are available. Material adverse changes in the final data compared to the interim data could significantly harm our business prospects.

Our product candidates may have serious adverse, undesirable or unacceptable side effects which may delay or prevent marketing approval. If such side effects are identified during the development of our product candidates or following approval, if any, we may need to abandon our development of such product candidates, the commercial profile of any approved label may be limited, or we may be subject to other significant negative consequences following marketing approval, if any.

Undesirable side effects that may be caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, the EMA or other comparable foreign authorities. While our preclinical and clinical studies for our product candidates to date have generally been well tolerated from a risk-benefit perspective, we have observed adverse events and treatment emergent adverse events in our clinical studies to date, and we may see additional adverse events and TEAEs in our ongoing and future trials, which may be more serious than those observed to date, and as a result, our ongoing and future trials may not support this conclusion.

The results of future clinical studies may show that our product candidates cause undesirable or unacceptable side effects or even death. In such an event, our trials could be suspended or terminated and the FDA, the EMA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly. Further, because all of our product candidates and preclinical programs, other than efgartigimod, are based on our SIMPLE Antibody™ platform, any adverse safety or efficacy findings related to any product candidate or preclinical program may adversely impact the viability of our other product candidates or preclinical programs.

Additionally, if any of our product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such products and require us to take our approved product off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- regulatory authorities may require a medication guide outlining the risks of such side effects for distribution to patients, or that we implement a risk evaluation and mitigation strategy, or REMS, plan to ensure that the benefits of the product outweigh its risks;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us, our collaborators or our potential future partners from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our products.

We face significant competition for our drug discovery and development efforts, and if we do not compete effectively, our commercial opportunities will be reduced or eliminated. We may not be successful in our efforts to use and expand our SIMPLE Antibody™ platform, our NHance® and ABDEG™ technologies, or the licensed POTELLIGENT® technology, to build a pipeline of product candidates and develop marketable products due to significant competition and technological change, which could limit or eliminate the market opportunity for our product candidates and technology platforms.

The market for pharmaceutical products is highly competitive. Our competitors include many established pharmaceutical companies, biotechnology companies, universities and other research or commercial institutions, many of which have substantially greater financial, research and development resources than we have. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing pharmaceutical products. Smaller and early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, the development of our products. The fields in which we operate are characterized by rapid technological change and innovation. There can be no assurance that our competitors are not currently developing, or will not in the future develop, technologies and products that are equally or more effective or are more economically attractive than any of our current or future technology or product. Competing products or technology platforms may gain faster or greater market acceptance than our products or technology platforms and medical advances or rapid technological development by competitors may result in our product candidates or technology platforms becoming non-competitive or obsolete before we are able to recover our research and development and commercialization expenses. If we, our product candidates or our technology

platforms do not compete effectively, it may have a material adverse effect on our business, prospects, financial condition and results of operation.

Competition in the autoimmune field is intense and involves multiple monoclonal antibodies, other biologics and small molecules either already marketed or in development by many different companies including large pharmaceutical companies such as AbbVie Inc. (Humira/rheumatoid arthritis); Amgen Inc. (Enbrel/rheumatoid arthritis); Biogen, Inc. (Tysabri/multiple sclerosis); GlaxoSmithKline plc, or GSK, (Benlysta/lupus); F. Hoffman-La Roche AG, or Roche (Rituxan/often used off label); and Janssen (Remicade/rheumatoid arthritis and Stelara/psoriasis). In some cases, these competitors are also our collaborators. In addition, these and other pharmaceutical companies have monoclonal antibodies or other biologics in clinical development for the treatment of autoimmune diseases. In addition to the current standard of care, we are aware that Alexion Pharmaceuticals, Inc. is selling Soliris for the treatment of adult patients with generalized MG who are anti-acetylcholine receptor antibody positive and that GSK; Roche; Novartis AG; CSL Behring; Grifols, S. A.; BioMarin Pharmaceutical, Inc.; Curavac; Millennium Pharmaceuticals, Inc.; UCB S.A.; Ra Pharmaceuticals; and Momenta Pharmaceuticals, among others, are developing drugs that may have utility for the treatment of MG. We are aware that Rigel Pharmaceuticals, Inc.; Dova Pharmaceuticals; Bristol-Myers Squibb; Immunomedics; Protalex, Inc.; Principia Biopharma and others are developing drugs that may have utility for the treatment of ITP. We are aware that Roche is selling Rituxan for the treatment of moderate to severe PV and Principia, Alexion and others are developing drugs that may have utility for the treatment of PV. Furthermore, we are aware of competing products specifically targeting FcRn and being developed by UCB S. A.; Momenta, Inc.; Alexion; Immunovant; and Affibody.

Competition in the leukemia and lymphoma space is intense, with many compounds in clinical trials by large multinational pharmaceutical companies and specialized biotech companies. Rituxan (Roche), Adcetris (Seattle Genetics, Inc. / Takeda Pharmaceutical Company, Ltd.), Darzalex (Janssen) and Poteligeo (Kyowa Hakko Kirin Co., Ltd.) are some examples of monoclonal antibodies approved for the treatment of Hodgkin's lymphoma, non-Hodgkin's lymphoma, multiple myeloma or other blood cancers. We are aware of AML drugs recently approved by the FDA, such as Daurismo (Pfizer), Mylotarg (Pfizer), Rydapt (Amgen), Vyxeos (Jazz Pharmaceuticals, Inc.) and IDHIFA (Agiros, Inc. and Celgene). In addition, we are aware of a number of other companies with development stage programs that may compete with cusatuzumab in the future, if it is approved. We anticipate that we will face intense and increasing competition as new treatments enter the market and advanced technologies become available.

There are several monoclonal antibody drug discovery companies that may compete with us in the search for novel therapeutic antibody targets, including Adimab LLC; Merus N.V.; Regeneron Pharmaceuticals, Inc.; Xencor Inc. and MorphoSys AG. We are aware that a product candidate in development by Scholar Rock, Inc. may compete with ABBV-151 (formerly named ARGX-115) and a product candidate in development by Ionis Pharmaceuticals, Inc. may compete with ARGX-116, if they are approved.

We depend on enrollment of patients in our clinical trials for our product candidates. If we are unable to enroll patients in our clinical trials, our research and development efforts and business, financial condition and results of operations could be materially adversely affected.

Identifying and qualifying patients to participate in our clinical trials is critical to our success. Patient enrollment depends on many factors, including the size and nature of the patient population, eligibility criteria for the trial, the proximity of patients to clinical sites, the design of the clinical protocol, the availability of competing clinical trials, the availability of new drugs approved for the indication the clinical trial is investigating, and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies. Since some of our product candidates are focused on addressing rare diseases and conditions, there are limited patient pools from which to draw in order to complete our clinical trials in a timely and cost-effective manner. For example, the number of patients suffering from each of MG; ITP; PV; T-cell lymphoma, or TCL; and acute myeloid leukemia, or AML, is small and has not been established with precision. If the actual number of patients with these disorders is smaller than we anticipate, we may encounter difficulties in enrolling

patients in our clinical trials, thereby delaying or preventing development and approval of our drug candidates. Even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials.

Furthermore, our efforts to build relationships with patient communities may not succeed, which could result in delays in patient enrollment in our clinical trials. In addition, any negative results we may report in clinical trials of our drug candidate may make it difficult or impossible to recruit and retain patients in other clinical trials of that same drug candidate. Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, some of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or at the commercial stage; and our product liability insurance may not cover all damages from such claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. Currently, we have no products that have been approved for commercial sale; however, the current and future use of product candidates by us and our corporate collaborators in clinical trials, and the potential sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients who use the product, healthcare providers, pharmaceutical companies, our corporate collaborators or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially adversely affect the market for our product candidates or any prospects for commercialization of our product candidates. Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products due to negative public perception;
- damage to our reputation;
- withdrawal of clinical trial participants or difficulties in recruiting new trial participants;
- initiation of investigations by regulators;
- costs to defend or settle the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenues from product sales; and
- the inability to commercialize any of our product candidates, if approved.

Although we maintain adequate product liability insurance for our product candidates, it is possible that our liabilities could exceed our insurance coverage. We intend to expand our insurance coverage to include the sale

of commercial products if we obtain marketing approval for any of our product candidates. However, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Should any of the events described above occur, this could have a material adverse effect on our business, financial condition and results of operations.

The regulatory approval processes of the U.S. Food and Drug Administration, the European Medicines Agency and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA, the EMA and comparable foreign authorities is unpredictable but typically takes many years, if obtained at all, following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, the EMA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials, including the size of our clinical trials or the doses tested;
- we may be unable to demonstrate to the satisfaction of the FDA, the EMA or comparable foreign regulatory authorities that a product candidate is safe, pure and potent or effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, the EMA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA, the EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials or may require us to test additional dose regimens of our product candidates;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a Biologics License Application, or BLA, to the FDA or other submission or to obtain regulatory approval in the United States, the European Union or elsewhere;
- the FDA, the EMA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the FDA, the EMA or comparable foreign regulatory authorities may fail to approve the companion diagnostics we contemplate developing with partners; and

- the approval policies or regulations of the FDA, the EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects. The FDA, the EMA and other comparable foreign authorities have substantial discretion in the approval process, and determining when or whether regulatory approval will be obtained for any of our product candidates. Even if we believe the data collected from clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA, the EMA or any other regulatory authority.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Even if our product candidates obtain regulatory approval, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

If the FDA, the EMA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval, all of which may result in significant expense and limit our ability to commercialize such products. In addition, any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate.

Our product candidates are classified as biologics in the United States and, therefore, can only be sold if we obtain a BLA from the FDA. The holder of a BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The holder of a BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Failure to comply with a BLA or any other ongoing regulatory obligation may result in suspension of approval to manufacture or distribute the relevant product, as well as fines or imprisonment for violations.

If there are changes in the application of legislation, regulations or regulatory policies, or if problems are discovered with a product or our manufacture of a product, or if we or one of our distributors, licensees or co-marketers fails to comply with regulatory requirements, the regulators could take various actions. These include imposing fines on us, imposing restrictions on the product or its manufacture and requiring us to recall or remove the product from the market. The regulators could also suspend or withdraw our marketing authorizations, requiring us to conduct additional clinical trials, change our product labeling or submit additional applications for marketing authorization. If any of these events occurs, our ability to sell such product may be impaired, and we may incur substantial additional expense to comply with regulatory requirements, which could materially adversely affect our business, financial condition and results of operations.

Due to our limited resources and access to capital, we must, and have in the past decided to, prioritize development of certain product candidates over other potential candidates. These decisions may prove to have been wrong and may adversely affect our revenues.

Because we have limited resources and access to capital to fund our operations, we must decide which product candidates to pursue and the amount of resources to allocate to each. Our decisions concerning the allocation of research, collaboration, management and financial resources toward particular compounds, product candidates or therapeutic areas may not lead to the development of viable commercial products and may divert resources away from better opportunities. Similarly, our decisions to delay, terminate or collaborate with third parties in respect of certain product development programs may also prove not to be optimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the market potential of our product candidates or misread trends in the biopharmaceutical industry, in particular for our lead product candidates, our business, financial condition and results of operations could be materially adversely affected.

Risks Related to Commercialization of Our Product Candidates

Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and may affect the prices we may set.

In the United States, the European Union and other foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, became law. The ACA is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the ACA of importance to our potential product candidates are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic products, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices and extending rebate liability to prescriptions for individuals enrolled in Medicare Advantage plans;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for products that are inhaled, infused, instilled, implanted or injected;
- expanding the types of entities eligible for the 340B drug discount program;
- establishing the Medicare Part D coverage gap discount program, which requires manufacturers to provide a 50% point-of-sale-discount off the negotiated price of applicable products to eligible

beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient products to be covered under Medicare Part D;

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of the Center for Medicare and Medicaid Innovation within Centers for Medicare & Medicaid, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription product spending (funding has been allocated to support the mission of the CMS Innovation through 2019).

Since its enactment, some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial, congressional, and executive challenges. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the ACA. The U.S. Supreme Court has upheld certain key aspects of the legislation, including a tax-based shared responsibility payment imposed on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly known as the requirement that all individuals maintain health insurance coverage or pay a penalty, referred to as the "individual mandate." However, as a result of tax reform legislation passed in December 2017, the individual mandate has been eliminated effective January 1, 2019. According to the Congressional Budget Office, the repeal of the individual mandate will cause 13 million fewer Americans to be insured in 2027 and premiums in insurance markets may rise.

Since January 2017, President Trump has signed several executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. One such Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. The loss of the cost share reduction payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. Further, on June 14, 2018, the U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than \$12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known.

Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed repeal legislation, it has enacted laws that modify certain provisions of the ACA, such as removing or delaying penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance, delaying the implementation of certain ACA-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. On December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseparable feature of the ACA, and therefore because the mandate was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. The Trump administration and CMS have both stated that the ruling will have no immediate effect, and on December 30, 2018, the same judge issued an order staying the judgment pending appeal. It is unclear how this decision and any subsequent appeals and other efforts to repeal and replace the ACA will impact the ACA and our business. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. We will continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These new laws may result in additional reductions in Medicare and other healthcare funding. For example, on August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2012 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to

subsequent legislative amendments to the statute, including without limitation the Bipartisan Budget Act of 2015, will remain in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. The Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

CMS may develop new payment and delivery models, such as bundled payment models. CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. On November 30, 2018, CMS announced a proposed rule that would amend the Medicare Advantage and Medicare Part D prescription drug benefit regulations to reduce out of pocket costs for plan enrollees and allow Medicare plans to negotiate lower rates for certain drugs. Among other things, the proposed rule changes would allow Medicare Advantage plans to use pre authorization (PA) and step therapy (ST) for six protected classes of drugs and, with certain exceptions, permit plans to implement PA and ST in Medicare Part B drugs; and change the definition of "negotiated prices" as well as add a definition of "price concession" in the regulations. It is unclear whether these proposed changes will be accepted, and if so, what effect such changes will have on our business.

In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Specifically, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Further, legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals, if any, of our product candidates, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing conditions and other requirements.

Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our current or any future products. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most European Union member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing European Union and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize any products for which we obtain marketing approval. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or our collaborators are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

We may be subject to healthcare and privacy laws, regulation and enforcement. Our failure to comply with these laws could harm our results of operations and financial conditions.

Although we do not currently have any products on the market, our current and future operations may be directly, or indirectly through our customers and third-party payors, subject to various U.S. federal and state healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute. Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. These laws may impact, among other things, our proposed sales, marketing and education programs and constrain our business and financial arrangements and relationships with third-party payors, healthcare professionals who participate in our clinical research program, healthcare professionals and others who recommend, purchase, or provide our approved products, and other parties through which we market, sell and distribute our products for which we obtain marketing approval. In addition, we may be subject to patient data privacy and security regulation by both the U.S. federal government and the other states and countries in which we conduct our business. See also the risk factor titled “We may fail to comply with evolving European and other privacy laws.” below. Finally, our current and future operations are subject to additional healthcare-related statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. The laws that may affect our ability to operate include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any

kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the U.S. federal false claims and civil monetary penalties laws, including, without limitation, the civil False Claims Act (which can be enforced through “qui tam,” or whistleblower actions, by private citizens on behalf of the federal government), which impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent or for knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government;
- the anti-inducement law prohibits, among other things, the offering or giving of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person know or should know is likely to influence the beneficiary’s selection of a particular supplier of items or services reimbursable by a federal or state governmental program;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, and as amended again by the Final HIPAA Omnibus Rule, published in January 2013, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and healthcare providers, as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information;
- the U.S. Federal Food, Drug, and Cosmetic Act, or FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. federal legislation commonly referred to as Physician Payments Sunshine Act, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’s Health Insurance Program to report annually to the CMS information related to certain payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing

information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts; and

- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm and the curtailment or restructuring of our operations. Defending against any such actions can be costly and time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

The risk of us being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. For example, the definition of the “remuneration” under the federal Anti-Kickback Statute has been interpreted to include anything of value. Further, courts have found that if “one purpose” of remuneration is to induce referrals, the federal Anti-Kickback Statute is violated.

Additionally, recent healthcare reform legislation has strengthened federal and state healthcare fraud and abuse laws. For example, the ACA amends the intent requirement of the federal Anti-Kickback Statute and criminal healthcare fraud statutes to clarify that liability under these statutes does not require a person or entity to have actual knowledge of the statutes or a specific intent to violate them. Moreover, the ACA provides that the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act. Furthermore, on January 31, 2019, the Department of Health and Human Services (HHS) and HHS Office of Inspector General (OIG) proposed an amendment to one of the existing Anti-Kickback safe harbors (42 C.F.R. 1001.952(h)) which would prohibit certain pharmaceutical manufacturers from offering rebates to pharmacy benefit managers (“PBMs”) in the Medicare Part D and Medicaid managed care programs. The proposed amendment would remove protection for “discounts” from Anti-Kickback enforcement action, and would include criminal and civil penalties for knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or reward the referral of business reimbursable under federal health care programs. At the same time, HHS also proposed to create a new safe harbor to protect point-of-sale discounts that drug manufacturers provide directly to patients, and adds another safe harbor to protect certain administrative fees paid by manufacturers to PBMs. If this proposal is adopted, in whole or in part, it could affect the pricing and reimbursement for any products for which we receive approval in the future. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management’s attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance or

reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

We may fail to comply with evolving European and other privacy laws.

In Europe, Directive 95/46/EC of the European Parliament and of the Council of October 24, 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, or the Directive, and Directive 2002/58/EC of the European Parliament and of the Council of July 12, 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (as amended by Directive 2009/136/EC), or the e-Privacy-Directive, have required the European Union, or EU member states, to implement data protection laws to meet strict privacy requirements. Violations of these requirements can result in administrative measures, including fines, or criminal sanctions. The e-Privacy Directive will likely be replaced in time by a new e-Privacy Regulation which may impose additional obligations and risk for our business.

Beginning on May 25, 2018, the Directive was replaced by Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, or the GDPR. The GDPR imposes a broad range of strict requirements on companies subject to the GDPR, such as us, including requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the European Economic Area, or the EEA, including to the United States, providing details to those individuals regarding the processing of their personal information, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, and record-keeping. The GDPR substantially increases the penalties to which we could be subject in the event of any non-compliance, including fines of up to 10,000,000 Euros or up to 2% of our total worldwide annual turnover for certain comparatively minor offenses, or up to 20,000,000 Euros or up to 4% of our total worldwide annual turnover for more serious offenses. Given the new law, we face uncertainty as to the exact interpretation of the new requirements, and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the new law.

In particular, national laws of member states of the EU are in the process of being adapted to the requirements under the GDPR, thereby implementing national laws which may partially deviate from the GDPR and impose different obligations from country to country, so that we do not expect to operate in a uniform legal landscape in the EU. Also, in the field of handling genetic data, the GDPR specifically allows national laws to impose additional and more specific requirements or restrictions, and European laws have historically differed quite substantially in this field, leading to additional uncertainty.

We must also ensure that we maintain adequate safeguards to enable the transfer of personal data outside of the EEA, in particular to the United States in compliance with European data protection laws, including the GDPR. We expect that we will continue to face uncertainty as to whether our efforts to comply with our obligations under European privacy laws will be sufficient. If we are investigated by a European data protection authority, we may face fines and other penalties. Any such investigation or charges by European data protection authorities could have a negative effect on our existing business and on our ability to attract and retain new clients or pharmaceutical partners. We may also experience hesitancy, reluctance, or refusal by European or multi-national clients or pharmaceutical partners to continue to use our products and solutions due to the potential risk exposure as a result of the current (and, in particular, future) data protection obligations imposed on them by certain data protection authorities in interpretation of current law, including the GDPR. Such clients or pharmaceutical partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to do business with us. Any of the foregoing could materially harm our business, prospects, financial condition and results of operations.

If we fail to obtain orphan drug designation or obtain or maintain orphan drug exclusivity for our products, our competitors may sell products to treat the same conditions and our revenue will be reduced.

Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the European Union, after a recommendation from the EMA's Committee for Orphan Medicinal Products, or COMP, the European Commission grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union. Additionally, designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biological product or where there is no satisfactory method of diagnosis, prevention or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity. In the European Union, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

We may from time to time seek orphan drug designation in the United States or Europe for certain indications addressed by our product candidates. For example, in September 2017, the FDA granted orphan drug designation for the use of efgartigimod for the treatment of MG. Even if we are able to obtain orphan designation, we may not be the first to obtain marketing approval for such indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan drug is approved, the FDA or the EMA can subsequently approve the same drug with the same active moiety for the same condition if the FDA or the EMA concludes that the later drug is safer, more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may obtain regulatory approval. The successful commercialization of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish adequate reimbursement levels and pricing policies. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

Even if our product candidates are approved for marketing, sales of such product candidates will depend, in part, on the extent to which third-party payors, including government health programs in the United States (such as Medicare and Medicaid), commercial health insurers, and managed care organizations, provide coverage and establish adequate reimbursement levels for such product candidates. Moreover, increasing efforts by

governmental and third-party payors in the European Union, the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

In the United States and markets in other countries, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered and patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use any product candidates we may develop unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of such product candidates. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse health care providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services and imposing controls to manage costs, especially on drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates and other therapies to be substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing drugs may limit the amount we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given drug product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates, and may not be able to obtain a satisfactory financial return on products that we may develop. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product candidate that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product candidate, and the cost of these studies would be in addition to the costs required to obtain FDA or other comparable marketing approvals. Even after pharmacogenomic studies are conducted, product candidates may not be considered medically necessary or cost-effective. A decision by a third-party payor not to cover any product candidates we may develop could reduce physician utilization of such product candidates once approved and have a material adverse effect on our sales, results of operations and financial condition. Additionally, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. For example, the payor may require co-payments that patients find unacceptably high. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor. Third-party reimbursement and coverage may not be adequate to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. The insurance coverage and reimbursement status of newly-approved products for orphan diseases is particularly uncertain, and failure to obtain or maintain adequate coverage and reimbursement for any such product candidates could limit our ability to generate revenue.

The containment of healthcare costs also has become a priority for U.S. federal and state and international governments and the prices of pharmaceuticals have been a focus in this effort. Governments have shown

significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, and mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Adoption of price controls and cost-containment measures, and the adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our potential revenue from the sale of any product candidates for which we may obtain approval. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more of our product candidates for which we or our collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Obtaining and maintaining reimbursement status is time-consuming and costly. No uniform policy for coverage and reimbursement for drug products exists among third-party payors in the United States. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

Further, there have been several recent U.S. congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, Congress and the Trump administration have each indicated that it will continue to pursue new legislative and/or administrative measures to control drug costs. Individual state legislatures have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing. Some of these measures include price or patient reimbursement constraints, discounts, restrictions on certain product access, marketing cost disclosure and transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

Outside the United States, we will face challenges in obtaining adequate coverage and payment for any product candidates we may develop. Pricing of prescription pharmaceuticals is subject to governmental control in many countries. Pricing negotiations with governmental authorities can extend well beyond the receipt of regulatory marketing approval for a product candidate and may require us to conduct a clinical trial that compares the effectiveness of any product candidates we may develop to other available therapies to support cost-effectiveness. The conduct of such a clinical trial could be expensive, involve additional risk and result in delays in our commercialization efforts.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed upon. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies (so called health technology assessments, or HTAs) in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its member states to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other member states allow companies to fix their own prices for products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceuticals, and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe

fiscal and debt crises experienced by many countries in the European Union. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel trade (arbitrage between low-priced and high-priced member states) can further reduce prices. Special pricing and reimbursement rules may apply to orphan drugs. Inclusion of orphan drugs in reimbursement systems tend to focus on the medical usefulness, need, quality and economic benefits to patients and the healthcare system in relation to those drugs. Acceptance of any medicinal product for reimbursement may come with cost, use and often volume restrictions, which again can vary by country. In addition, results-based rules of reimbursement may apply. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates, if approved in those countries.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of healthcare and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most European Union member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing European Union and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize any products for which we obtain marketing approval.

The future commercial success of our product candidates will depend on the degree of market acceptance of our potential products among physicians, patients, healthcare payers and the medical community.

Our product candidates are at varying stages of development and we may never have a product that is commercially successful. To date, we have no product authorized for marketing. Our lead product candidates are in early stages of clinical development. Our lead product candidates will require further clinical investigation, regulatory review, significant marketing efforts and substantial investment before they can provide us with any revenues. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many other companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval for the marketing of their product. Due to the inherent risk in the development of pharmaceutical products, it is probable that not all or none of the product candidates in our portfolio will successfully complete development and be commercialized. We do not expect to be able to commercialize any of our products for a number of years. Furthermore, when available on the market, our products may not achieve an adequate level of acceptance by physicians, patients and the medical community, and we may not become profitable. In addition, efforts to educate the medical community and third-party payers on the benefits of our products may require significant resources and may never be successful which would prevent us from generating significant revenues or becoming profitable. Market acceptance of our future products by physicians, patients and healthcare payers will depend on a number of factors, many of which are beyond our control, including, but not limited to:

- the wording of the product label;

- changes in the standard of care for the targeted indications for any product candidate;
- sales, marketing and distribution support;
- potential product liability claims;
- acceptance by physicians, patients and healthcare payers of each product as safe, effective and cost-effective;
- relative convenience, ease of use, ease of administration and other perceived advantages over alternative products;
- prevalence and severity of adverse events or publicity;
- limitations, precautions or warnings listed in the summary of product characteristics, patient information leaflet, package labeling or instructions for use;
- the cost of treatment with our products in relation to alternative treatments;
- the extent to which products are approved for inclusion and reimbursed on formularies of hospitals and managed care organizations; and
- whether our products are designated in the label, under physician treatment guidelines or under reimbursement guidelines as a first-line, second-line, or third-line or last-line therapy.

If our product candidates fail to gain market acceptance, this will have a material adverse impact on our ability to generate revenues to provide a satisfactory, or any, return on our investments. Even if some products achieve market acceptance, the market may prove not to be large enough to allow us to generate significant revenues.

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of our pharmaceutical product candidates even if they are granted marketing approval. We may not be able to successfully achieve support among such third parties for our product candidates, and our relationships with such parties are subject to regulations.

Our current and future arrangements with providers, researchers, consultants, third-party payors and customers are subject to broadly applicable federal and state fraud and abuse, anti-kickback, false claims, transparency and patient privacy laws and regulations and other healthcare laws and regulations that may constrain our business and/or financial arrangements. Restrictions under applicable federal and state healthcare laws and regulations include, without limitation, the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program, such as Medicare and Medicaid;
- the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false, fictitious, or fraudulent or knowingly making, using, or causing to be made or used a false record or statement to avoid, decrease, or conceal an obligation to pay money to the federal government;

- HIPAA, which created additional federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by HITECH, and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without the appropriate authorization by entities subject to the law, such as healthcare providers, health plans and healthcare clearinghouses and their respective business associates;
- the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the ACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or CMS, within the U.S. Department of Health and Human Services, information related to payments and other transfers of value made by that entity to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring pharmaceutical manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

We will be required to spend substantial time and money to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations. Recent healthcare reform legislation has strengthened these federal and state healthcare laws. For example, the ACA amends the intent requirement of the federal Anti-Kickback Statute and criminal healthcare fraud statutes to clarify that liability under these statutes does not require a person or entity to have actual knowledge of the statutes or a specific intent to violate them. Moreover, the ACA provides that the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

Violations of these laws can subject us to criminal, civil and administrative sanctions, including monetary penalties, damages, fines, disgorgement, individual imprisonment and exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm, and the required curtailment or restructuring of our operations. Moreover, we expect that there will continue to be federal and state laws and regulations, proposed and implemented, that could impact our future operations and business.

We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize our products on our own or together with suitable collaboration partners.

We do not have a sales or marketing infrastructure and have no experience in the sale or marketing of pharmaceutical products. To achieve commercial success for any approved product, we must develop or acquire a

sales and marketing organization, outsource these functions to third parties or enter into collaboration arrangements with third parties.

We may decide to establish our own sales and marketing capabilities and promote our product candidates if and when regulatory approval has been obtained in the major European Union countries and the United States. There are risks involved should we decide to establish our own sales and marketing capabilities or enter into arrangements with third parties to perform these services. Even if we establish sales and marketing capabilities, we may fail to launch our products effectively or to market our products effectively since we have no experience in the sales and marketing of pharmaceutical products. In addition, recruiting and training a sales force is expensive and time consuming and could delay any product launch. In the event that any such launch is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- unforeseen costs and expenses associated with creating an independent sales and marketing organization; and
- costs of marketing and promotion above those anticipated by us.

If we enter into arrangements with third parties to perform sales and marketing services, our product revenues or the profitability of these product revenues to us could be lower than if we were to market and sell any products that we develop ourselves. Such collaborative arrangements may place the commercialization of our products outside of our control and would make us subject to a number of risks including that we may not be able to control the amount or timing of resources that our collaborative partner devotes to our products or that our collaborator's willingness or ability to complete its obligations, and our obligations under our arrangements may be adversely affected by business combinations or significant changes in our collaborator's business strategy. In addition, we may not be successful in entering into arrangements with third parties to sell and market our products or may be unable to do so on terms that are favorable to us. Acceptable third parties may fail to devote the necessary resources and attention to sell and market our products effectively.

If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we may not be successful in commercializing our products, which in turn would have a material adverse effect on our business, prospects, financial condition and results of operations.

Our product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the

safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar product, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

Risks Related to Our Business and Industry

Nearly all aspects of our activities are subject to substantial regulation. No assurance can be given that any of our product candidates will fulfill regulatory compliance. Failure to comply with such regulations could result in delays, suspension, refusals and withdrawal of approvals, as well as fines.

The international biopharmaceutical and medical technology industry is highly regulated by the FDA, the EMA and other comparable foreign authorities and by other national or supra-national regulatory authorities that impose substantial requirements covering nearly all aspects of our activities notably on research and development, manufacturing, preclinical tests, clinical trials, labeling, marketing, sales, storage, record keeping, promotion and pricing of our product candidates. Such regulation is further subject to regular review by the FDA, the EMA and other comparable foreign authorities which may result in changes in applicable regulation. If we do not comply with one or more of these requirements in a timely manner, or at all, our product development could experience significant delays as a result of the FDA, the EMA or other comparable regulatory authorities recommending non-approval or restrictions on approval of a product candidate, leading to an inability to successfully commercialize any of our product candidates, which would materially harm our business. Any failure of any of our product candidates in clinical studies or to receive regulatory approval could have a material adverse effect on our business, results of operations and financial condition. If any of our product candidates fails to obtain approval on the basis of any applicable condensed regulatory approval process, this will prevent such product candidate from obtaining approval in a shortened time frame, or at all, resulting in increased expenses which would materially harm our business.

Compliance with requirements laid down by local regulatory authorities is necessary in each country where we, or any of our partners or licensees, conduct said activities in whole or in part. Local regulatory authorities notably include the EMA and the FDA. In order to market our future products in regions such as the European Economic Area, United States of America, Asia Pacific and many other foreign jurisdictions, we must obtain separate regulatory approvals. The approval procedures vary among countries and can require additional clinical testing, and the time required to obtain approval may differ from that required to obtain for example FDA or EMA approval. Moreover, clinical studies conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA or EMA does not ensure approval by the comparable foreign authorities in other countries, and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other foreign countries or by the FDA or EMA.

There can be no assurance that our product candidates will fulfil the criteria required to obtain necessary regulatory approval to access the market. Also, at this time, we cannot guarantee or know the exact nature, precise timing and detailed costs of the efforts that will be necessary to complete the remainder of the development of our research programs and products candidates. Each of the FDA, the EMA and other comparable foreign authorities may impose its own requirements, may discontinue an approval or revoke a license, may refuse to grant approval, or may require additional data before granting approval, notwithstanding that approval may have been granted by the FDA, the EMA or one or more other comparable foreign authority. The FDA, the EMA or other comparable foreign authorities may also approve a product candidate for fewer or more limited indications or patient

sub-segments than requested or may grant approval subject to the performance of post-marketing studies. The EMA's, the FDA's or other regulatory authority's approval may be delayed, limited or denied for a number of reasons, most of which are beyond our control. Such reasons could include, among others, the production process or site not meeting the applicable requirements for the manufacture of regulated products, or the products not meeting applicable requirements for safety, purity or potency, or efficacy, during the clinical development stage or after marketing. No assurance can be given that clinical trials will be approved by the FDA, the EMA or other comparable foreign authorities or that products will be approved for marketing by such regulatory authorities in any pre-determined indication or intended use. Any of the FDA, the EMA and other comparable foreign authorities may disagree with our interpretation of data submitted for their review.

We and our collaborative partners are, or may become subject to, numerous ongoing other regulatory obligations, such as data protection, environmental, health and safety laws and restrictions on the experimental use of animals. The costs of compliance with such applicable regulations, requirements or guidelines could be substantial, and failure to comply could result in sanctions, including fines, injunctions, civil penalties, denial of applications for marketing authorization of our products, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly increase our or our collaborative partners' costs or delay the development and commercialization of our product candidates.

Because we are subject to environmental, health and safety laws and regulations, we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities which may adversely affect our business and financial condition.

Our operations, including our research, development, testing and manufacturing activities, are subject to numerous environmental, health and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, handling, release and disposal of and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens. If we fail to comply with such laws and regulations, we could be subject to fines or other sanctions.

As with other companies engaged in activities similar to ours, we face a risk of environmental liability inherent in our current and historical activities, including liability relating to releases of or exposure to hazardous or biological materials. Environmental, health and safety laws and regulations are becoming more stringent. We may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case, our production and development efforts may be interrupted or delayed and our financial condition and results of operations may be materially adversely affected.

Our employees, independent contractors, principal investigators, CROs, consultants, vendors and collaboration partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, consultants, vendors and collaboration partners may engage in fraudulent conduct or other illegal activities. Misconduct by these parties could include intentional, reckless and negligent conduct or unauthorized activities that violate: (i) the regulations of the FDA, the EMA and other comparable foreign authorities, including those laws that require the reporting of true, complete and accurate information to such authorities; (ii) manufacturing standards; (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad; or (iv) laws that require the reporting of true, complete and accurate financial information and data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in

the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other U.S. federal healthcare programs, individual imprisonment, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, other sanctions, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Our high dependency on public perception of our products may negatively influence the success of these products.

If any of our product candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of the safety and quality of our products. We could be adversely affected if we were subject to negative publicity or if any of our products or any similar products distributed by other companies prove to be, or are asserted to be, harmful to patients. Because of our dependence upon consumer perception, any adverse publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies could have a material adverse impact on our business, prospects, financial condition and results of operations.

Future adverse events in research into the cancer, inflammation and severe autoimmune diseases that we focus our research efforts on, or the biopharmaceutical industry more generally, could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our products. Any increased scrutiny could delay or increase the costs of obtaining regulatory approval for our product candidates.

Failure to successfully identify, develop and commercialize additional products or product candidates could impair our ability to grow.

Although a substantial amount of our efforts will focus on the continued preclinical and clinical testing and potential approval of our product candidates in our current pipeline, a key element of our long-term growth strategy is to develop and market additional products and product candidates. Because we have limited financial and managerial resources, research programs to identify product candidates will require substantial additional technical, financial and human resources, whether or not any product candidates are ultimately identified. The success of this strategy depends partly upon our ability to identify, select and develop promising product candidates and products. Our technology platforms may fail to discover and to generate additional product candidates that are suitable for further development. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate may not be suitable for clinical development as a result of its harmful side effects, limited efficacy or other characteristics that indicate that it is unlikely to be a product that will receive approval by the FDA, the EMA and other comparable foreign regulatory authorities and achieve market acceptance. If we do not successfully develop and commercialize product candidates based upon our technological approach, we may not be able to obtain product or collaboration revenues in future periods, which would adversely affect our business, prospects, financial condition and results of operations.

Our long-term growth strategy to develop and market additional products and product candidates is heavily dependent on precise, accurate and reliable scientific data to identify, select and develop promising pharmaceutical product candidates and products. Our business decisions may therefore be adversely influenced by

improper or fraudulent scientific data sourced from third parties. Any irregularities in the scientific data used by us to determine our focus in research and development of product candidates and products could have a material adverse effect on our business, prospects, financial condition and results of operations.

Service or supply failures, or other failures, business interruptions or other disasters affecting the manufacturing facilities of any party participating in the supply chain would adversely affect our ability to supply our products.

Our product candidates are biologics and require processing steps that are more difficult than those required for most chemical pharmaceuticals. Accordingly, multiple steps are needed to control the manufacturing processes. Problems with these manufacturing processes, even minor deviations from the normal process or from the materials used in the manufacturing process, which may not be detectable by us in a timely manner, could lead to product defects or manufacturing failures, resulting in lot failures, product recalls, product liability claims and insufficient inventory.

Also, certain raw materials or other products necessary for the manufacture and formulation of our product candidates, some of which are difficult to source, are provided by single-source unaffiliated third-party suppliers. In addition, we rely on certain third parties to perform filling, finishing, distribution, laboratory testing and other services related to the manufacture of our product candidates, and to supply various raw materials and other products. We would be unable to obtain these raw materials, other products, or services for an indeterminate period of time if any of these third parties were to cease or interrupt production or otherwise fail to supply these materials, products, or services to us for any reason, including due to regulatory requirements or actions (including recalls), adverse financial developments at or affecting the supplier, failure by the supplier to comply with cGMPs, contamination, business interruptions, or labor shortages or disputes. In any such circumstances, we may not be able to engage a backup or alternative supplier or service provider in a timely manner or at all. This, in turn, could materially and adversely affect our ability to supply product candidates, which could materially and adversely affect our business and future prospects.

Certain of the raw materials required in the manufacture and the formulation of our product candidates may be derived from biological sources, including mammalian tissues, bovine serum and human serum albumin. There are certain European regulatory restrictions on using these biological source materials. If we are required to substitute for these sources to comply with European regulatory requirements, our clinical development or commercial activities may be delayed or interrupted.

Our business may be adversely affected as a result of computer system failures. We may suffer data leaks or become the target of cyber-attacks, as a result of which our financial assets, confidential information and/or intellectual property may be materially negatively impacted. We may not be able to successfully protect our computer systems against unauthorized access by third parties.

Any of the internal computer systems belonging to us or our third-party service providers are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failure. Like other companies, we have on occasion experienced, and will continue to experience, threats to our data and systems, including malicious codes and viruses, phishing, business email compromise attacks, or other cyber-attacks. The number and complexity of these threats continue to increase over time. Any system failure, accident or security breach that causes interruptions in our own or in third-party service vendors' operations could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our or our partners' regulatory approval efforts and significantly increase our costs in order to recover or reproduce the lost data. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability, our product development programs and competitive position may be adversely affected and the further development of our product candidates may be delayed. If the integrity of our cybersecurity systems is breached, the effects may be significant, including remediation expenses, lost revenues, litigation costs, and increased insurance premiums and may also experience reputational damage and the

erosion of shareholder value. Furthermore, we may incur additional costs to remedy the damage caused by these disruptions or security breaches.

In order to successfully commercialize and market our products in the future, we may need to implement additional enterprise resource management systems, which is a complex process that may cause us to face delays. We may also need to implement computer systems, such as additional global enterprise research systems, or ERP systems, in which we have limited experience and which may prove a complex process that could cause delays in our commercialization process.

Risks Related to Our Dependence on Third Parties

We rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators and third-party CROs, to conduct our preclinical studies and clinical trials and to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, the EMA and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we, our investigators or any of our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Further, these investigators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. If independent investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of any product candidates that we develop. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated.

There is a limited number of third-party service providers that specialize or have the expertise required to achieve our business objectives. If any of our relationships with these third-party CROs or clinical investigators terminate, we may not be able to enter into arrangements with alternative CROs or investigators or to do so on commercially reasonable terms. If CROs or clinical investigators do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be

able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding additional CROs (or investigators) involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We rely and will continue to rely on collaborative partners regarding the development of our research programs and product candidates. If we fail to enter into new strategic relationships our business, financial condition, commercialization prospects and results of operations may be materially adversely affected.

We are, and expect to continue to be, dependent on partnerships with partners relating to the development and commercialization of our existing and future research programs and product candidates. We currently have collaborative research relationships with various pharmaceutical companies, such as Janssen, AbbVie, Shire and with various academic and research institutions worldwide, for the development of product candidates resulting from such collaborations. We had, have and will continue to have discussions on potential partnering opportunities with various pharmaceutical companies. If we fail to enter into or maintain collaborations on reasonable terms or at all, our ability to develop our existing or future research programs and product candidates could be delayed, the commercial potential of our products could change and our costs of development and commercialization could increase.

Our dependence on collaborative partners subjects us to a number of risks, including, but not limited to, the following:

- we may not be able to control the amount and timing of resources that the collaboration partner devotes to our research programs and product candidates;
- for collaboration agreements where we are solely or partially responsible for funding development expenses through a defined milestone event, the payments we receive from the collaboration partner may not be sufficient to cover the expenses we have or would need to incur in order to achieve that milestone event;
- for collaboration agreements where we are solely or partially responsible for funding development expenses over a significant time period in the future, we may not be able to accurately predict or control the amount of resources spent within the budgets for which we may be partially responsible, as a result of which we may end up spending more on such development activities than we had previously assessed or as a result of which the funds spent by us may not be used in the most efficient manner;
- we may be required to relinquish significant rights, including intellectual property, marketing and distribution rights;
- our anticipated payments under any partnership agreement (e.g., royalty payments for licensed products) may not materialize;
- our current and future collaborators may fail to exercise their options to license certain of our product candidates, which may occur for reasons unrelated to the therapeutic or commercial potential of our product candidates but may nevertheless adversely impact our ability to develop and commercialize such product candidates;

- our current and future collaborators may terminate their collaborations with us, and in such case we may not be willing or able to find other collaborators and/or to develop and commercialize the relevant product candidate(s) independently;
- we rely on the information and data received from third parties regarding their research programs and product candidates and will not have control of the process conducted by the third party in gathering and composing such data and information. We may not have formal or appropriate guarantees from such third parties with respect to the quality and the completeness of such data;
- if our collaborators fail to exercise their options to license our product candidates, or if rights to develop and commercialize our product candidates subject to collaborations revert to us for any reason, we may not have sufficient financial resources to develop such product candidates, which may result in us failing to recognize any value from our investments in developing such product candidates;
- a collaborative partner may develop a competing product either by itself or in collaboration with others, including one or more of our competitors;
- our collaborative partners' willingness or ability to complete their obligations under our partnership arrangements may be adversely affected by business combinations or significant changes in a collaborative partner's business strategy;
- we may experience delays in, or increases in the costs of, the development of our research programs and product candidates due to the termination or expiration of collaborative research and development arrangements;
- we may have disagreements with collaborative partners, including disagreements over proprietary rights, contract interpretation or the preferred course of development, that might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborative partners may not properly maintain or defend our intellectual property rights or may use proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation; or
- collaborative partners may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability.

We face significant competition in seeking appropriate collaborative partners. Our ability to reach a definitive agreement for a partnership will depend, among other things, upon an assessment of the collaborator's resources and expertise, the terms and conditions of the proposed partnership and the proposed collaborator's evaluation of a number of factors. These factors may include the design or results of clinical trials, the likelihood of regulatory approval, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership regardless of the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a partnership could be more attractive than the one with us.

We rely on third parties to supply and manufacture our product candidates, and we expect to continue to rely on third parties to manufacture our products, if approved. The development of such product candidates and the commercialization of any products, if approved, could be stopped, delayed or made less profitable if any such third party fails to provide us with sufficient quantities of product candidates or products or fails to do so at acceptable quality levels or prices or fails to maintain or achieve satisfactory regulatory compliance

We do not currently have, nor do we plan to acquire, the infrastructure or capability internally to manufacture our product candidates for use in the conduct of our clinical studies or for commercial supply, if our products are approved. Instead, we rely on, and expect to continue to rely on contract manufacturing organizations, or CMOs. We currently rely mainly on Lonza Sales AG, or Lonza, based in Slough, UK and Singapore for the manufacturing of the drug substance of all our products and the production cell line POTELLIGENT® CHOK1SV jointly owned by Lonza and BioWa, Inc. for clinical and commercial scale production of ADCC enhanced antibody products. Reliance on third-party providers may expose us to more risk than if we were to manufacture our product candidates ourselves. We do not control the manufacturing processes of the CMOs we contract with and are dependent on those third parties for the production of our product candidates in accordance with relevant regulations (such as cGMP), which includes, among other things, quality control, quality assurance and the maintenance of records and documentation.

If we were to experience an unexpected loss of supply of or if any supplier were unable to meet our demand for any of our product candidates, we could experience delays in our research or planned clinical studies or commercialization. We could be unable to find alternative suppliers of acceptable quality, in the appropriate volumes and at an acceptable cost. Moreover, our suppliers are often subject to strict manufacturing requirements and rigorous testing requirements, which could limit or delay production. The long transition periods necessary to switch manufacturers and suppliers, if necessary, would significantly delay our clinical studies and the commercialization of our products, if approved, which would materially adversely affect our business, prospects, financial condition and results of operation.

In complying with the manufacturing regulations of the FDA, the EMA and other comparable foreign authorities, we and our third-party suppliers must spend significant time, money and effort in the areas of design and development, testing, production, record-keeping and quality control to assure that the products meet applicable specifications and other regulatory requirements. The failure to comply with these requirements could result in an enforcement action against us, including the seizure of products and shutting down of production. We and any of these third-party suppliers may also be subject to audits by the FDA, the EMA or other comparable foreign authorities. If any of our third-party suppliers fails to comply with cGMP or other applicable manufacturing regulations, our ability to develop and commercialize the products could suffer significant interruptions. We face risks inherent in relying on a single CMO, as any disruption, such as a fire, natural hazards or vandalism at the CMO could significantly interrupt our manufacturing capability. We currently do not have alternative production plans in place or disaster-recovery facilities available. In case of a disruption, we will have to establish alternative manufacturing sources. This would require substantial capital on our part, which we may not be able to obtain on commercially acceptable terms or at all. Additionally, we would likely experience months of manufacturing delays as we build or locate replacement facilities and seek and obtain necessary regulatory approvals. If this occurs, we will be unable to satisfy manufacturing needs on a timely basis, if at all. Also, operating any new facilities may be more expensive than operating our current facility. Further, business interruption insurance may not adequately compensate us for any losses that may occur and we would have to bear the additional cost of any disruption. For these reasons, a significant disruptive event of the manufacturing facility could have drastic consequences, including placing our financial stability at risk.

The manufacturing of all of our product candidates requires using cells which are stored in a cell bank. We have one master cell bank for each product manufactured in accordance with cGMP. Working cell banks have not yet been manufactured. Half of each master cell bank is stored at a separate site so that in case of a catastrophic event at one site we believe sufficient vials of the master cell banks are left at the alternative storage site to continue manufacturing. We believe sufficient working cell banks could be produced from the vials of the master cell bank stored at a given site to assure product supply for the future. However, it is possible that we could lose

multiple cell banks and have our manufacturing significantly impacted by the need to replace these cell banks, which could materially adversely affect our business, prospects, financial condition and results of operations.

For our financial reporting, we are partially dependent on financial information received from our collaborative partners, which we do not control and which may not be received in a timely manner and which may not be accurate. Our reliance on financial information received from our collaboration partners may impact our own internal and external financial reporting and any delay in the provision of such financial information to us or any failure by us to identify mistakes in the financial information provided to us may cause our own financial statements to be partially inaccurate.

We have collaborated, and plan to continue to collaborate, with third parties on product candidates that we believe have promising utility in disease areas or patient populations that are better served by resources of larger biopharmaceutical companies. See “Collaborations” in “Item 4B.—Business Overview” for a more detailed description of these collaborations. As part of some of these collaborations, our collaboration partners are responsible for providing us with financial information regarding specific projects, including funds spent, liabilities incurred and expected future costs, on which we rely for our own financial reporting. In the event that our collaboration partners fail to provide us with the necessary financial information within the agreed upon timeframes, or if such financial information proves partially inaccurate, this is likely to impact the accuracy of our own financial reporting. Any inaccuracy in our financial reporting could cause investors to lose confidence in our financial reporting, which may negatively impact the price of our ADSs.

Risks Related to Intellectual Property

We rely on patents and other intellectual property rights to protect our product candidates and the SIMPLE Antibody™, NHance® and ABDEG™ platform technologies, the enforcement, defense and maintenance of which may be challenging and costly. Failure to enforce or protect these rights adequately could harm our ability to compete and impair our business.

Our commercial success depends in part on obtaining and maintaining patents and other forms of intellectual property rights for our product candidates, methods used to manufacture those products and the methods for treating patients using those products, or on licensing in such rights. Failure to protect or to obtain, maintain or extend adequate patent and other intellectual property rights could materially adversely affect our ability to develop and market our products and product candidates.

We cannot be certain that patents will be issued or granted with respect to applications that are currently pending, or that issued or granted patents will not later be found to be invalid or enforceable. The patent position of biopharmaceutical companies is generally uncertain because it involves complex legal and factual considerations. The standards applied by the European Patent Office, the United States Patent and Trademark Office, or USPTO, and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biopharmaceutical patents. Consequently, patents may not issue from our pending patent applications. As such, we do not know the degree of future protection that we will have on our proprietary products and technology. The scope of patent protection that the European Patent Office and the USPTO will grant with respect to the antibodies in our antibodies product pipeline is uncertain. It is possible that the European Patent Office and the USPTO will not allow broad antibody claims that cover antibodies closely related to our product candidates as well as the specific antibody. As a result, upon receipt of EMA or FDA approval, competitors may be free to market antibodies almost identical to ours, including biosimilar antibodies, thereby decreasing our market share. However, a competitor cannot submit to the FDA an application for a biosimilar product based on one of our products until four years following the date of approval of our “reference product,” and the FDA may not approve such a biosimilar product until 12 years from the date on which the reference product was approved. See the section of this annual report titled “Item 4.—Business—Government Regulation—Licensure and Regulation of Biologics in the United States—Biosimilars and Exclusivity” for more details regarding biosimilar regulatory exclusivities.

The patent prosecution process is expensive and time-consuming, and we and our current or future licensors, licensees or collaboration partners may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our licensors, licensees or collaboration partners will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Further, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors', licensees' or collaboration partners' patent rights are highly uncertain. Our and our licensors' pending and future patent applications may not result in patents being issued that protect our technology or products, in whole or in part, or that effectively prevent others from commercializing competitive technologies and products. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, or we may need to enter into new license or royalty agreements, covering technology that we license from or license to third parties or have developed in collaboration with our collaboration partners and are reliant on patent procurement activities of our licensors, licensees or collaboration partners. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If our current or future licensors, licensees or collaboration partners fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors, licensees or collaboration partners are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. The patent examination process may require us or our licensors, licensees or collaboration partners to narrow the scope of the claims of our or our licensors', licensees' or collaboration partners' pending and future patent applications, which may limit the scope of patent protection that may be obtained. We cannot assure you that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents cover our product candidates, third parties may initiate an opposition, interference, re-examination, post-grant review, *inter partes* review, nullification or derivation action in court or before patent offices, or similar proceedings challenging the validity, enforceability or scope of such patents, which may result in the patent claims being narrowed or invalidated. Our and our licensors', licensees' or collaboration partners' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology.

Because patent applications are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our licensors were the first to file any patent application related to a product candidate. Furthermore, as to the United States, if third parties have filed such patent applications on or before March 15, 2013, an interference proceeding can be initiated by such third parties to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. If third parties have filed such applications after March 15, 2013, a derivation proceeding can be initiated by such third parties to determine whether our invention was derived from theirs. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing our invention where the other party can show that they used the invention in commerce before our filing date, or if the other party is able to obtain a compulsory license.

Issued patents covering one or more of our products or the SIMPLE Antibody™, NHance® and ABDEG™ platform technologies could be found invalid or unenforceable if challenged in court.

To protect our competitive position, we may from time to time need to resort to litigation in order to enforce or defend any patents or other intellectual property rights owned by or licensed to us, or to determine or challenge the scope or validity of patents or other intellectual property rights of third parties. Enforcement of intellectual property rights is difficult, unpredictable and expensive, and many of our or our licensors' or collaboration partners' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors or collaboration partners can. Accordingly, despite our or our licensors' or collaboration partners' efforts, we or our licensors or collaboration partners may not prevent third parties from infringing upon or misappropriating intellectual property rights we own or control, particularly in countries where the laws may not protect those rights as fully as in the European Union and the United States. We may fail in enforcing our rights—in which case our competitors may be permitted to use our technology without being required to pay us any license fees. In addition, however, litigation involving our patents

carries the risk that one or more of our patents will be held invalid (in whole or in part, on a claim-by-claim basis) or held unenforceable. Such an adverse court ruling could allow third parties to commercialize our products or use our SIMPLE Antibody™, NHance® and ABDEG™ platform technologies, and then compete directly with us, without payment to us.

If we were to initiate legal proceedings against a third party to enforce a patent covering one of our products, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States or in Europe, defendant counterclaims alleging invalidity or unenforceability are commonplace. A claim for a validity challenge may be based on failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. A claim for unenforceability could involve an allegation that someone connected with prosecution of the patent withheld relevant information from the European Patent Office or the USPTO or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our products or certain aspects of our SIMPLE Antibody™, NHance® and ABDEG™ platform technologies. Such a loss of patent protection could have a material adverse impact on our business. Further, litigation could result in substantial costs and diversion of management resources, regardless of the outcome, and this could harm our business and financial results. Patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without infringing our patents or other intellectual property rights.

Intellectual property rights of third parties could adversely affect our ability to commercialize our product candidates, such that we could be required to litigate or obtain licenses from third parties in order to develop or market our product candidates. Such litigation or licenses could be costly or not available on commercially reasonable terms.

Our competitive position may suffer if patents issued to third parties or other third-party intellectual property rights cover our products or elements thereof, our manufacture or uses relevant to our development plans, the targets of our product candidates, or other attributes of our product candidates or our technology. In such cases, we may not be in a position to develop or commercialize products or product candidates unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned, or enter into a license agreement with the intellectual property right holder, if available on commercially reasonable terms. We are aware of certain U.S. issued patents held by third parties that some may argue cover certain aspects of our product candidates, including cusatuzumab and ARGX-111. The patent relating to cusatuzumab is scheduled to expire in 2026, and the patents relating to ARGX-111 are scheduled to expire between 2024 and 2032. In the event that a patent has not expired at the time of approval of such product candidate and the patent owner were to bring an infringement action against us, we may have to argue that our product, its manufacture or use does not infringe a valid claim of the patent in question. Alternatively, if we were to challenge the validity of any issued U.S. patent in court, we would need to overcome a statutory presumption of validity that attaches to every U.S. patent. This means that in order to prevail, we would need to present clear and convincing evidence as to the invalidity of the patent's claims. There is no assurance that a court would find in our favor on questions of infringement or validity. In the event that a patent is successfully asserted against us such that the patent is found to be valid and enforceable and infringed by our product, unless we obtain a license to such a patent, which may not be available on commercially reasonable terms or at all, we could be prevented from continuing to develop or commercialize our product. Similarly, the targets for certain of our product candidates have also been the subject of research by other companies, which have filed patent applications or have patents on aspects of the targets or their uses. There can be no assurance any such patents will not be asserted against us or that we will not need to seek licenses from such third parties. We may not be able to secure such licenses on acceptable terms, if at all, and any such litigation would be costly and time-consuming.

It is also possible that we failed to identify relevant patents or applications. For example, certain U.S. applications filed after November 29, 2000 that will not be filed outside the United States may remain confidential until patents issue. In general, patent applications in the United States and elsewhere are published approximately

18 months after the earliest filing from which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our products or platform technology could have been filed by others without our knowledge. Furthermore, we operate in a highly competitive field, and given our limited resources, it is unreasonable to monitor all patent applications purporting to gain broad coverage in the areas in which we are active. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies, our products or the use of our products.

Third-party intellectual property right holders, including our competitors, may actively bring infringement claims against us. The granting of orphan drug status in respect of any of our product candidates does not guarantee our freedom to operate and is separate from our risk of possible infringement of third parties' intellectual property rights. We may not be able to successfully settle or otherwise resolve such infringement claims. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage or continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in marketing our products.

If we fail in any such dispute, in addition to being forced to pay damages, we or our licensees may be temporarily or permanently prohibited from commercializing any of our product candidates that are held to be infringing. We might, if possible, also be forced to redesign product candidates so that we no longer infringe the third-party intellectual property rights. Or, we may be required to seek a license to any such technology that we are found to infringe, which license may not be available on commercially reasonable terms, or at all. Even if we or our licensors or collaboration partners obtain a license, it may be non-exclusive (for example, the POTELLIGENT[®] platform), thereby giving our competitors access to the same technologies licensed to us or our licensors or collaboration partners. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. Any of these events, even if we were to ultimately prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

In addition, if the breadth or strength of protection provided by our or our licensors' or collaboration partners' patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Our ability to compete may be adversely affected if we are unsuccessful in defending against any claims by competitors or others that we are infringing upon their intellectual property rights.

The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. In addition, companies producing therapeutics to treat and potentially cure cancer have employed intellectual property litigation as a means to gain an advantage over their competitors. As a result, we may be required to defend against claims of intellectual property infringement that may be asserted by our competitors against us and, if the outcome of any such litigation is adverse to us, it may affect our ability to compete effectively.

Our involvement in litigation, and in, *e.g.*, any interference, derivation, reexamination, *inter partes* review, opposition or post-grant proceedings or other intellectual property proceedings inside and outside of the European Union or the United States may divert management time from focusing on business operations, could cause us to spend significant amounts of money and may have no guarantee of success. Any current and potential intellectual property litigation also could force us to do one or more of the following:

- stop selling, incorporating, manufacturing or using our products in the United States or other jurisdictions that use the subject intellectual property;

- obtain from a third party asserting its intellectual property rights, a license to sell or use the relevant technology, which license may not be available on reasonable terms, or at all, or may be non-exclusive thereby giving our competitors access to the same technologies licensed to us;
- redesign those products or processes that use any allegedly infringing or misappropriated technology, which may result in significant cost or delay to us, or which redesign could be technically infeasible; or
- pay damages, including the possibility of treble damages in a patent case if a court finds us to have willfully infringed certain intellectual property rights.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, this could have a substantial adverse effect on the price of the ADSs. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

Because our programs may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license, maintain or use these proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

For example, we sometimes collaborate with U.S. and non-U.S. academic institutions to accelerate our preclinical research or development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our applicable product candidate or program.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain a license to third-party intellectual property rights necessary for the development of a product candidate or program, we may have to abandon development of that product candidate or program and our business and financial condition could suffer.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition by potential partners or customers in our markets of interest. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. If other entities use trademarks similar to ours in different jurisdictions, or have senior rights to ours, it could interfere with our use of our current trademarks throughout the world.

Although we have trademark registrations for arGEN-X, this trademark may be considered as confusing with other registered trademarks and we may not be in a position to keep exclusive rights over the use of it. We do not expect the potential loss of this trademark registration to have an adverse impact on our business as we are not planning to use arGEN-X as a product name.

If we do not obtain protection under the Hatch-Waxman Amendments and similar non-U.S. legislation for extending the term of patents covering each of our product candidates, our business may be materially harmed.

Patents have a limited duration. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates, their manufacture, or use are obtained, once the patent life has expired, we may be open to competition from competitive medications, including biosimilar medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act and similar legislation in the European Union. The Hatch-Waxman Act permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. The patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent applicable to an approved drug may be extended. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner than we expect. As a result, our revenue from applicable products could be reduced, possibly materially.

We enjoy only limited geographical protection with respect to certain patents and may face difficulties in certain jurisdictions, which may diminish the value of intellectual property rights in those jurisdictions.

We often file our first patent application (i.e., priority filing) at the UK Intellectual Property Office, the European Patent Office or the USPTO. International applications under the Patent Cooperation Treaty, or PCT, are usually filed within twelve months after the priority filing. Based on the PCT filing, national and regional patent applications may be filed in additional jurisdictions where we believe our product candidates may be marketed. We have so far not filed for patent protection in all national and regional jurisdictions where such protection may be available. In addition, we may decide to abandon national and regional patent applications before grant. Finally, the grant proceeding of each national/regional patent is an independent proceeding which may lead to situations in which applications might in some jurisdictions be refused by the relevant patent offices, while granted by others. It

is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology.

Competitors may use our and our licensors' or collaboration partners' technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we and our licensors or collaboration partners have patent protection, but enforcement is not as strong as that in the United States and the European Union. These products may compete with our product candidates, and our and our licensors' or collaboration partners' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws in the United States and the European Union, and companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition from others in those jurisdictions.

Some countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired and our business and results of operations may be adversely affected.

Proceedings to enforce our and our licensors' or collaboration partners' patent rights in foreign jurisdictions could result in substantial costs and divert our and our licensors' or collaboration partners' efforts and attention from other aspects of our business, could put our and our licensors' or collaboration partners' patents at risk of being invalidated or interpreted narrowly and our and our licensors' or collaboration partners' patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensors or collaboration partners. We or our licensors or collaboration partners may not prevail in any lawsuits that we or our licensors or collaboration partners initiate and the damages or other remedies awarded, if any, may not be commercially meaningful.

If we fail to comply with our obligations under the agreements pursuant to which we license intellectual property rights from third parties, or otherwise experience disruptions to our business relationships with our licensors, we could lose the rights to intellectual property that are important to our business.

We are a party to license agreements under which we are granted rights to intellectual property that are important to our business and we expect that we may need to enter into additional license agreements in the future. Existing license agreements impose, and we expect that future license agreements will impose, various development obligations, payment of royalties and fees based on achieving certain milestones, as well as other obligations. If we fail to comply with our obligations under these agreements, the licensor may have the right to terminate the license. The termination of any license agreements or failure to adequately protect such license agreements could prevent us from commercializing product candidates covered by the licensed intellectual property. Several of our existing license agreements are sublicenses from third parties which are not the original licensor of the intellectual property at issue. Under these agreements, we must rely on our licensor to comply with its obligations under the primary license agreements under which such third party obtained rights in the applicable intellectual property, where we may have no relationship with the original licensor of such rights. If the licensors fail to comply with their obligations under these upstream license agreements, the original third-party licensor may have the right to terminate the original license, which may terminate the sublicense. If this were to occur, we would no longer have rights to the applicable intellectual property and, in the case of a sublicense, if we were not able to secure our own direct license with the owner of the relevant rights, which it may not be able to do at a reasonable cost or on reasonable terms, it may adversely affect our ability to continue to develop and commercialize the product candidates incorporating the relevant intellectual property.

Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under any collaboration relationships we might enter into in the future;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make compounds that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.
- The patents of third parties may have an adverse effect on our business.
- We or our licensors or any current or future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed.
- We or our licensors or any future strategic partners might not have been the first to file patent applications covering certain of our inventions.
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights.
- It is possible that our pending patent applications will not lead to issued patents.
- Issued patents that we own or have exclusively licensed may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors.
- Our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.

- Third parties performing manufacturing or testing for us using our products or technologies could use the intellectual property of others without obtaining a proper license.
- We may not develop additional technologies that are patentable.
- The patents of others may have an adverse effect on our business. In particular, our product candidates may in the future be tested for new indications. If one of our product candidates would prove to be effective against a specific new indication, we may be confronted with existing patents covering such indication.

Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological complexity and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time-consuming and inherently uncertain. In addition, the America Invents Act, or the AIA, has been enacted in the United States, resulting in significant changes to the U.S. patent system.

An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application, but circumstances could prevent us from promptly filing patent applications on our inventions.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. The AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Additionally, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and protect other proprietary information.

We consider proprietary trade secrets, confidential know-how and unpatented know-how to be important to our business. We may rely on trade secrets or confidential know-how to protect our technology, especially where patent protection is believed to be of limited value. However, trade secrets and confidential know-how are difficult to maintain as confidential.

To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, contractors and advisors to enter into confidentiality agreements with us. However, current or former employees, consultants, contractors and advisers may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third party obtained illegally and is using trade secrets or confidential know-how is expensive, time consuming and unpredictable. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. Furthermore, if a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret.

Failure to obtain or maintain trade secrets or confidential know-how trade protection could adversely affect our competitive position. Moreover, our competitors may independently develop substantially equivalent proprietary information and may even apply for patent protection in respect of the same. If successful in obtaining such patent protection, our competitors could limit our use of our trade secrets or confidential know-how.

Under certain circumstances, we may also decide to publish some know-how to attempt to prevent others from obtaining patent rights covering such know-how.

We may be subject to claims by third parties asserting that we or our employees or consultants have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our consultants and employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these consultants and employees executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our consultants and employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these consultants and employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such consultant's or employee's former employer, or have breached their non-competition agreement. Litigation may be necessary to defend against these claims.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we successfully prosecute or defend against such claims, litigation could result in substantial costs and distract management.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO, the European Patent Office and foreign patent agencies in several stages over the lifetime of the patent. The USPTO, the European Patent Office and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors or collaboration partners fail to maintain the patents and patent

applications covering our product candidates, our competitors might be able to enter the market, which would have an adverse effect on our business.

Risks Related to Our Organization and Operations

Our future growth and ability to compete depends on retaining our key personnel and recruiting additional qualified personnel.

Our success depends upon the continued contributions of our key management, scientific and technical personnel, many of whom have been instrumental for us and have substantial experience with our therapies and related technologies. These key management individuals include the members of our board of directors and executive management, including Tim Van Hauwermeiren, our co-founder and Chief Executive Officer; Keith Woods, our Chief Operating Officer; Eric Castaldi, our Chief Financial Officer; Prof. Hans de Haard, our co-founder and Chief Scientific Officer; Dr. Nicolas Leupin, our Chief Medical Officer; Torsten Dreier, our co-founder and Chief Development Officer; and Dirk Beusaert, our General Counsel.

The loss of key managers and senior scientists could delay our research and development activities. In addition, our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified management, scientific and medical personnel. Many other biotechnology and pharmaceutical companies and academic institutions that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. Therefore, we might not be able to attract or retain these key persons on conditions that are economically acceptable. Furthermore, we will need to recruit new managers and qualified scientific, commercial, regulatory and financial personnel to develop our business if we expand into fields that will require additional skills. Our inability to attract and retain these key persons could prevent us from achieving our objectives and implementing our business strategy, which could have a material adverse effect on our business and prospects.

We expect to expand our development, regulatory and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We may not be able to integrate efficiently or achieve the expected benefits of any acquisitions of complementary businesses, product candidates or technologies.

Since our inception in 2008, we have grown organically without any acquisitions. Should we in the future contemplate to acquire any complementary business, product candidates or technologies, our ability to integrate and manage acquired businesses, product candidates or technologies effectively will depend upon a number of factors including the size of the acquired business, the complexity of any product candidate or technology and the resulting difficulty of integrating the acquired business's operations, if any. Our relationship with current employees or employees of any acquired business may become impaired. We may also be subject to unexpected claims and liabilities arising from such acquisitions. These claims and liabilities could be costly to defend, could be material to our financial position and might exceed either the limitations of any applicable indemnification provisions or the financial resources of the indemnifying parties. There can also be no assurance that we will be able to assess ongoing profitability and identify all actual or potential liabilities of a business, product candidate or technology prior to its acquisition. If we acquire businesses, product candidates or technologies that result in

assuming unforeseen liabilities in respect of which it has not obtained contractual protections or for which protection is not available, this could materially adversely affect our business, prospects, financial condition and results of operations.

Our business is subject to economic, political, regulatory and other risks associated with international operations.

Our business is subject to risks associated with conducting business internationally. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation, or political instability in particular non-U.S. economies and markets;
- differing regulatory requirements for drug approvals;
- differing jurisdictions could present different issues for securing, maintaining or obtaining freedom to operate in such jurisdictions;
- potentially reduced protection for intellectual property rights;
- difficulties in compliance with different, complex and changing laws, regulations and court systems of multiple jurisdictions and compliance with a wide variety of foreign laws, treaties and regulations;
- changes in regulations and customs, tariffs and trade barriers;
- changes in currency exchange rates of the euro, U.S. dollar, British pound and Swiss francs and currency controls;
- changes in a specific country's or region's political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by governments;
- differing reimbursement regimes and price controls in certain international markets;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad, including, for example, the variable tax treatment in different jurisdictions of stock options granted under our share-based employee incentive plans;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- litigation or administrative actions resulting from claims against us by current or former employees or consultants individually or as part of class actions, including claims of wrongful terminations, discrimination, misclassification or other violations of labor law or other alleged conduct;
- litigation resulting from claims against us by third parties, including claims of breach of noncompete and confidentiality provisions of our employees' former employment agreements with such third parties;

- difficulties associated with staffing and managing international operations, including differing labor relations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

We have obtained significant funding from agencies of the government of the Flemish region of Belgium and have benefited from certain research and development incentives. The tax authorities may challenge our eligibility for or our calculation of such incentives.

We have contracted over the past years numerous funding agreements with agencies of the Flemish government to partially finance our research and development programs. These funding agreements are subject to various criteria linked to employment and investment in the Flemish region of Belgium. We have committed to establish our operational site in the Flemish region, which must remain our major effective operational site, and to maintain our site and all our existing activities, including research and development in the Flemish region. Similarly, our funding agreement with one such agency of the Flemish government requires us to maintain substantial research and development activities in the Flemish region. Such undertakings restrict our ability to choose the most convenient or cost-effective location of our premises.

If we were to breach these contractual obligations, we may be held liable by the agencies of the Flemish government with which we have funding agreements for any damage incurred by the such agencies resulting from the breach of contract and we could be required to reimburse in full the subsidies granted by such agencies.

Further, pursuant to the general terms of each grant, certain Flemish agencies are entitled to re-evaluate the subsidies granted to us in case of a fundamental change in our shareholding base, which is not defined in the general terms, but we believe would involve a change of control of us. Any such reevaluation could negatively impact the funding that we receive or have received from the Flemish agencies.

The research and development incentives from which we have benefited as a company active in research and development in Belgium can be offset against Belgian corporate income tax due. The excess portion may be refunded at the end of a five-year fiscal period for the Belgian research and development incentive. The research and development incentives are both calculated based on the amount of eligible research and development expenditure. The Belgian tax authorities may audit each research and development program in respect of which a tax credit has been claimed and assess whether it qualifies for the tax credit regime. The tax authorities may challenge our eligibility for, or our calculation of, certain tax reductions or deductions in respect of our research and development activities and, should such a claim of the Belgian tax administration be successful, we may be liable for additional corporate income tax, and penalties and interest related thereto, which could have a significant impact on our results of operations and future cash flows. Furthermore, if the Belgian government decide to eliminate, or reduce the scope or the rate of, the research and development incentive benefit, either of which it could decide to do at any time, our results of operations could be adversely affected.

Exchange rate fluctuations or abandonment of the euro currency may materially affect our results of operations and financial condition.

Due to the international scope of our operations, our assets, earnings and cash flows are influenced by movements in exchange rates of several currencies, particularly the U.S. dollar, British pound and Swiss francs. Our functional currency is the euro and the majority of our operating expenses are paid in euros, but we also receive payments from our main business partners Janssen, AbbVie and Shire in U.S. dollars and we regularly acquire services, consumables and materials in U.S. dollars, Swiss francs and British pounds. Further, potential future revenue may be derived from abroad, particularly from the United States. As a result, our business and share price may be affected by fluctuations in foreign exchange rates between the euro and these other currencies, which

may also have a significant impact on our reported results of operations and cash flows from period to period. Currently, we do not have any exchange rate hedging arrangements in place.

In addition, the possible abandonment of the euro by one or more members of the European Union could materially affect our business in the future. Despite measures taken by the European Union to provide funding to certain European Union member states in financial difficulties and by a number of European countries to stabilize their economies and reduce their debt burdens, it is possible that the euro could be abandoned in the future as a currency by countries that have adopted its use. This could lead to the re-introduction of individual currencies in one or more European Union member states, or in more extreme circumstances, the abandonment of the euro or the dissolution of the European Union. The effects on our business of a potential dissolution of the European Union, the exit of one or more European Union member states from the European Union or the abandonment of the euro as a currency, are impossible to predict with certainty, and any such events could have a material adverse effect on our business, financial condition and results of operations.

We face a compliance burden from an organizational and regulatory perspective as a European public company with limited liability under Dutch law with our shares listed on Euronext Brussels and the Nasdaq Stock Exchange and with the majority of our operations outside the Netherlands.

We face a compliance burden from an organizational and regulatory perspective as a European public company with limited liability under Dutch law with our shares listed on Euronext Brussels and with the majority of our operations outside the Netherlands. For example, we continue to need the services provided by our independent auditors as required under both Dutch law in respect of argenx SE and Belgian law in respect of argenx BVBA and would continue to owe increased fees in respect thereof.

Recent developments relating to the United Kingdom's referendum vote in favor of withdrawal from the European Union could adversely affect us.

The United Kingdom held a referendum on June 23, 2016 in which a majority voted for the United Kingdom's withdrawal from the European Union, or Brexit. As a result of this vote, on March 29, 2017 the United Kingdom officially started the separation process and negotiations are underway to determine the terms of the United Kingdom's withdrawal from the European Union as well as its relationship with the European Union going forward, including the terms of trade between the United Kingdom and the European Union. The effects of Brexit have been and are expected to continue to be far-reaching. Brexit and the perceptions as to its impact may adversely affect business activity and economic conditions in Europe and globally and could continue to contribute to instability in global financial and foreign exchange markets. Brexit could also have the effect of disrupting the free movement of goods, services and people between the United Kingdom and the European Union; however, the full effects of Brexit are uncertain and will depend on any agreements the United Kingdom may make to retain access to European Union markets.

In addition, we expect that Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the United Kingdom determines which European Union laws to replicate or replace. If the United Kingdom were to significantly alter its regulations affecting the pharmaceutical industry, we could face significant new costs. It may also be time-consuming and expensive for us to alter our internal operations in order to comply with new regulations. Altered regulations could also add time and expense to the process by which our product candidates receive regulatory approval in the United Kingdom and European Union. Similarly, it is unclear at this time what Brexit's impact will have on our intellectual property rights and the process for obtaining, maintaining and defending such rights. It is possible that certain intellectual property rights, such as trademarks, granted by the European Union will cease being enforceable in the United Kingdom absent special arrangements to the contrary, and we may be required to refile our trademarks and other intellectual property applications domestically in the United Kingdom. As a result of the Brexit, other European countries may seek to conduct referenda with respect to their continuing membership in the European Union. Given these possibilities and others we may not anticipate, as well as the lack of comparable precedent, we cannot be certain of the full extent to which Brexit could adversely affect our business, results of operations and financial condition.

We are exposed to unanticipated changes in tax laws and regulations, adjustments to our tax provisions, exposure to additional tax liabilities, or forfeiture of our tax assets.

The determination of our provision for income taxes and other tax liabilities requires significant judgment, including the adoption of certain accounting policies and our determination of whether our deferred tax assets are, and will remain, tax effective. We cannot guarantee that our interpretation or structure will not be questioned by the relevant tax authorities, or that the relevant tax laws and regulations, or the interpretation thereof, including through tax rulings, by the relevant tax authorities, will not be subject to change. Any adverse outcome of such a review may lead to adjustments in the amounts recorded in our financial statements, and could have a materially adverse effect on our operating results and financial condition.

We are subject to laws and regulations on tax levies and other charges or contributions in different countries, including transfer pricing and tax regulations for the compensation of personnel and third parties. Dealings between current and former group companies, as well as additional companies that may form part of our group in the future, are subject to transfer pricing regulations, which may be subject to change and could affect us.

Our effective tax rates could be adversely affected by changes in tax laws, treaties and regulations, both internationally and domestically, or the interpretation thereof by the relevant tax authorities, including changes to the patent income deduction, possible changes to the corporate income tax base, wage withholding tax incentive for qualified research and development personnel in Belgium and other tax incentives and the implementation of new tax incentives such as the innovation deduction. An increase of the effective tax rates could have an adverse effect on our business, financial position, results of operations and cash flows.

In addition, we may not be able to use, or changes in tax regulations may affect the use of, certain tax assets or credits that we have built over the years. For instance, as of December 31, 2018, we had €117.1 million of consolidated tax loss carry forwards. In general, some of these tax loss carry forwards may be forfeited in whole, or in part, as a result of various transactions, or their utilization may be restricted by statutory law in the relevant jurisdiction. Any corporate reorganization by us or any transaction relating to our shareholding structure may result in partial or complete forfeiture of tax loss carry forwards. For instance, under Belgian law, argenx BVBA may lose its tax loss carry forwards in case of a change of control, through an acquisition or otherwise, not meeting legitimate financial or economic needs as well as in case of a tax neutral reorganization, such as a merger or a demerger, involving argenx BVBA. The tax burden would increase if profits, if any, could not be offset against tax loss carry forwards.

Furthermore, as explained in detail in “Item 4.A.—History and Development of the Company—Overview of Our Restructuring and Possible Redomiciliation,” we have effected a restructuring of our intellectual property rights involving a transfer of those rights from argenx SE to our Belgian subsidiary argenx BVBA. The restructuring resulted in a taxable amount for argenx SE of €2.4 million, subject to Dutch corporate income tax, and an elimination of its tax loss carryforward for Dutch corporate income tax purposes in an amount of €77.5 million. The restructuring is expected to bring additional deductible costs to the Belgian BVBA for an amount of up to €80 million. However, whether we will be allowed to treat the amount of €80 million as a deductible cost for the Belgian BVBA depends on the outcome of a ruling procedure we have initiated and of which we do not control the outcome. We may not obtain the tax ruling from the Belgian ruling commission, and we may not be allowed to treat the amount of €80 million as a deductible cost for the Belgian BVBA, which would lead to a loss of deductible costs. If the company would become profitable in the future, and these deductible costs are not or no longer useable, we may face a higher tax burden as a result thereof, which would impact our operating results and financial condition for the relevant period.

Risks Related to the ADSs

The price of the ADSs may be volatile and may fluctuate due to factors beyond our control. An active public trading market may not be sustained.

The trading price of the ADSs and the ordinary shares has fluctuated, and is likely to continue to fluctuate, substantially. The trading price of those securities depends on a number of factors, including those described in this “Risk Factors” section, many of which are beyond our control and may not be related to our operating performance. In addition, although the ADSs are listed on the Nasdaq Global Select Market and our ordinary shares are listed on Euronext Brussels, we cannot assure you that a trading market for those securities will be maintained.

The market price of the ADSs may fluctuate significantly due to a variety of factors, many of which are beyond our control, including:

- positive or negative results of testing and clinical trials by us, strategic partners or competitors;
- delays in entering into strategic relationships with respect to development or commercialization of our product candidates or entry into strategic relationships on terms that are not deemed to be favorable to us;
- technological innovations or commercial product introductions by us or competitors;
- changes in government regulations;
- developments concerning proprietary rights, including patents and litigation matters;
- public concern relating to the commercial value or safety of any of our product candidates;
- financing or other corporate transactions;
- publication of research reports or comments by securities or industry analysts;
- general market conditions in the pharmaceutical industry or in the economy as a whole;
- price and volume fluctuations attributable to inconsistent trading volume levels of the ADSs and/or ordinary shares; or
- other events and factors, many of which are beyond our control.

These and other market and industry factors may cause the market price and demand for the ADSs and ordinary shares to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their ADSs or ordinary shares and may otherwise negatively affect the liquidity of our ADSs and ordinary shares. In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

Future sales, or the possibility of future sales, of a substantial number of our securities could adversely affect the price of the shares and dilute shareholders.

Sales of a substantial number of our ADSs and ordinary shares in the public market, or the perception that these sales might occur, could depress the market price of our ADSs and ordinary shares and could impair our

ability to raise capital through the sale of additional equity securities. We are also unable to predict the effect that such sales may have on the prevailing market price of our ADSs and ordinary shares.

Fluctuations in exchange rates may increase the risk of holding our ADSs and ordinary shares.

Due to the international scope of our operations, our assets, earnings and cash flows are influenced by movements in exchange rates of several currencies, particularly the euro, U.S. dollar, British pound and Swiss franc. Our functional currency is the euro, and the majority of our operating expenses are paid in euros, but we also receive payments from our main business partners Janssen, AbbVie and Shire in U.S. dollars and we regularly acquire services, consumables and materials in U.S. dollars, Swiss francs and British pounds. Further, potential future revenue may be derived from abroad, particularly from the United States. As a result, our business and the price of the ADSs and ordinary shares may be affected by fluctuations in foreign exchange rates between the euro and these other currencies, which may also have a significant impact on our reported results of operations and cash flows from period to period. Currently, we do not have any exchange rate hedging arrangements in place.

Moreover, because our ordinary shares currently trade on Euronext Brussels in euros, and the ADSs trade on the Nasdaq Global Select Market in U.S. dollars, fluctuations in the exchange rate between the U.S. dollar and the euro may result in temporary differences between the value of the ADSs and the value of our ordinary shares, which may result in heavy trading by investors seeking to exploit such differences. In order to finance the growth of our activities in the United States, we have invested in U.S. dollar denominated cash deposit accounts and in current financial assets with a significant portion of the proceeds from our initial U.S. public offering completed in May 2017 and our follow-on U.S. public offerings completed in December 2017 and September 2018. Depending on the exchange rate fluctuations of the U.S. dollar, this may result in unrealized exchange rate losses which may impact negatively the reporting of our cash, cash equivalents and current financial assets at reporting dates when translating to euros these U.S. denominated cash deposits accounts and current financial assets. In addition, as a result of fluctuations in the exchange rate between the U.S. dollar and the euro, the U.S. dollar equivalent of the proceeds that a holder of the ADSs would receive upon the sale on Euronext Brussels of any ordinary shares withdrawn from the depositary and the U.S. dollar equivalent of any cash dividends paid in euros on our shares represented by the ADSs could also decline.

Holders of ADSs are not treated as holders of our ordinary shares.

Holders of ADSs are not treated as holders of our ordinary shares, unless they withdraw the ordinary shares underlying their ADSs in accordance with the deposit agreement and applicable laws and regulations. The depositary is the holder of the ordinary shares underlying the ADSs. Holders of ADSs therefore do not have any rights as holders of our ordinary shares, other than the rights that they have pursuant to the deposit agreement. See “Item 12.D. —American Depositary Shares.”

Holders of ADSs may be subject to limitations on the transfer of their ADSs and the withdrawal of the underlying ordinary shares.

ADSs are transferable on the books of the depositary. However, the depositary may close its books at any time or from time to time when it deems expedient in connection with the performance of its duties. The depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary think it is advisable to do so because of any requirement of law, government or governmental body, or under any provision of the deposit agreement, or for any other reason, subject to the right of ADS holders to cancel their ADSs and withdraw the underlying ordinary shares. Temporary delays in the cancellation of your ADSs and withdrawal of the underlying ordinary shares may arise because the depositary has closed its transfer books or we have closed our transfer books, the transfer of ordinary shares is blocked to permit voting at a shareholders’ meeting or we are paying a dividend on our ordinary shares. In addition, ADS holders may not be able to cancel their ADSs and withdraw the underlying ordinary shares when they owe money for fees, taxes and similar charges and when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of ordinary shares or other deposited securities.

You will not have the same voting rights as the holders of our ordinary shares and may not receive voting materials in time to be able to exercise your right to vote.

Except as described in this annual report and the deposit agreement, holders of the ADSs will not be able to exercise voting rights attaching to the ordinary shares represented by the ADSs. Under the terms of the deposit agreement, holders of the ADSs may instruct the depositary to vote the ordinary shares underlying their ADSs. Otherwise, holders of ADSs will not be able to exercise their right to vote unless they withdraw the ordinary shares underlying their ADSs to vote them in person or by proxy in accordance with applicable laws and regulations and our Articles of Association. Even so, ADS holders may not know about a meeting far enough in advance to withdraw those ordinary shares. If we ask for the instructions of holders of the ADSs, the depositary, upon timely notice from us, will notify ADS holders of the upcoming vote and arrange to deliver our voting materials to them. Upon our request, the depositary will mail to holders a shareholder meeting notice that contains, among other things, a statement as to the manner in which voting instructions may be given. We cannot guarantee that ADS holders will receive the voting materials in time to ensure that they can instruct the depositary to vote the ordinary shares underlying their ADSs. A shareholder is only entitled to participate in, and vote at, the meeting of shareholders, provided that its shares are recorded in its name at midnight (Central European Time) at the end of the twenty eighth day preceding the date of the meeting of shareholders. In addition, the depositary's liability to ADS holders for failing to execute voting instructions or for the manner of executing voting instructions is limited by the deposit agreement. As a result, holders of ADSs may not be able to exercise their right to give voting instructions or to vote in person or by proxy and they may not have any recourse against the depositary or us if their ordinary shares are not voted as they have requested or if their shares cannot be voted.

Holders of our ordinary shares outside the Netherlands, and ADS holders may not be able to exercise pre-emptive rights or preferential subscription rights, respectively.

In the event of an increase in our share capital, holders of our ordinary shares are generally entitled under Dutch law to full pre-emptive rights, unless these rights are excluded either by a resolution of the shareholders at the General Meeting, or by a resolution of the board of directors (if the board of directors has been designated by the shareholders at the General Meeting for this purpose).

However, making pre-emptive rights available to holders of ordinary shares or ADSs representing ordinary shares also requires compliance with applicable securities laws in the jurisdictions where holders of those securities are located, which we may be unable or unwilling to do. In particular, holders of ordinary shares or ADSs located in the United States would not be able to participate in a pre-emptive rights offering unless we registered the securities to which the rights relate under the Securities Act or an exemption from the registration requirements of that Act is available. In addition, ADS holders would not be able to participate in a pre-emptive rights offering unless we made arrangements with the depositary to extend that offering to ADS holders, which we are not required to do.

We are a Dutch European public company with limited liability (Societas Europaea or SE). The rights of our shareholders may be different from the rights of shareholders in companies governed by the laws of U.S. jurisdictions.

We are a Dutch European public company with limited liability (Societas Europaea or SE). Our corporate affairs are governed by our Articles of Association and by the laws governing companies incorporated in the Netherlands. The rights of shareholders and the responsibilities of members of our board of directors may be different from the rights and obligations of shareholders in companies governed by the laws of U.S. jurisdictions. In the performance of its duties, our board of directors is required by Dutch law to consider the interests of our company, our shareholders, our employees and other stakeholders, in all cases with due observation of the principles of reasonableness and fairness. It is possible that some of these parties will have interests that are different from, or in addition to, your interests as a shareholder.

We will continue to incur, increased costs as a result of operating as a U.S.-listed public company, and our board of directors will be required to devote substantial time to compliance initiatives and corporate governance practices.

As a public company, we will continue to incur significant legal, accounting and other expenses that we did not incur as a public company listed on Euronext Brussels. We are a Dutch European public company with limited liability (*Societas Europaea* or *SE*). The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Stock Market, or Nasdaq, and other applicable securities rules and regulations impose various requirements on non-U.S. reporting public companies, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our board of directors and other personnel are and will continue to be required to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors.

However, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our board of directors on our internal control over financial reporting. We ceased to be an emerging growth company on December 31, 2018, and, as such, are now required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we are engaged in a process to document and evaluate our internal control over financial reporting, which is challenging and involves substantial accounting expenses. In this regard, we will need to continue to dedicate internal resources, including significant management time, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Certain significant shareholders own a substantial number of our securities and as a result, may be able to exercise control over us, including the outcome of shareholder votes. These shareholders may have different interests from us or your interests.

We have a number of significant shareholders. For an overview of our current significant shareholders, please see “Item 7A.—Major Shareholders.” As of the date of this annual report, these significant shareholders and their affiliates, in the aggregate, own approximately 33.6% of our ordinary shares and ADSs.

Currently, we are not aware that any of our existing shareholders have entered or will enter into a shareholders’ agreement with respect to the exercise of their voting rights. Nevertheless, depending on the level of attendance at our general meetings of shareholders, or the General Meeting, these significant shareholders could, alone or together, have the ability to determine the outcome of decisions taken at any such General Meeting. Any such voting by these shareholders may not be in accordance with our interests or those of our shareholders. Among other consequences, this concentration of ownership may have the effect of delaying or preventing a change in control and might therefore negatively affect the market price of the ADSs.

Provisions of our Articles of Association or Dutch corporate law, might deter acquisition bids for us that might be considered favorable and prevent or frustrate any attempt to replace or remove the then board of directors.

Provisions of our Articles of Association may make it more difficult for a third party to acquire control of us or effect a change in our board of directors. We have adopted several provisions that may have the effect of making a takeover of our company more difficult or less attractive. These provisions include a requirement that certain matters, including an amendment of our Articles of Association, may only be brought to our shareholders for a vote upon a proposal by our board of directors. These provisions could discourage potential takeover attempts that other shareholders may consider to be in their best interest and could adversely affect the market price of our securities. These provisions may also have the effect of depriving ADS holders of the opportunity to sell their ADSs at a premium.

We do not expect to pay cash dividends in the foreseeable future.

We have not paid any cash dividends since our incorporation. Even if future operations lead to significant levels of distributable profits, we currently intend that any earnings will be reinvested in our business and that cash dividends will not be paid until we have an established revenue stream to support continuing cash dividends. In addition, payment of any future dividends to shareholders would be subject to shareholder approval at our General Meeting, upon proposal of the board of directors, which proposal would be subject to the approval of the majority of the non-executive directors after taking into account various factors including our business prospects, cash requirements, financial performance and new product development. In addition, payment of future cash dividends may be made only if our shareholders' equity exceeds the sum of our paid-in and called-up share capital plus the reserves required to be maintained by Dutch law or by our Articles of Association. Accordingly, investors cannot rely on cash dividend income from ADSs and any returns on an investment in the ADSs will likely depend entirely upon any future appreciation in the price of the ADSs.

We are not obligated to, and do not comply with, all the best practice provisions of the Dutch Corporate Governance Code, which may affect your rights as a shareholder.

As a Dutch European public company with limited liability (*Societas Europaea* or *SE*), we are subject to the Dutch Corporate Governance Code, or the DCGC. The DCGC contains both principles and best practice provisions for board of directors, management boards, supervisory boards, shareholders and general meetings of shareholders, financial reporting, auditors, disclosure, compliance and enforcement standards. The DCGC applies to all Dutch companies listed on a regulated market, including Euronext Brussels. The principles and best practice provisions apply to our board of directors (in relation to role and composition, conflicts of interest and independency requirements, board committees and remuneration), shareholders and the General Meeting (for example, regarding anti-takeover protection and our obligations to provide information to our shareholders) and financial reporting (such as external auditor and internal audit requirements). We do not comply with all the best practice provisions of the DCGC. As a Dutch company, we are required to disclose in our annual report, filed in the Netherlands, whether we comply with the provisions of the DCGC. If we do not comply with the provisions of the DCGC (for example, because of a conflicting Nasdaq requirement or otherwise), we must list the reasons for any deviation from the DCGC in our annual report. See "Item 16G.—Corporate Governance."

Claims of U.S. civil liabilities may not be enforceable against us.

We are incorporated under the laws of the Netherlands, and if we complete our possible redomiciliation we will be incorporated under the laws of Belgium. Substantially all of our assets are located outside the United States. The majority of the members of our board of directors reside outside the United States. As a result, it may not be possible for investors to effect service of process within the United States upon such persons or to enforce against them or us in U.S. courts, including judgments predicated upon the civil liability provisions of the U.S. federal securities laws.

The United States currently does not have a treaty with either the Netherlands or Belgium providing for the reciprocal recognition and enforcement of judgments, other than arbitration awards, in civil and commercial

matters. Consequently, a final judgment for payment given by a court in the United States, whether or not predicated solely upon U.S. securities laws, would not automatically be recognized or enforceable in the Netherlands or Belgium. In order to obtain a judgment which is enforceable in the Netherlands, the party in whose favor a final and conclusive judgment of the U.S. court has been rendered will be required to file its claim with a court of competent jurisdiction in the Netherlands. Such party may submit to the Dutch court the final judgment rendered by the U.S. court. If and to the extent that the Dutch court finds that the jurisdiction of the U.S. court has been based on grounds which are internationally acceptable and that proper legal procedures have been observed, the court of the Netherlands will, in principle, give binding effect to the judgment of the U.S. court, unless such judgment contravenes principles of public policy of the Netherlands. Dutch courts may deny the recognition and enforcement of punitive damages or other awards. Moreover, a Dutch court may reduce the amount of damages granted by a U.S. court and recognize damages only to the extent that they are necessary to compensate actual losses or damages. Enforcement and recognition of judgments of U.S. courts in the Netherlands are solely governed by the provisions of the Dutch Code of Civil Procedure (*Wetboek van Burgerlijke Rechtsvordering*).

In order to obtain a judgment for the payment of money based on civil liability which is enforceable in Belgium, the judgment must be recognized and be declared enforceable by a Belgian court pursuant to the relevant provisions of the 2004 Belgian Code of Private International Law, or the PIL Code. Recognition or enforcement does not imply a review of the merits of the case and is irrespective of any reciprocity requirement. A U.S. judgment will, however, not be recognized or declared enforceable in Belgium if it infringes upon one or more of the grounds for refusal which are listed in article 25 of the PIL Code. In addition to recognition or enforcement, a judgment by a federal or state court in the United States against us may also serve as evidence in a similar action in a Belgian court if it meets the conditions required for the authenticity of judgments according to the law of the state where it was rendered. In addition, with regard to enforcements by legal proceedings in Belgium (including the recognition of foreign court decisions in Belgium), a registration tax at the rate of 3% of the amount of the judgment is payable by the debtor, if the sum of money which the debtor is ordered to pay by a Belgian court, or by a foreign court judgment that is either (i) automatically enforceable and registered in Belgium, or (ii) rendered enforceable by a Belgian court, exceeds €12,500. The registration tax is payable by the debtor. The debtor is liable for the payment of the registration tax, in the proportion determined by the decision ordering payment or liquidation or determining priority for creditors made or established against it. The debtor(s) are jointly and severally liable in the event that they are ordered to pay jointly and severally. A stamp duty is payable for each original copy of an enforcement judgment rendered by a Belgian court, with a maximum of €1,450.

Based on the lack of a treaty as described above, U.S. investors may not be able to enforce against us or members of our board of directors or certain experts named herein who are residents of the Netherlands or Belgium or countries other than the United States any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities laws.

We are a foreign private issuer and, as a result, we are not subject to U.S. proxy rules and are subject to Exchange Act reporting obligations that, to some extent, are more lenient and less frequent than those of a U.S. domestic public company.

We report under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as a non-U.S. company with foreign private issuer status. Because we qualify as a foreign private issuer under the Exchange Act, we are exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including (i) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act; (ii) the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and (iii) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events. In addition, foreign private issuers are not required to file their annual report on Form 20-F until 120 days after the end of each fiscal year, while U.S. domestic issuers that are accelerated filers are required to file their annual report on Form 10-K within 75 days after the end of each fiscal year. Foreign private issuers are also exempt from the Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information. As a result of the above,

you may not have the same protections afforded to shareholders of companies that are not foreign private issuers. However, we are subject to Dutch laws and regulations, and if we complete our possible redomiciliation, Belgian laws and regulations, with regard to such matters and intend to furnish quarterly unaudited financial information to the SEC on Form 6-K.

As a foreign private issuer and as permitted by the listing requirements of Nasdaq, we rely on certain home country governance practices rather than the corporate governance requirements of Nasdaq.

We qualify as a foreign private issuer. As a result, in accordance with the listing requirements of Nasdaq, we rely on home country governance requirements and certain exemptions thereunder rather than relying on the corporate governance requirements of Nasdaq. In accordance with Dutch law and generally accepted business practices, our Articles of Association do not provide quorum requirements generally applicable to General Meetings. To this extent, our practice varies from the requirement of Nasdaq Listing Rule 5620(c), which requires an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting stock. Although we must provide shareholders with an agenda and other relevant documents for the General Meeting, Dutch law does not have a regulatory regime for the solicitation of proxies and the solicitation of proxies is not a generally accepted business practice in the Netherlands, thus our practice will vary from the requirement of Nasdaq Listing Rule 5620(b). In addition, we have opted out of certain Dutch shareholder approval requirements for the issuance of securities in connection with certain events such as the acquisition of stock or assets of another company, the establishment of or amendments to equity-based compensation plans for employees, a change of control of us and certain private placements. To this extent, our practice varies from the requirements of Nasdaq Rule 5635, which generally requires an issuer to obtain shareholder approval for the issuance of securities in connection with such events. For an overview of our corporate governance principles, see “Item 16G.—Corporate Governance.” Accordingly, you may not have the same protections afforded to shareholders of companies that are subject to these Nasdaq requirements.

We may lose our foreign private issuer status which would then require us to comply with the Exchange Act’s domestic reporting regime and cause us to incur significant legal, accounting and other expenses.

We are a foreign private issuer, and therefore we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers. We may no longer be a foreign private issuer as of June 30, 2019 (the end of our second fiscal quarter in the fiscal year after our initial U.S. public offering), which would require us to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers as of January 1, 2020 and would also trigger a 10-K filing for the year ended December 31, 2019. In order to maintain our current status as a foreign private issuer, either (a) a majority of our ordinary shares must be either directly or indirectly owned of record by non-residents of the United States or (b)(i) a majority of our executive officers or directors may not be U.S. citizens or residents, (ii) more than 50% of our assets cannot be located in the United States and (iii) our business must be administered principally outside the United States. As of March 22, 2019, we believe at least 50% of our outstanding ordinary shares were held by U.S. residents (assuming that all our ordinary shares represented by ADSs were held by residents of the United States). If we lose this status, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC and Nasdaq rules. The regulatory and compliance costs to us under U.S. securities laws if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be significantly higher than the cost we would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities highly time consuming and costly. We also expect that if we were required to comply with the rules and regulations applicable to U.S. domestic issuers, it would make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our board of directors.

We may lose our status as a Small or Medium Size Enterprise as defined under the European Commission Recommendation of 6 May 2003 (Commission Recommendation 2003/361/EC).

We currently qualify as a “Small or Medium Size Enterprise,” or SME, as defined in European Commission Recommendation 2003/361/EC, which status is assigned upon application to the European Medicines Agencies for two-year periods to companies meeting certain requirements. Our SME status has been granted for the period from January 1, 2018 to December 31, 2019, after which we may apply for renewal of the SME status. We will only be able to apply for extension of this status if we meet the criteria set out in the European Commission Recommendation of 6 May 2003 regarding SME status at the time of our application for renewal. We will only qualify for renewing our SME status if (i) we have less than 250 employees, and (ii) we either have (a) an annual turnover of less than €50 million or (b) an annual balance sheet total of less than €43 million. On December 31, 2018, we had 105 employees, our annual turnover for the period ending December 31, 2018 totaled €21.5 million and our balance sheet totaled €578.5 million.

If the SME-status is no longer applicable to us for any period following December 31, 2019, we will lose certain benefits currently available to us as a result of qualifying as an SME, including:

- direct assistance by phone, email, teleconference or through briefing meetings on regulatory aspects of the pharmaceutical legislation. SMEs receive help on how to navigate the array of services available, support in identifying the most relevant guidance, or advice on regulatory strategy for a product development or authorization;
- fee exemptions and reductions for pre- and post-authorization regulatory procedures, including scientific advice, inspections and pharmacovigilance;
- assistance with translations of product information into all official EU languages for the purpose of granting an initial marketing authorization;
- inclusion in an online SME register. The register is an important source of information on EU/European Economic Area-based SMEs involved in the manufacturing, development or marketing of medicines and promotes partnering and networking between SMEs;
- guidance on clinical data publication and a free redaction tool license;
- liaison with academic investigators in pediatric-medicine research through the European Network of Pediatric Research at the European Medicines Agency (Enpr-EMA); and
- workshops and training sessions.

Whereas not all of these available benefits are currently used by us, we may want to use some or all of these benefits in the future, which we will not be able to do if we no longer qualify as an SME. As a result, we may face an increased financial burden because certain fee-exemptions no longer apply to us, and we may incur costs to obtain services or assistance currently offered by the EMA from third party service providers.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of the ADSs.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our

internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of the ADSs.

Our management is required to assess the effectiveness of our internal controls and procedures annually. We ceased to be an emerging growth company on December 31, 2018, and, as such, we will no longer be able to avail ourselves of exemptions from various reporting requirements applicable to other public companies but not to “emerging growth companies.” For example, Section 404 requires us to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on, and our independent registered public accounting firm potentially to attest to, the effectiveness of our internal control over financial reporting. We previously availed ourselves of the exemption from the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404. However, we are no longer able to avail ourselves of this exemption. Our management is required to issue an annual report on internal control over financial reporting, and our independent registered public accounting firm is now required to undertake an assessment of our internal control over financial reporting, which could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation. The rules governing the standards that must be met for our management to assess our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act are complex and require significant documentation, testing and possible remediation. These stringent standards require that our audit committee be advised and regularly updated on management's review of internal control over financial reporting in connection with issuing our consolidated financial statements as of and for the year ended December 31, 2018.

Moreover, if we are not able to comply with the requirements of Section 404 applicable to us in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of the ADSs or ordinary shares could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources. Furthermore, investor perceptions of our company may suffer if deficiencies are found, and this could cause a decline in the market price of the ADSs or ordinary shares. Irrespective of compliance with Section 404, any failure of our internal control over financial reporting could have a material adverse effect on our stated operating results and harm our reputation. If we are unable to implement these requirements effectively or efficiently, it could harm our operations, financial reporting, or financial results and could result in an adverse opinion on our internal control over financial reporting from our independent registered public accounting firm.

We have identified material weaknesses relating to the effectiveness of risk assessment, design and operating effectiveness of control activities, information and communication and monitoring activities as of December 31, 2018. If our remediation of these material weaknesses is not effective, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of the ADSs.

In connection with the risk assessment process and the design and implementation of our updated internal control frameworks as of December 31, 2018, we identified material weaknesses relating to the effectiveness of risk assessment, design and implementation and operating effectiveness of control Activities, information and communication and monitoring activities as of December 31, 2018. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. The company commenced the risk assessment process and the design and implementation of updated internal control frameworks for activities related to argenx. These processes covered the following activities: revenues and accounts receivable, other income, expenditure and payables, the financial closing and reporting process and general information technology controls, or GITC. The GITC deficiencies are related to the financial reporting system and the scope and conclusion of the service auditors' reports for the service organizations used by argenx's

accounting software. These risk assessment activities were undertaken to establish control frameworks necessary to support the company. However, the risk assessment process and the design and implementation of these control frameworks were not completed as of December 31, 2018, and certain business process controls and GITCs were not implemented in a timely manner to operate with a sufficient number of instances or for a sufficient period of time to have effective monitoring activities as of December 31, 2018.

We are implementing measures designed to improve our internal control over financial reporting to remediate these material weaknesses, including the following:

- hiring a full-time Internal Controls Manager to lead the monitoring and testing of internal controls over financial reporting;
- developing enhanced controls related to database administrator access with a specific focus on systems supporting our financial reporting processes;
- increasing the frequency of user access review controls on privileged users;
- implementing an improvement plan together with our external information technology service provider; and
- improving quarterly reporting on the remediation measures to the Audit Committee.

We cannot assure you that the measures we have taken to date, and are continuing to implement, will be sufficient to remediate the material weaknesses we have identified or avoid potential future material weaknesses. If the steps we take do not correct the material weaknesses in a timely manner, we will be unable to conclude that we maintain effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected on a timely basis.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on internal control over financial reporting. The Sarbanes-Oxley Act also requires that our management report on internal control over financial reporting be attested to by our independent registered public accounting firm.

We are in the process of designing and implementing the internal control over financial reporting required to comply with this obligation, which process will be time consuming, costly and complicated. If we identify any additional material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 in a timely manner, if we are unable to assert that our internal control over financial reporting is effective, or when required in the future, if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of the ADSs could be adversely affected, and we could become subject to investigations by the Nasdaq Global Select Market or Euronext Brussels, the SEC, or other regulatory authorities, which could require additional financial and management resources.

If securities or industry analysts cease coverage of us, or publish inaccurate or unfavorable research about our business, the price of the ADSs and our trading volume could decline.

The trading market for the ADSs will depend in part on the research and reports that securities or industry analysts publish about us or our business. If no or too few securities or industry analysts cover us, the trading price for the ADSs would likely be negatively affected. If one or more of the analysts who cover us downgrade the ADSs or publish inaccurate or unfavorable research about our business, the price of the ADSs would likely decline. If one

or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for the ADSs could decrease, which might cause the price of the ADSs and trading volume to decline.

We do not anticipate being treated as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes for the 2018 taxable year, but this conclusion is a factual determination that is made annually and thus may be subject to change. If we were to qualify as a PFIC, this could result in adverse U.S. tax consequences to certain U.S. holders.

Generally, if, for any taxable year, at least 75% of our gross income is passive income, or at least 50% of the value of our assets is attributable to assets that produce passive income or are held for the production of passive income, including cash, we would be characterized as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. For purposes of these tests, passive income includes dividends, interest, and gains from the sale or exchange of investment property and rents and royalties other than rents and royalties which are received from unrelated parties in connection with the active conduct of a trade or business. Our status as a PFIC depends on the composition of our income and the composition and value of our assets (for which purpose the total value of our assets may be determined in part by the market value of the ordinary shares and the ADSs, which are subject to change) from time to time. If we are characterized as a PFIC, U.S. holders of ADSs may suffer adverse tax consequences, including having gains realized on the sale of ADSs treated as ordinary income, rather than capital gain, the loss of the preferential rate applicable to dividends received on ADSs by individuals who are U.S. holders, and having interest charges apply to distributions by us and the proceeds of sales of ADSs. See “Item 10.E—Taxation—Certain Material U.S. Federal Income Tax Considerations to U.S. Holders—Passive Foreign Investment Company Considerations.”

Based upon the expected value of our assets, including any goodwill, and the expected composition of our income and assets, we do not anticipate being treated as a PFIC with respect to the 2018 taxable year. However, our status as a PFIC is a fact-intensive determination made on an annual basis, and we cannot provide any assurances regarding our PFIC status for the current, prior or future taxable years.

ITEM 4. INFORMATION ON THE COMPANY

A. HISTORY AND DEVELOPMENT OF THE COMPANY

Our legal and commercial name is argenx SE. We were incorporated under the laws of the Netherlands on April 25, 2008 as a private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*). On May 28, 2014, we converted to a Dutch public company with limited liability (*naamloze vennootschap*). On April 26, 2017, we converted to a Dutch European public company with limited liability (*Societas Europaea* or *SE*). Our official seat is in Rotterdam, the Netherlands, and our registered office is at Willemstraat 5, 4811 AH, Breda, the Netherlands. We are registered with the trade register of the Dutch Chamber of Commerce under number 24435214. Our telephone number is +32 9 310 34 00. Our website address is <http://www.argenx.com>. The information contained on, or that can be accessed through, our website is not a part of, and shall not be incorporated by reference into, this annual report. We have included our website address as an inactive textual reference only. The registered agent for service of process in the United States is C T Corporation System, with an address at 111 8th Avenue, New York, NY 10011.

Our actual capital expenditures for the years ended December 31, 2016, 2017 and 2018 amounted to €0.9 million, €0.4 million and €0.7 million respectively. These capital expenditures primarily consisted of office and laboratory equipment and information technology equipment. We expect our capital expenditures to increase in absolute terms in the near term as we continue to advance our research and development programs and grow our operations. We anticipate our capital expenditure in 2019 to be financed from the cash flows from operating activities and cash reserves. For more information on our capital expenditures, see the section of this annual report titled “Item 5.B.—Liquidity and Capital Resources—Cash Flows—Operating and Capital Expenditure Requirements.”

Overview of Our Restructuring and Possible Redomiciliation

Background

From our incorporation in 2008 until August 28, 2009, our research and development activities were performed in the Netherlands by argenx N.V. and its legal predecessors arGEN-X B.V. and arGEN-X N.V. On August 28, 2009, we moved our research and development activities to Belgium for various business reasons. Accordingly, as of August 28, 2009, our wholly owned subsidiary, argenx BVBA, or the Belgian BVBA, has performed all research and development activities under a license provided by argenx N.V. and has assigned all resulting intellectual property rights to argenx N.V. As a consequence, argenx N.V. remained the legal owner of the intellectual property rights relating to our platform technologies until these intellectual property rights were transferred to argenx BVBA on May 5, 2017 as described below.

Since all our research and development activities have been performed by the Belgian BVBA since August 28, 2009, we considered that value creation was not adequately aligned with our intellectual property ownership structures as required under the Base Erosion and Profit Shifting project of the Organization for Economic Co-operation and Development. In order to achieve such alignment, on May 5, 2017, we transferred the legal ownership of all intellectual property rights of argenx SE to the Belgian argenx BVBA, effective retroactively as of January 1, 2017. As a result, as of January 1, 2017, (i) argenx BVBA holds all legal and economic ownership of our intellectual property rights, and (ii) the research and development agreement between argenx SE and the Belgian BVBA has been terminated.

Dutch Tax Consequences of Our Restructuring

The tax consequences of our restructuring were discussed with the Dutch tax authorities and the Belgian tax authorities. On April 20, 2017, we reached an agreement with the Dutch tax authorities that the economic ownership of our intellectual property rights was effectively transferred from argenx SE to the Belgian BVBA as of August 28, 2009. Since then, argenx SE should have been treated only as the legal owner of our intellectual property rights, for which it should have received a low but stable remuneration only, instead of being the party absorbing all research and development costs. In order to compensate argenx SE for the restructuring, the Belgian BVBA has paid an arm's length compensation to argenx SE in the form of an indemnification payment effective as of January 1, 2017 consisting of (i) compensation for the value of the economic ownership of our intellectual property rights as of September 2009 to January 1, 2017, (ii) accrued interest thereon and (iii) an adjustment for the difference between (a) the applied transfer pricing policy and (b) the appropriate transfer pricing policy taking into account the transfer of economic ownership as of August 28, 2009 in the period from September 2009 through 2016. The total indemnification payment amounted to €80 million and was charged by argenx SE to the Belgian BVBA. argenx SE was able to off-set the full amount of its tax loss carry forwards against the taxable profits it realized as a result of the indemnification payment. The transfer of legal ownership of our intellectual property rights from argenx SE to the Belgian BVBA as of January 1, 2017 is an integral part of the restructuring and does not result in an additional transfer subject to tax in the Netherlands. The tax consequences of the restructuring, including the indemnification payment, will not be affected or impacted in case we do not complete our possible redomiciliation. Altogether, the restructuring resulted in a taxable amount for argenx SE of €2.4 million, which has been subject to corporate income tax in the Netherlands at a tax rate of 25% (20% for the first €200,000 of taxable income).

Belgian Tax Consequences of Our Restructuring

In view of the above considerations, on April 4, 2017, we requested a tax ruling from the Belgian ruling commission with respect to the following aspects of the restructuring:

- the indemnification payment that was paid by the Belgian BVBA to argenx SE for the restructuring does not deviate from what would have been agreed by two independent companies in a similar

relational situation, including the previously built relationships which have effect in the framework of the restructuring and will not give rise to an adjustment on the basis of article 185 §2 of the Belgian Income Tax Code;

- the Belgian BVBA will not grant or receive an abnormal or benevolent advantage within the meaning of Articles 26, 79 and 207 of the Belgian Income Tax Code;
- the indemnification payment paid by the Belgian BVBA to argenx SE for the restructuring is expected to qualify as a deductible cost for the Belgian BVBA under article 49 §2 of the Belgian Income Tax Code, being (partly) incurred in the fiscal period in which the restructuring has been implemented and (partly) incurred in the following years in the form of a periodic amortization if the accounting treatment of the restructuring requires that the compensation is to be (partly) activated; and
- the restructuring was justified by other motives than the avoidance of income taxes within the meaning of Article 344 of the Belgian Income Tax Code.

In summary, the restructuring has resulted in a taxable amount for argenx SE of €2.4 million subject to Dutch corporate income tax at a tax rate set out above and an elimination of its tax loss carry forwards for Dutch corporate income tax purposes an amount of €77.5 million. On the other hand, the restructuring is expected to bring additional deductible costs to the Belgian BVBA for an amount of up to €80 million.

As set out in “Item 3.D.—Risk Factors—Risks Related to Our Organization and Operations—The restructuring and its contemplated tax treatment is subject to approval by the Belgian tax authorities,” we may not obtain the tax ruling from the Belgian ruling commission, and we may not be allowed to treat the amount of €80 million as a deductible cost for the Belgian BVBA.

Transfer of Our Registered Office from the Netherlands to Belgium

In addition to the alignment of value creation with intellectual property ownership structure, we face a compliance burden from an organizational and regulatory perspective as a company incorporated and existing under Dutch law, while our shares are listed on Euronext Brussels and Nasdaq. Due to this burden, we may possibly transfer our registered seat (statutaire zetel) from the Netherlands to Belgium.

There is currently no clear legal framework under Dutch law for a transfer of registered office (statutaire zetel) by a Dutch public company with limited liability (naamloze vennootschap). However, it is possible for a European public company with limited liability (Societas Europaea or SE) to cross-border transfer its registered office pursuant to the relevant provisions of the European Council Regulation (EC) No 2157/2001 of 8 October 2001 on the Statute for a European company (Societas Europaea or SE), or the SE regulation. In preparation for a possible redomiciliation, at our General Meeting held on April 26, 2017 our shareholders approved our conversion into a Dutch European public company with limited liability (Societas Europaea or SE) pursuant to a notarial deed of conversion and amendment, which notarial deed was executed on the same date.

On February 28, 2019, the Belgian parliament adopted the new Belgian Code for Companies and Association, replacing the current Belgian Companies Code and which will enter into force on 1 May 2019. In addition, the Belgian Corporate Governance Committee is currently finalizing its work on a new version of the Belgian Corporate Governance Code. As the new corporate governance code is closely intertwined with the revision of the Belgian Companies Code, the Belgian Corporate Governance Committee announced that it would await the approval of the revised Companies Code to publish the new corporate governance code.

We are currently in the process of reviewing the impact of the changes to the Belgian corporate law which follow from the new Belgian Code for Companies and Association, and are awaiting the publishing of the new Belgian Corporate Governance Code to be able to review the expected impact of the changes made to the current Belgian Companies Code. Particularly we need to assess the extent to which these newly applicable laws and the new corporate governance code would affect us, and in which way, if we should decide to pursue our possible redomiciliation.

Given these recent and expected major changes to Belgian corporate law, we expect to postpone seeking shareholder approval for our possible redomiciliation until we have carefully evaluated the effect of the new Belgian laws on us, should we complete our possible redomiciliation. We expect that our board of directors will be able to consider and resolve this topic once we are able to ascertain the effects that the new Belgian Code for Companies and Association and the new Belgian Corporate Governance Code would have on our governance and our organizational, compliance and reporting obligations.

If we seek to implement our possible redomiciliation, this will be subject to a procedure governed by the SE regulation, which can be summarized as follows:

- our board of directors will draw up draft terms of migration (including the Belgian Articles of Association, the address of the new registered office, the proposed timetable of our possible redomiciliation and any rights provided for the protection of our shareholders and/or creditors) and a report explaining and justifying the legal and economic aspects of our possible redomiciliation and indicating the implications for our shareholders and for the employees;
- following the filing and announcement of these draft terms of our possible redomiciliation, a two-month waiting period will commence in which creditors may file their objections against our possible redomiciliation and in which the Dutch Minister of Justice has the right to object to our possible redomiciliation by filing a declaration to that effect with the trade register of the Dutch Chamber of Commerce;
- following the two-month waiting period, our shareholders will be asked to approve and resolve upon our possible redomiciliation at a General Meeting. The resolution of the shareholders at a General Meeting requires an absolute majority of the votes cast, unless less than half of our issued and outstanding share capital is present or represented at that meeting, in which case a majority of at least two-thirds of the votes cast will be required;
- if and when our shareholders at a General Meeting approve our possible redomiciliation, a Dutch civil notary will issue a certificate confirming that the procedural rules in relation to our possible redomiciliation have been complied with; and
- following receipt of this Dutch civil notary certificate, our possible redomiciliation will be recorded in a notarial deed passed before a Belgian notary.

We may decide not to, or may not be able to successfully, complete our possible redomiciliation, in which case we will remain a European public company with limited liability (*Societas Europaea* or SE) under Dutch law.

B. BUSINESS OVERVIEW

We are a clinical-stage biotechnology company developing a deep pipeline of differentiated antibody-based therapies for the treatment of severe autoimmune diseases and cancer. Utilizing our suite of technologies, we are focused on developing product candidates with the potential to be either first-in-class against novel targets or best-in-class against known, but complex, targets in order to treat diseases with a significant unmet medical need. Our SIMPLE Antibody™ Platform, based on the powerful llama immune system, allows us to exploit novel and complex targets, and our three antibody Fc engineering technologies are designed to enable us to expand the therapeutic index of our product candidates. Together with our antibody discovery and development expertise, this suite of technologies has enabled our pipeline of eight product candidates. Two of our product candidates are in Phase 2 and Phase 3 trials for multiple indications, one of which has achieved clinical proof-of-concept in two indications and is in Phase 3 clinical development for the first indication.

In September 2018, we launched our first Phase 3 trial for efgartigimod (ARGX-113), our most advanced product candidate for the treatment of the rare autoimmune disease myasthenia gravis, or MG. The full data from the Phase 2 trial in myasthenia gravis were reported in April 2018. In addition, we recently completed a Phase 2 clinical trial for efgartigimod in immune thrombocytopenia, or ITP, where we reported for the second time a proof-

of-concept of our lead product candidate with strong clinical improvement over placebo. In both Phase 2 studies, efgartigimod was observed to have a favorable tolerability profile consistent with that observed in our Phase 1 clinical trial. In September 2017, we initiated a Phase 2 clinical trial of efgartigimod for the treatment of a third rare autoimmune disease, pemphigus vulgaris, or PV. In June 2018, we reported interim data from the first cohort of this Phase 2 proof-of-concept clinical trial where rapid disease control was observed with a favorable tolerability profile. For efgartigimod, we are also developing a subcutaneous, or SC, product formulation designed to enable administration potentially outside the hospital setting. In June 2018, we reported that at the same dose level the SC formulation was comparable across key measures, including half-life, pharmacodynamics and tolerability, to the intravenous, or IV, formulation used in clinical studies to date.

We continued to develop our second lead product candidate, cusatuzumab (ARGX-110), for the rare and aggressive hematological cancer acute myeloid leukemia, or AML, as well as high-risk myelodysplastic syndrome, or MDS. In December 2016, we commenced the dose-escalation part of the Phase 1/2 clinical trial of cusatuzumab in combination with azacytidine. In December 2018, we reported a 92% response rate in the treated newly diagnosed AML patients. The transition into the Phase 2 part of this clinical trial was announced in August 2018.




We have a disciplined strategy to maximize the value of our pipeline whereby we plan to retain development and commercialization rights to those product candidates that we believe we can ultimately commercialize successfully on our own if they are approved. We plan to collaborate on product candidates that we believe have promising utility in disease areas or patient populations that are better served by the resources of larger biopharmaceutical companies. We have entered into collaborations with a number of biopharmaceutical companies, including our collaboration with Cilag GmbH International, an affiliate of Janssen. In January 2019, we received a \$300 million upfront payment and Johnson & Johnson Innovation Inc., or JJDC, made a €176.7 million equity investment in argenx. In addition, in August 2018, our collaborator AbbVie S.A.R.L, or AbbVie, exercised its exclusive option to license ARGX-115 (ABBV-151), a cancer immunotherapy-focused product candidate against the novel target glycoprotein A repetitions predominant, or GARP.

Our product candidates are focused on indications for which there is a solid biological rationale and for which we believe there is an advantage to utilizing our suite of technologies outlined below:

- **Our proprietary SIMPLE Antibody™ Platform** sources antibody V-regions from the immune system of outbred llamas, each of which has a different genetic background. The V-region is responsible for targeting a specific antibody to an antigen, which is a substance that induces an immune response, and is different for every type of antibody. The llama produces highly diverse panels of antibodies with a high human homology, or similarity, in their V-regions when immunized with targets of human disease. By contrast, most antibody platforms start with antibodies generated in inbred mice or synthetic antibody library systems, approaches that we believe are limited by insufficient antibody repertoires and limited diversity, respectively. Our SIMPLE Antibody™ Platform allows us to access and explore a broad target universe, including novel and complex targets, while minimizing the long timelines associated with generating antibody candidates using traditional methods.
- **Our Fc engineering technologies**—NHance®, ABDEG™ and POTELLIGENT®—focus on engineering the Fc region of antibodies in order to augment their intrinsic therapeutic properties. These technologies are designed to enable us to expand the therapeutic index of our product candidates, which is the ratio between toxic and therapeutic dose, by modifying their half-life, tissue penetration, rate of disease target clearance and potency.

Our product candidate pipeline includes both wholly-owned and partnered programs. We refer to programs for which we retain the exclusive right to develop and commercialize the product candidate on a worldwide basis as our wholly-owned programs. We refer to programs for which we have entered into collaboration agreements with third parties for the development and commercialization of the product candidate as our partnered programs.

Our product candidate pipeline enabled by our suite of technologies is set forth below:

Product Candidate	Target	Indication	Preclinical	Phase 1	Phase 2	Phase 3	BLA	Next Milestone / Commentary	
Wholly-Owned & Co-Development Product Candidates									
ARGX-113 Efgartigimod	FcRn	Myasthenia Gravis						3Q18: Phase 3 initiated	
		Immune Thrombocytopenia (ITP)							2H19: Phase 3 initiation
		ITP Subcutaneous Formulation							1H19: Phase 2 initiation
		Pemphigus Vulgaris							1H19: Cohort 3 initiation
		Chronic Inflammatory Demyelinating Polyneuropathy							2H19: Phase 2 initiation
ARGX-117	Novel complement target	Severe Autoimmune Diseases						Antibody-mediated autoimmune diseases Complementary to ARGX-113	
ARGX-110 Cusatuzumab	CD70	Acute Myeloid Leukemia						\$500 mm upfront (of which \$200* mm equity investment) Eligible for up to \$1.3 billion in milestones; tiered royalties	

We believe that our clinical expertise and execution capabilities position us well to advance our product pipeline and enter into collaborations designed to maximize the value of our portfolio. We have assembled a team of over 130 employees and consultants with experience across the spectrum of antibody drug discovery and development and business development. Members of our board of directors, management team and key personnel have extensive experience in the life sciences industry and have previously served at companies including Alexion Pharmaceutical, Inc.; Cambridge Antibody Technology Group Plc; Celgene Corporation; Galapagos NV; GlaxoSmithKline plc; Janssen; Micromet, Inc.; Nicox S.A.; The Procter & Gamble Company; Quintiles IMS Holdings, Inc; Shire Plc (now part of Takeda Pharmaceutical Company Limited) and Unilever N.V.

Our Competitive Strengths

We believe that the combination of our technologies, expertise and disciplined focus will enable us to overcome many of the challenges associated with antibody drug development and positions us to be a leader in delivering therapies to patients suffering from severe autoimmune disease and cancers for which the current treatment paradigm is inadequate. Our competitive strengths include:

- Phase 3 lead product candidate with clinical proof-of-concept in MG and ITP; pipeline-in-a-product opportunity with an ongoing Phase 3 clinical trial and Phase 2 clinical trials in two additional indications.** We launched a Phase 3 clinical trial in MG for our lead product candidate, efgartigimod, in September 2018. We announced full data from the Phase 2 clinical trial in ITP in December 2018. We expect to prepare for Phase 3 clinical development in this indication in the second half of 2019, subject to discussions at an end-of-Phase 2 meeting with the FDA, EMA and the Japanese Pharmaceuticals and Medical Devices Agency, or PMDA, which we intend to schedule in the first half of 2019. We reported interim data of the additional Phase 2 clinical trial of efgartigimod in PV in June 2018 and announced the planned launch of an additional Phase 2 clinical trial in CIDP during the second half of 2019. MG, ITP, PV and CIDP are four rare, severe autoimmune diseases in which there is high unmet medical need. Each indication is characterized by high levels of pathogenic immunoglobulin G, or IgG, antibodies, and we designed efgartigimod to reduce IgG antibody levels. All patients in the treatment arm of our Phase 2 clinical trial in MG showed a rapid and deep reduction of their total IgG levels and disease improvement was found to correlate with reduction in

pathogenic IgG levels. The treated ITP patients in the Phase 2 clinical trial showed a correlation between IgG reduction, platelet count increase and reduction of bleeding events. In addition, interim data from the treated PV patients showed a rapid disease control in 4 out of 6 patients. As such, we believe efgartigimod is a pipeline-in-a-product opportunity for us in these three, and potentially other, indications. In a Phase 1 clinical trial of efgartigimod with healthy volunteers, we observed a reduction of circulating IgG antibody levels of 50% to 85%. We believe that a reduction of pathogenic IgG antibody levels, which are a subset of circulating IgG antibodies in people with autoimmune disease, of at least 30% would be clinically meaningful. We expect to launch a Phase 2 trial with the SC formulation and start the third cohort of the Phase 2 clinical trial in PV in the first half of 2019. By the second half of 2019, we expect to launch a Phase 2 clinical trial in our fourth indication, CIDP. Depending on the outcome of the discussions with regulatory agencies, we intend to enter into Phase 3 clinical development in ITP.

- ***Productive discovery capabilities that fuel a deep pipeline of clinical and preclinical product candidates.*** We are advancing a deep pipeline of both clinical- and preclinical-stage product candidates for the treatment of severe autoimmune diseases and cancer. Leveraging our technology suite and clinical expertise, we have advanced six product candidates into clinical development—efgartigimod, cusatuzumab, ARGX-111, ARGX-109, ARGX-112 and ARGX-115 (ABBV-151); two into the preclinical stage—ARGX-116 and ARGX-117; and we currently have multiple programs in the discovery stage. Our second lead product candidate, cusatuzumab, was being investigated in Phase 1/2 clinical trials, and we reported proof-of-concept results from these trials in December 2018. We believe this level of productivity affords us a breadth of options with regard to independently advancing or partnering our pipeline assets.
- ***The ability to exploit novel and complex targets for maximum therapeutic effect.*** Our SIMPLE Antibody™ Platform, which is based on outbred llamas, allows us to access and explore a broad target universe. We believe the benefit of our platform is that it provides a broader set of human-like V-regions as compared to other sources such as mice or synthetic antibody libraries. With this breadth of antibodies, we are able to test many different epitopes, which are binding sites on antigens capable of eliciting an immune response. Being able to test many different epitopes with our antibodies enables us to search for an optimized combination of safety, potency and species cross-reactivity with the potential for maximum therapeutic effect on disease.
- ***The ability to use our Fc engineering technologies to modulate immune response.*** We employ technologies—NHance®, ABDEG™ and POTELLIGENT®—that focus on engineering the Fc region of antibodies in order to augment their intrinsic therapeutic properties. These technologies are designed to expand the therapeutic index of our product candidates by modifying their half-life, tissue penetration, rate of disease target clearance and potency.
- ***Validating strategic collaborations to maximize pipeline value.*** Our productive discovery capabilities and deep pipeline have provided us with multiple product candidates for which we seek to capture the greatest value. We have partnered, and expect to continue to partner, product candidates that we believe have promising utility in disease areas or patient populations that are better served by the resources of larger biopharmaceutical companies. As a result, we have entered into collaborations with a number of biopharmaceutical companies, including our collaboration with Janssen for cusatuzumab, our product candidate targeting CD70 for rare and aggressive hematological cancers, and with AbbVie for ARGX-115 (ABBV-151), a cancer immunotherapy-focused product candidate against the novel target GARP.

Our Strategy

Our goal is to deliver therapies that are either first-in-class or best-in-class to patients suffering from severe autoimmune diseases and various cancers for which there exists a significant unmet medical need. We are also focused on attaining this goal in a manner that is disciplined for a company of our size. We plan to:

- ***Rapidly advance efgartigimod to regulatory approval in MG and through clinical proof-of-concept in three additional indications.*** We are currently developing our lead product candidate, efgartigimod for the treatment of patients with MG, ITP and PV and plan for a fourth indication, CIDP. We chose these indications based on the biological rationale of targeting the neonatal Fc receptor, or FcRn, thereby reducing the pathogenic IgG antibody levels that drive all of these disease states. We launched a Phase 3 clinical trial in MG for efgartigimod in September 2018, aiming for a first approval in MG. We announced full data from the Phase 2 clinical trial in ITP in December 2018. We expect to prepare for Phase 3 clinical development in this indication in the second half of 2019, subject to discussions at an end-of-Phase 2 meeting with the FDA, which we intend to schedule in the first quarter of 2019. We reported interim data of the additional Phase 2 clinical trials of efgartigimod in PV in June 2018 and announced the launch of an additional Phase 2 clinical trial in CIDP. In the first half of 2019, we expect to launch a Phase 2 with the SC formulation and start the third cohort of the Phase 2 clinical trial in PV. During the second half of 2019, we will launch a Phase 2 clinical trial in our fourth indication CIDP. Depending on the outcome of the discussions with regulatory agencies, we intend to enter into Phase 3 clinical development in ITP or more of these indications.
- ***Advance cusatuzumab to regulatory approval through clinical proof-of-concept in AML and adjacent hematological tumors.*** In December 2016, we initiated an open-label, Phase 1/2 clinical trial of cusatuzumab in combination with the standard of care, azacytidine, in newly diagnosed AML and high-risk MDS patients. We reported topline results from the dose-escalation part of this clinical trial in December 2018, and we announced the transition into the Phase 2 part of this clinical trial in August 2018. In December 2018, argenx and Janssen have agreed to a joint global clinical development plan to evaluate cusatuzumab in AML, MDS and other potential future indications. We also reported full data on the Phase 2 part of an open-label Phase 1/2 clinical trial of cusatuzumab for the treatment of adult relapsed or refractory CD70-positive CTCL patients in December 2018. Given the potential of cusatuzumab in newly diagnosed AML patients based on early data from the Phase 1/2 proof-of-concept trial, we prioritized the development of cusatuzumab in AML and MDS over CTCL and do not expect to devote resources to its further development in CTCL.
- ***Expand applications for our existing product candidates.*** Our goal is to maximize the commercial potential of our existing product candidates by exploring additional indications, as well as formulations that may expand the target patient populations within existing indications. For example, our development work in efgartigimod is based on its ability to reduce circulating IgG antibodies, and this has given us the ability to leverage a single Phase 1 clinical trial in healthy volunteers into one Phase 3 and three Phase 2 clinical trials in different indications, MG, ITP, PV and CIDP where we believe this mechanism of action may have therapeutic benefit. In addition, we believe there are other autoimmune diseases beyond MG, ITP, PV and CIDP that may benefit from treatment with efgartigimod. We plan to employ a similar strategy of leveraging the strong biological rationale for other product candidates into multiple indications, thereby maximizing the value of our pipeline. We also expanded the use of our product candidates in existing indications by developing new formulations, such as a SC version of efgartigimod, which was tested in a Phase 1 healthy volunteer clinical trial, that may make our product candidates accessible to larger patient populations, including patients requiring chronic therapy, potentially outside of the hospital setting.
- ***Focus our discovery and development efforts on novel and complex targets to generate new first-in-class and best-in-class product candidates for autoimmune diseases and cancer.*** Our SIMPLE Antibody™ Platform allows us to access and explore a broad target universe, including novel and complex targets, while minimizing the long timelines associated with generating antibody candidates using traditional methods. By exploring a broad target universe, we are able to develop a breadth of antibodies to test many different epitopes. Being able to test many different epitopes with our antibodies enables us to search for an optimized combination of safety, potency and species cross-reactivity. We believe our Fc engineering technologies will allow us to augment our antibodies for maximum therapeutic effect.

- **Independently commercialize our product candidates in indications and geographies where we believe we can extract maximum value.** We plan to independently develop and commercialize those product candidates that we believe have a clear clinical and regulatory approval pathway and that we believe we can commercialize successfully, if approved. Our commercialization strategy for any product candidates that are approved will focus on key academic centers, specialist physicians and advocacy groups, as well as on providing patients with support programs and maximizing product access and reimbursement.
- **Selectively leverage our suite of technologies to seek strategic collaborations and maximize the value of our pipeline.** Our suite of technologies and productive discovery capabilities have yielded us several potential product candidates for which we seek to capture value, while maintaining our focus and discipline. We plan to collaborate on product candidates that we believe have promising utility in disease areas or patient populations that are better served by the resources of larger biopharmaceutical companies. In addition to collaborating on our product candidates, we may also elect to enter into collaborations for third-party product candidates for which we believe that our technologies and expertise may be valuable.

Our Suite of Technologies

Harnessing the Therapeutic Potential of Antibodies

Antibodies are Y-shaped proteins used by the immune system to target and clear foreign bodies, including pathogens, such as bacteria and viruses, and tumor cells. Antibodies are composed of two structurally independent parts, the variable region, or V-region, and the constant, or Fc, region. The V-region is responsible for targeting a specific antibody to an antigen and is different for every type of antibody. The Fc region does not interact with antigens, but rather interacts with components of the immune system through a variety of receptors on immune and other cells. These interactions allow antibodies to regulate the immune response and levels of cell-killing ability, or cytotoxicity, as well as their persistence in circulation and tissues. Fc regions are the same and interchangeable from antibody to antibody.

As shown in *Figure 1*, we apply a unique suite of technologies to create antibodies with optimized V-regions and an enhanced Fc region. Used alone or in combination, we believe that our suite of technologies enable us to create product candidates with potential first-in-class and best-in-class therapeutic activity against a wide range of targets.

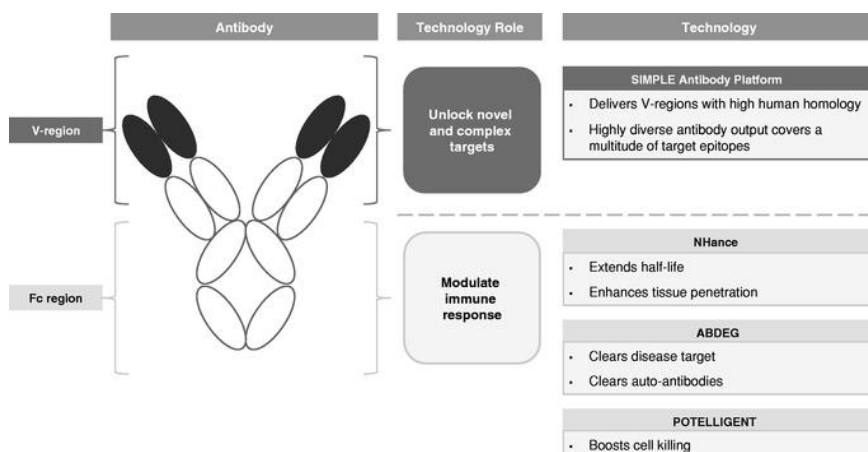


Figure 1: Overview of our suite of technologies

Our Proprietary SIMPLE Antibody™ Platform

Our proprietary SIMPLE Antibody™ Platform sources V-regions from conventional antibodies existing in the immune system of outbred llamas. Outbred llamas are those that have been bred from genetically diverse parents, and each has a different genetic background. The llama produces highly diverse panels of antibodies with a high human homology in their V-regions when immunized with human disease targets. We then combine these llama V-regions with Fc regions of fully human antibodies, resulting in antibodies that we then produce in industry-validated production cell lines. The resulting antibodies are diverse and, due to their similarity to human antibodies, we believe they are well suited to human therapeutic use. With this breadth of antibodies, we are able to test many different epitopes. Being able to test many different epitopes with our antibodies enables us to search for an optimized combination of safety, potency and species cross-reactivity with the potential for maximum therapeutic effect on disease. These antibodies are often cross-reactive with the rodent version of chosen disease targets. This rodent cross-reactivity enables more efficient preclinical development of our product candidates because most animal efficacy models are rodent-based. By contrast, most other antibody discovery platforms start with antibodies generated in inbred mice or synthetic antibody libraries, approaches that we believe are limited by insufficient antibody repertoires and limited diversity, respectively. Our SIMPLE Antibody™ Platform allows us to access and explore a broad target universe, including novel and complex targets, while minimizing the long timelines associated with generating antibody candidates using traditional methods.

Our Fc Engineering Technologies

Our antibody engineering technologies—NHance®, ABDEG™ and POTELLIGENT®—focus on engineering the Fc region of antibodies in order to augment their interactions with components of the immune system, thereby potentially expanding the therapeutic index of our product candidates by modifying their half-life, tissue penetration, rate of disease target clearance and potency. For example, our NHance® and ABDEG™ engineering technologies enable us to modulate the interaction of the Fc region with FcRn, which is responsible for regulating half-life, tissue distribution and pharmacodynamic properties of IgG antibodies. Similarly, our POTELLIGENT® engineering technology modulates the interaction of the antibody Fc region with receptors located on specialized immune cells known as natural killer, or NK, cells. These NK cells can destroy the target cell, resulting in enhanced antibody-dependent cell-mediated cytotoxicity, or ADCC.

NHance® and ABDEG™: Modulation of Fc Interaction with FcRn

An illustration of the FcRn-mediated antibody recycling mechanism is shown in *Figure 2*. ❶ Serum proteins, including IgG antibodies, are routinely removed from the circulation by cell uptake. ❷ Antibodies can bind to FcRn, which serves as a dedicated recycling receptor in the endosomes, which have an acidic environment, and then ❸A return to the circulation by binding with their Fc region to FcRn. ❸B Unbound antibodies end up in the lysosomes and are degraded by enzymes. Because this Fc/FcRn interaction is highly pH-dependent, antibodies tightly bind to FcRn at acidic pH (pH 6.0) in the endosomes, but release again at neutral pH (pH 7.4) in the circulation.

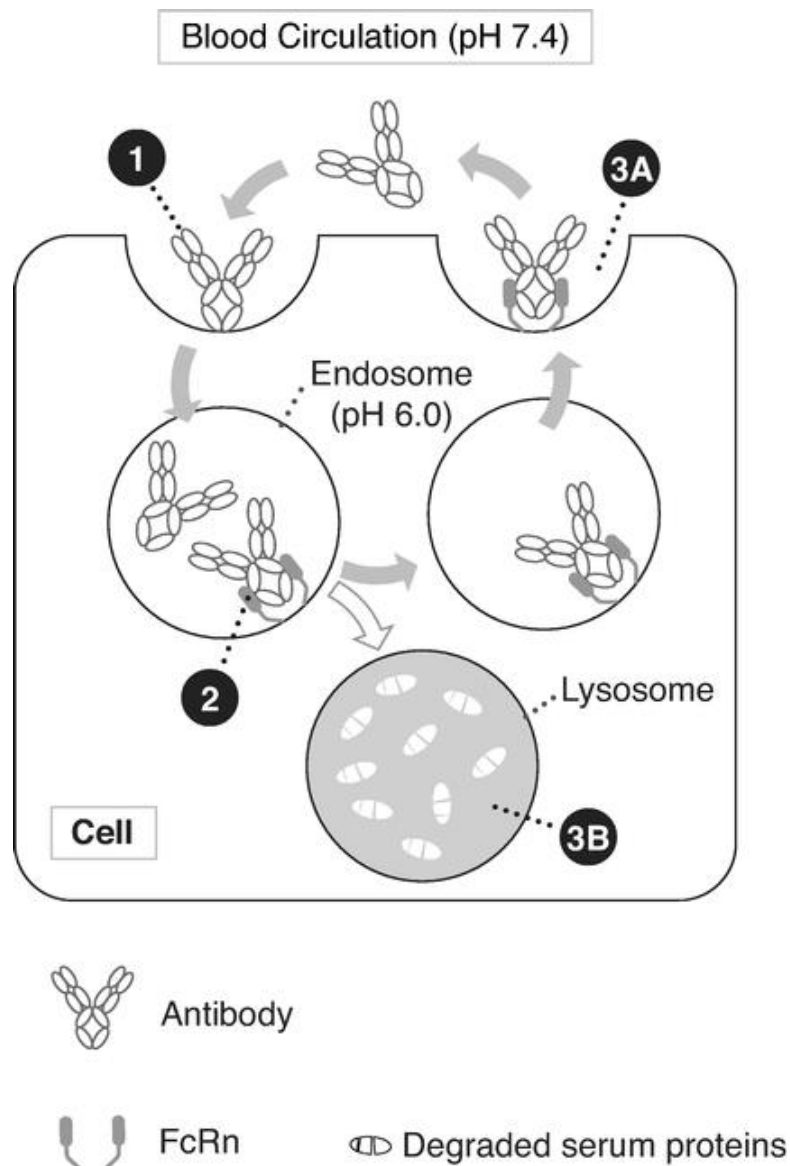


Figure 2: The FcRn-mediated recycling mechanism

NHance®

NHance® refers to two mutations that we introduce into the Fc region of an IgG antibody. NHance® is designed to extend antibody serum half-life and increase tissue penetration. In certain cases, it is advantageous to engineer antibodies that remain in the circulation longer, allowing them to potentially exert a greater therapeutic effect or be dosed less frequently. As shown in *Figure 3*, ❶ NHance® antibodies bind to FcRn with higher affinity, specifically under acidic pH conditions. ❷ Due to these tighter bonds, NHance® FcRn-mediated antibody recycling is strongly favored over lysosomal degradation, although some degradation does occur. ❸ NHance®

allows a greater proportion of antibodies to return to the circulation potentially resulting in increased bioavailability and reduced dosing frequency. ARGX-111, ARGX-109 and a number of our discovery-stage programs utilize NHance®.

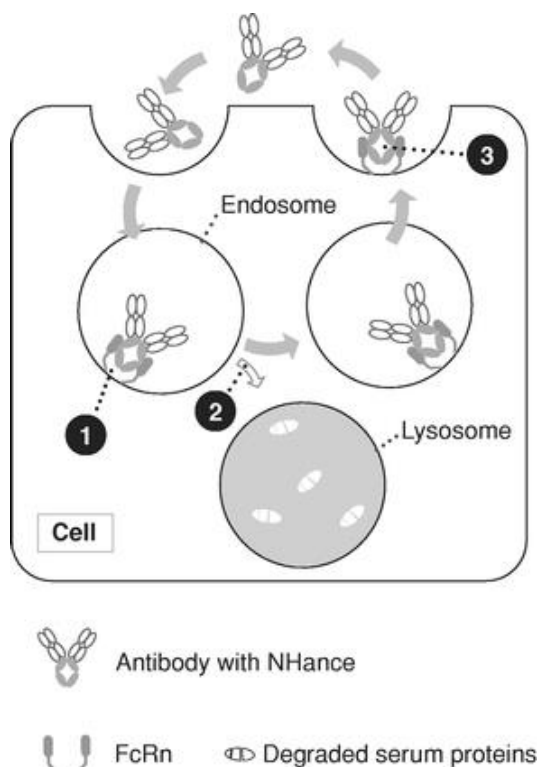


Figure 3: NHance® mutations favor the FcRn-mediated recycling of IgG antibodies

ABDEG™

ABDEG™ refers to five mutations that we introduce in the Fc region that increase its affinity for FcRn at both neutral and acidic pH. In contrast to NHance®, ABDEG™-modified Fc regions remain bound to FcRn if the pH changes, occupying FcRn with such high affinity that they deprive endogenous IgG antibodies of their recycling mechanism, leading to enhanced clearance of such antibodies by the lysosomes. Some diseases mediated by IgG antibodies are directed against self-antigens. These self-directed antibodies are referred to as auto-antibodies. We use our ABDEG™ technology to reduce the level of these pathogenic auto-antibodies in the circulation by increasing the rate at which they are cleared by the lysosomes. ABDEG™ is a component in a number of our product candidates, including efgartigimod.

As shown in *Figure 4*, our ABDEG™ technology can also be used with our pH-dependent SIMPLE Antibodies in a mechanism referred to as sweeping. Certain SIMPLE Antibodies bind to their target in a pH-dependent manner. These antibodies ① bind tightly to a target at neutral pH while in circulation, and ② release the target at acidic pH in the endosome. ③ The unbound target is degraded in the lysosome. ④ However, when equipped with our ABDEG™ technology, the therapeutic antibodies remain tightly bound to FcRn at all pH levels and are not degraded themselves. Instead, they are returned to the circulation where they can bind new targets. We believe this is especially useful in situations where high levels of the target are circulating or where the target needs to be cleared very quickly from the system.

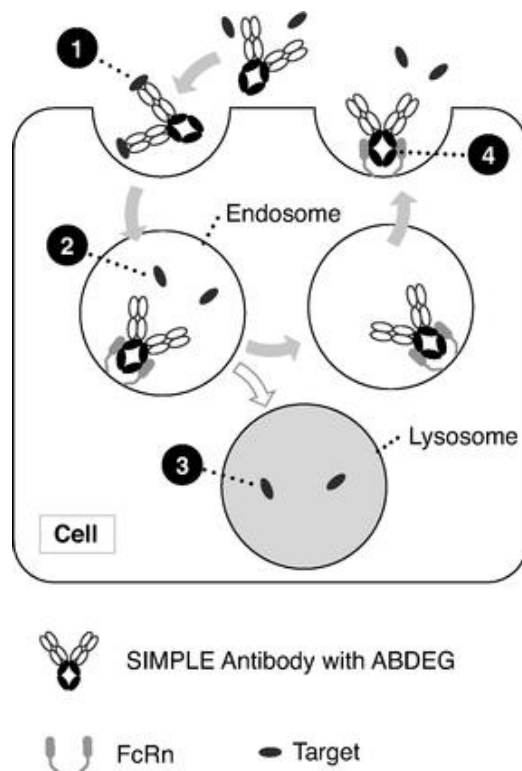


Figure 4: SIMPLE Antibody™ and ABDEG™ technologies work in concert to sweep disease targets

POTELLIGENT®: Modulation of Fc Interaction with NK Cells

POTELLIGENT® modulates the interaction of the Fc region with the Fc gamma receptor IIIa located on specialized immune cells, known as NK cells. These NK cells can destroy the target cell, resulting in enhanced ADCC. POTELLIGENT® changes the Fc structure by excluding a particular sugar unit such that it enables a tighter fit with the Fc gamma receptor IIIa. The strength of this interaction is a key factor in determining the killing potential of NK cells. An independent publication reported that the exclusion of this sugar unit of the Fc region increases the ADCC-mediated cell-killing potential of antibodies by 10- to 1000-fold. Cusatuzumab and ARGX-111 utilize POTELLIGENT®.

Our Wholly-Owned Programs

The following is the pipeline of our wholly-owned product candidates and discovery programs:

Product Candidate	Target	Indication	Preclinical	Phase 1	Phase 2	Phase 3	BLA	Next Milestone / Commentary
Wholly-Owned & Co-Development Product Candidates								
ARGX-113 <u>Efgartigimod</u>	FcRn	Myasthenia Gravis						3Q18: Phase 3 initiated
		Immune Thrombocytopenia (ITP)						2H19: Phase 3 initiation
		ITP Subcutaneous Formulation						1H19: Phase 2 initiation
		Pemphigus Vulgaris						1H19: Cohort 3 initiation
		Chronic Inflammatory Demyelinating Polyneuropathy						2H19: Phase 2 initiation
ARGX-117	Novel complement target	Severe Autoimmune Diseases						Antibody-mediated autoimmune diseases Complementary to ARGX-113
ARGX-110 <u>Cusatuzumab</u>	CD70	Acute Myeloid Leukemia						\$500 mm upfront (of which \$200* mm equity investment) Eligible for up to \$1.3 billion in milestones; tiered royalties

* €176.7 million (based on the exchange rate in effect as of the date the payment was received)

Efgartigimod (formerly referred to as ARGX-113)

We are developing our lead product candidate, efgartigimod, for the treatment of patients with MG (Phase 3), ITP (Phase 2) and PV (Phase 2), all of which are rare and severe autoimmune diseases associated with high levels of circulating pathogenic IgG antibodies for which there are few innovative biologic treatments and a severe unmet medical need exists. We also selected a fourth indication, CIDP. Efgartigimod utilizes our ABDEG™ engineering technology and is designed to block the recycling of IgG antibodies, which results in their removal from circulation. We believe that our approach presents potential benefits relative to the current standard of care for MG, ITP and PV: corticosteroids and immunosuppressants in the early stages, followed by IV IgG, or IVIg, and plasma exchange, or plasmapheresis, as the disease progresses. We believe these potential benefits include improved time of onset, increased magnitude and duration of therapeutic benefit, a more favorable safety and tolerability profile and a reduced cost burden to the healthcare system.

We announced full data from a double-blind, placebo-controlled Phase 2 clinical trial of efgartigimod in 24 patients with generalized MG in April 2018. We advanced efgartigimod into Phase 3 clinical development in September 2018 based on positive feedback received from the FDA and Japan's PMDA. We announced in September 2017 and in March 2018 that the FDA and EMA, respectively, granted orphan drug designation for the use of efgartigimod for the treatment of MG.

In parallel, we performed a second Phase 2 clinical trial of efgartigimod in 38 patients with ITP. In December 2018, we reported full study data. We will advance into a Phase 3 clinical trial, subject to discussions at an end-of-Phase 2 meeting with the FDA, which we intend to schedule in the first quarter of 2019, aiming for a second approval in this indication. In addition, we reported interim data of a third Phase 2 clinical trial of efgartigimod in patients with PV in June 2018. In addition to the IV formulation of efgartigimod that we are using in our current clinical trials, we are also developing a SC formulation designed to make efgartigimod accessible to larger patient populations, including patients requiring chronic therapy, potentially outside of the hospital setting.

We initiated a Phase 1 clinical trial in healthy volunteers for a SC formulation of efgartigimod and reported in June 2018 data from this clinical trial demonstrating comparable characteristics to the IV formulation.

Overview of Myasthenia Gravis

MG is an autoimmune disorder associated with muscle weakness that is triggered by IgG auto-antibodies. These antibodies attack critical signaling proteins at the junction between nerve and muscle cells, thereby impairing their communication signals. As shown in *Figure 5*, in MG these auto-antibodies either bind and occupy or cross-link and internalize the receptor on the muscle cells, thereby preventing the binding of acetylcholine, the signal sent by the nerve cell. In addition, these auto-antibodies can cause destruction of the neuromuscular junction by recruiting complement, a potent cell-destroying mechanism of the human immune system.

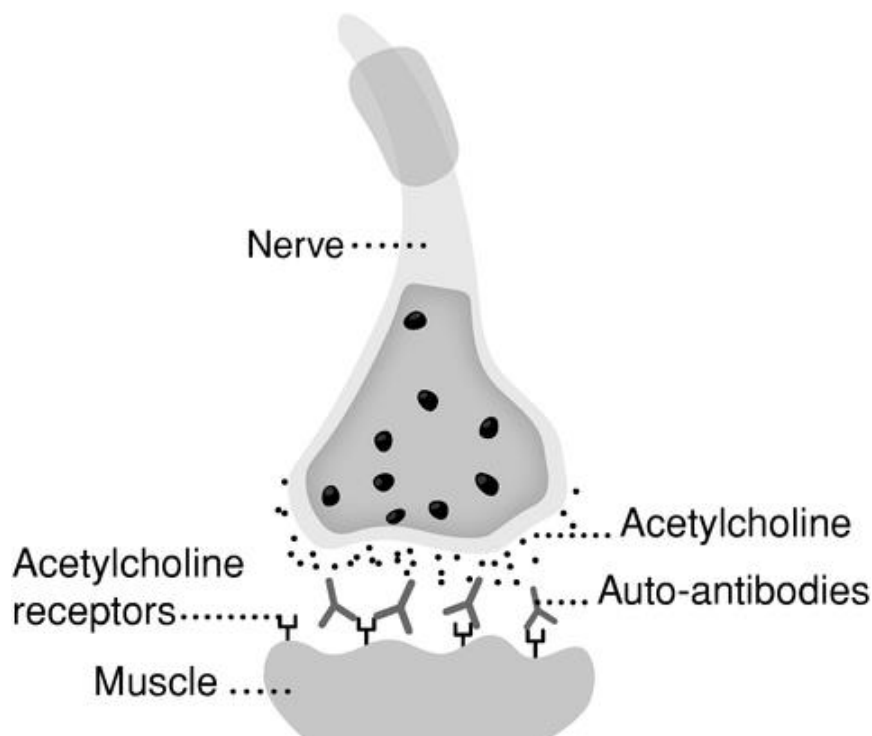


Figure 5: MG is caused by auto-antibodies attacking the transmission of nerve impulses to muscles

The muscle weakness associated with MG usually presents initially in ocular muscles and can then spread into a generalized form affecting multiple muscles. MG initially causes droopy eyelids and blurred or double vision due to partial paralysis of eye movements. As MG becomes generalized it affects muscles in the neck and jaw, causing problems in speaking, chewing and swallowing. MG can also cause weakness in skeletal muscles leading to problems in limb function. In the most severe cases, respiratory function can be weakened to the point where it becomes life-threatening. These respiratory crises occur at least once in the lives of approximately 15% to 20% of MG patients.

The U.S. prevalence of MG is estimated at approximately 20 cases per 100,000. Currently, there are an estimated 64,000 MG patients in the United States, of which an estimated 55,000 patients are suffering from generalized MG. We believe that the prevalence in Europe is at a similar level. Our initial focus is on generalized MG patients whose disease is not well-controlled with corticosteroids and immunosuppressants, which we believe represents a majority of generalized MG patients.

Limitations of Current MG Treatments

Early in their disease, patients are treated with cholinesterase inhibitors, such as pyridostigmine, followed by corticosteroids and immunosuppressants. The majority of patients with MG require some form of immunotherapy at some point during their illness. Corticosteroids are associated with a number of significant side effects, including bone thinning, weight gain, diabetes, hypertension, osteoporosis and depression. The side effects of immunosuppressants, depending on the particular immunosuppressant, include weakness, sweating, transaminase elevations, neutropenia, including severe neutropenia with infection, acute deep venous thrombosis, nausea, vomiting and the incidence of cancer. As MG becomes more advanced, patients can be treated with IVIg and plasmapheresis. Both of these approaches are associated with significant side effects.

Treatment with IVIg is based on the principle of altering the balance between synthesis and degradation of antibodies in the body. IVIg treatment results in a large increase in the quantity of IgG antibodies in circulation. This excess of exogenously added IgG antibodies competes with the endogenous autoimmune antibodies for various pathways including the FcRn antibody recycling pathway. Saturation of this pathway with exogenous IgG antibodies promotes antibody destruction, which in turn leads to a decrease in the level of autoimmune antibodies. IVIg treatment is associated with a number of adverse events including fever, myalgia, headache, nausea and impaired kidney function or kidney disease, and IVIg can lead to life-threatening complications such as pulmonary edema, acute kidney dysfunction or stroke in elderly patients.

Plasmapheresis involves collecting blood from a patient and physically removing the IgG antibodies and other serum proteins from the plasma before returning it to the patient. Plasmapheresis is also associated with known limitations and drawbacks. Potential complications include thrombotic events, bleeding, catheter occlusion, infection, nausea, hypotension and arrhythmias. In most cases, these symptoms are mild and transient, but in some cases they can be severe and life-threatening.

Both of these approaches place a heavy cost burden on the healthcare system. In addition to the costs of the IVIg or plasmapheresis treatment itself, hospitalization of patients receiving these treatments further adds to this cost burden. According to a 2011 study, the average short-term cost for utilizing IVIg or plasmapheresis for MG crisis was \$78,814 and \$101,140 per patient, respectively. In addition to patients experiencing an MG crisis, we believe a substantial number of MG patients receive chronic IVIg or plasmapheresis for which they require frequent hospitalization.

Recently, the FDA and European Medicines Agency approved the use of Soliris® for the treatment of generalized MG patients who have autoantibodies directed against the acetylcholine receptor. Soliris is an anti-C5 antibody blocking the activity of complement recruited by the pathogenic IgGs directed against the acetylcholine receptor at the neuromuscular junction. However, Soliris does not address the blocking of the acetylcholine receptor by pathogenic IgGs, nor the receptor cross-linking and internalization by these IgGs. In addition, a sub-set of MG patients is known to have anti-MuSK antibodies, which are known not to activate the complement cascade. The price of Soliris in MG amounts to approximately \$700,000 per patient per year, placing, we believe, a substantial cost burden on the health care system.

Finally, a minority of MG patients undergo thymectomy, the surgical removal of the thymus, an immune organ which is believed to play a role in the pathogenesis of the disease.

For MG patients who have advanced to the point where they are not well-controlled with corticosteroids and immunosuppressants, we believe efgartigimod may offer advantages over IVIg and plasmapheresis, including the potential to deliver a faster onset of action, a larger and longer lasting therapeutic effect and an improved safety and tolerability profile. In addition, a SC formulation of efgartigimod could further expand its use to patients requiring chronic therapy, potentially outside of the hospital setting.

Overview of Primary Immune Thrombocytopenia

ITP is a bleeding disease caused by an autoimmune reaction in which a patient develops antibodies that attack and destroy their own platelets, which are blood cells that help blood to clot, or their own platelet-forming cells. ITP, which develops for no known reason, is differentiated from secondary immune thrombocytopenia, which is associated with other illnesses, such as infections or autoimmune diseases, or which occurs after transfusion or taking other drugs, such as cancer drugs. Platelet deficiency, or thrombocytopenia, can cause bleeding in tissues, bruising and slow blood clotting after injury. ITP affects approximately 72,000 patients in the United States.

Limitations of Current ITP Treatments

Treatment for ITP is focused on either reducing the autoimmune activity that is causing accelerated platelet destruction and allowing the platelets to recover on their own, or directly stimulating platelet production with specific growth factors. Patients with less severe ITP are treated with corticosteroids and immunosuppressants, which are associated with significant side effects also seen with such treatment of other autoimmune diseases, such as MG. For more severe ITP, splenectomy is sometimes used as treatment, although its use is rapidly declining. The use of thrombopoietin receptor agonists, which stimulate the production and differentiation of platelets and are approved for last-line therapy, is increasing. Patients diagnosed with severe ITP are primarily offered IVIg or, to a lesser extent, plasmapheresis.

IVIg can raise the platelet count within days in most patients, but the effect is usually transient. IVIg introduces high levels of exogenously added IgG antibodies to the blood stream that compete with the patient's auto-antibodies for various pathways including the FcRn-dependent antibody recycling pathway, thereby lowering the impact of the auto-antibodies. IVIg treatment for ITP requires IV dosing of up to 2 g/kg per day of IVIg and is associated with many of the adverse events seen with IVIg treatment of other autoimmune diseases, such as MG as described above. Both IVIg and plasmapheresis when used to treat ITP carry a high cost burden on the healthcare system as they do when used to treat MG.

The production of platelets in patients refractory to other treatments can be stimulated by drugs such as romiplostim (Nplate) or eltrombopag (Promacta) that mimic thrombopoietin. While these therapies lead to increases in blood platelet counts, they do not address the underlying cause of the disease, which is the destruction of platelets by the immune system. Romiplostim (Nplate) and Eltrombopag (Promacta) are approved as last-line therapy for ITP and have generated global revenues of \$584 million and \$635 million in 2016, respectively.

Overview of Pemphigus Vulgaris

PV is an autoimmune disorder associated with mucosal and skin blisters that lead to pain, difficulty swallowing and skin infection. This chronic, potentially life-threatening disease is triggered by IgG auto-antibodies targeting desmoglein-1 and -3, which are present on the surface of keratinocytes and important for cell-to-cell adhesion in the epithelium. Auto-antibodies targeting desmogleins result in loss of cell adhesion, the primary cause of blister formation in PV. Similar to MG and ITP, disease severity of PV correlates to the amount of pathogenic IgGs targeting desmogleins.

Currently, there are an estimated 17,400 pemphigus patients in the United States, of which an estimated 13,100 patients are suffering from PV. We believe that the prevalence in Europe is at a similar level. Our initial focus is on mild-to-moderate PV patients who are either newly diagnosed or not well-controlled with corticosteroids and immunosuppressants.

Several disease activity measurements exist for the clinical evaluation of PV patients, including the pemphigus disease area index, or PDAI; autoimmune bullous skin disorder intensity score, or ABSIS; and the PV activity score, or PVAS. The PDAI is reported to have the highest validity and is recommended for use in clinical trials of PV.

Limitations of Current PV Treatments

The goals for the treatment of PV are twofold: (1) decrease blister formation and promote healing of blisters and erosions, and (2) determine the minimal dose of medication necessary to control the disease process. The current treatment regime for PV patients is limited. Typically, corticosteroids are used as first-line therapy, possibly in combination with immunosuppressants. Patients not well-controlled by these therapies may then receive IVIg or Rituxan. The latter is becoming more common in the treatment regime due to the significant side effects associated with corticosteroids and immunosuppressants. Rituxan was recently approved by the FDA for the treatment of moderate to severe PV. Rituxan carries infusion reaction risks, including anaphylaxis, and the risk of opportunistic infections, including progressive multifocal leukoencephalopathy, a rare and usually fatal viral disease.

Even with aggressive PV therapy, it takes two to three weeks for blisters to stop forming and about six to eight weeks for blisters to heal. Even with IVIg and Rituxan, complete remissions may take several months, and some patients do not respond to these treatments. The serious complications that can arise from use of these drug classes leave a large unmet medical need for effective therapy with a faster onset of action and better safety profile.

Overview of Chronic Inflammatory Demyelinating Polyneuropathy

CIDP is a chronic autoimmune disorder of peripheral nerves and nerve roots caused by an autoimmune-mediated destruction of the myelin sheath, or myelin producing cells, insulating the axon of the nerves and enabling speed of signal transduction. The cause of CIDP is unknown, but abnormalities in both cellular and humoral immunity have been shown. CIDP is a chronic and progressive disease: onset and progression occur over at least eight weeks in contrast with the more acute Guillain-Barré-syndrome. Demyelination and axonal damage in CIDP lead to loss of sensory and/or motor neuron function, which can lead to weakness, sensory loss, imbalance and/or pain. CIDP affects approximately 16,000 patients in the United States.

Limitations of Current CIDP Treatments

Most CIDP patients require treatment and IVIg, which is the preferred first-line therapy. Glucocorticoids and plasma exchange are used to a lesser extent as they are either limited by side effects upon chronic use, in the case of glucocorticoids, or invasiveness of the procedure and access, which is restricted to specialized centers in case of plasma exchange. Alternative immunosuppressant agents are typically reserved for patients ineligible for or refractory to IVIg, glucocorticoids or plasma exchange. While IVIg therapy can usually control CIDP, most patients require repeated treatments every two to six weeks for many years. This is due to the fact that IVIg monotherapy does not usually lead to long-term remission. IVIg introduces high levels of exogenously added IgG antibodies to the blood stream that compete with the patient's auto-antibodies for various pathways, including the FcRn-dependent antibody recycling pathway, thereby lowering the impact of the auto-antibodies. IVIg treatment for CIDP requires IV dosing of up to 2 g/kg per day of IVIg and is associated with many of the adverse events seen with IVIg treatment of other autoimmune diseases, such as MG. Both IVIg and plasmapheresis, when used to treat CIDP, carry a high cost burden on the healthcare system, as they do when used to treat MG or ITP. CIDP is the largest indication for IV/SC Ig in the United States.

Our Solution: efgartigimod

Our lead product candidate, efgartigimod, is an antibody Fc fragment that we believe has the potential to overcome many of the limitations of the current standard of care for MG, ITP and PV, including with respect to time of onset, magnitude and duration of therapeutic benefit and safety profile. We developed efgartigimod using our ABDEG™ Fc engineering technology.

Efgartigimod targets FcRn with high affinity, thereby reducing levels of all four classes of IgG antibodies, which are referred to as IgG1, IgG2, IgG3 and IgG4. In the case of MG, the large majority of patients have auto-antibodies of the IgG1 and IgG3 classes, while in the case of ITP these auto-antibodies consist mainly of the IgG1 class. In the case of PV, the pathogenic auto-antibodies consist mainly of the IgG1 and IgG4 class. As shown

in *Figure 6*, efgartigimod's mechanism of action is to block the recycling of IgG antibodies and remove them from circulation. Antibodies are routinely removed from circulation by being internalized into cells, where they can either become destined for degradation in the lysosomes or recycled back into circulation. IgG antibodies not bound to FcRn are degraded, while those bound to FcRn are recycled back into circulation. ❶ As a result of our ABDEG™ technology and the modifications we made to the Fc region, efgartigimod binds to FcRn with high affinity making this receptor unavailable to circulating IgG antibodies. ❷ The IgG antibodies can then no longer effectively be rescued and end up in the lysosomes where they are degraded. Compared to alternative immunosuppressive approaches, such as B-lymphocyte, or B-cell, depleting agents, efgartigimod acts in a highly selective manner by reducing IgG antibody levels, while leaving levels of antibodies of the immunoglobulin A, or IgA, immunoglobulin M, or IgM, and immunoglobulin D, or IgD, types as well as all components of the innate immune system intact.

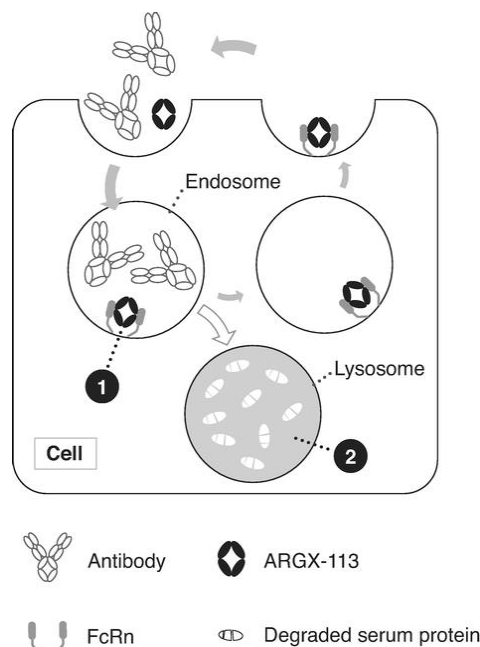


Figure 6: Efgartigimod's mechanism of action blocks the recycling of IgG antibodies and removes them from circulation

Based on our preclinical studies and early clinical trial results, we believe that efgartigimod has the potential to reduce levels of pathogenic IgG antibodies. Our clinical data suggest that efgartigimod reduces circulating IgG antibodies more rapidly than current therapies, which we believe could translate into faster therapeutic benefit if replicated with respect to pathogenic IgG antibodies. Our clinical data also suggest that the quantity of efgartigimod required to achieve and maintain suppression of circulating antibodies is lower than the levels of IVIg required for therapeutic benefit, which could translate into fewer infusions, shorter infusion time and a more favorable safety and tolerability profile.

In addition to MG, ITP and PV, we believe there are other autoimmune diseases that may benefit from the mechanism of action of efgartigimod therapy. We intend to pursue initial approval for MG and then plan to expand to ITP and, potentially, PV because these diseases have significant unmet medical needs. We then intend to expand our clinical development efforts for efgartigimod into additional indications also mediated by pathogenic IgG antibodies. Pathogenic auto-antibodies have been shown to be associated with other neuromuscular diseases such as Guillain-Barré, Lambert Eaton, chronic inflammatory demyelinating polyradiculoneuropathy; with other

hematological diseases such as hemolytic anemia; and with other autoimmune blistering diseases such as bullous pemphigoid and epidermolysis bullosa; as well as with systemic lupus erythematosus and multiple sclerosis, which affect larger numbers of patients.

Clinical Development Plan

We completed a Phase 2 clinical trial of efgartigimod in patients with MG and ITP, and we are currently evaluating efgartigimod in another Phase 2 clinical trial in patients with PV and are planning to start a fourth Phase 2 clinical trial in CIDP. We reported full data from the MG and ITP clinical trial in April and December 2018, respectively. We also reported interim data from the PV clinical trial in June 2018. We are currently advancing efgartigimod into Phase 3 clinical development in MG. We will advance into a Phase 3 clinical trial in ITP, subject to discussions at an end-of-Phase 2 meeting with the FDA, which we intend to schedule in the first quarter of 2019, aiming for a second approval in this indication. In addition, we reported interim data of a third Phase 2 clinical trial of efgartigimod in patients with PV in June 2018. In addition to the IV formulation of efgartigimod that we are using in our current clinical trials, we are also developing a SC formulation designed to make efgartigimod accessible to larger patient populations, including patients requiring chronic therapy, potentially outside of the hospital setting. We initiated a Phase 1 clinical trial in healthy volunteers for a SC formulation of efgartigimod, and in June 2018, we reported data from this clinical trial demonstrating comparable characteristics to the IV formulation.

Phase 2 Clinical Trial in MG

We conducted a randomized, double-blind, placebo-controlled Phase 2 clinical trial to evaluate the safety and tolerability, efficacy, pharmacodynamics and pharmacokinetics of efgartigimod. This clinical trial was conducted in 24 generalized MG patients with an MG-Activity-of-Daily-Living, or MG-ADL, score of 5 points or higher, with more than 50% of the score consisting of non-ocular items, and who are on a stable dose of cholinesterase inhibitors, steroids and/or immunosuppressants which make up the typical first- and second-line standard-of-care therapies. We conducted the clinical trial at 19 sites across Europe, Canada and the United States. Patients were randomly assigned to two arms of 12 patients each. Patients in one treatment arm received 10 mg/kg of efgartigimod, and the other treatment arm received placebo. All patients continued to receive the standard of care. Dosing took place during a three-week period which included four weekly doses of efgartigimod or placebo. Patients received follow-up for eight weeks after treatment.

The primary objectives of this Phase 2 clinical trial were to evaluate the safety and tolerability of efgartigimod with primary endpoints evaluating the incidence and severity of adverse events and serious adverse events, and evaluating vital signs, electrocardiogram and laboratory assessments. Secondary endpoints of the trial included efficacy as measured by the change from baseline of the MG-ADL; Quantitative MG; and MG Composite disease severity scores and the impact on quality of life as measured by the MG Quality of Life score. In addition, an assessment of pharmacokinetics, pharmacodynamics and immunogenicity was performed. All 24 enrolled patients were evaluable.

Phase 2 Topline Results

We announced full data from this Phase 2 clinical trial in April 2018. The primary endpoint analysis demonstrated efgartigimod to be well-tolerated in all patients, with most treatment emergent adverse events, or TEAEs, observed characterized as mild (CTCAE Grading 1 and 2). No TEAE severity with CTCAE Grade 3 or higher were reported. No clinically significant laboratory, vital signs and/or electrocardiogram findings were observed. No laboratory abnormality including albumin similar to the findings cynomolgus monkeys and in clinical trials. No TEAE leading to discontinuation, No serious TEAEs and no deaths were reported during the trial. The observed tolerability profile was consistent with the Phase 1 healthy volunteer trial as well as our Phase 2 clinical trial in ITP.

All TEAEs reported, as well as TEAEs deemed to be drug-related by the investigator in at least two patients, are summarized in *Table 1*.

Table 1. Overview of TEAEs and drug-related TEAEs reported in at least two patients in efgartigimod Phase 2 Clinical Trial in MG

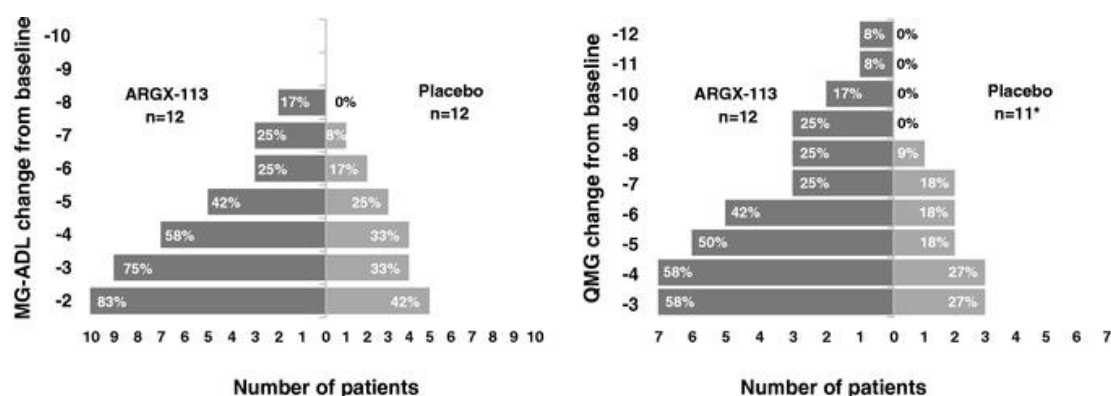
TEAEs Reported in ≥ 2 patients		Placebo (N = 12)	Efgartigimod (N = 12)
TEAEs (Total)		10 (83.3%)	10 (83.3%)
<input type="checkbox"/> Headache		3 (25.0%)	4 (33.3%)
<input type="checkbox"/> Nausea		1 (8.3%)	1 (8.3%)
<input type="checkbox"/> Diarrhea		1 (8.3%)	1 (8.3%)
<input type="checkbox"/> Abdominal pain upper		1 (8.3%)	1 (8.3%)
<input type="checkbox"/> Arthralgia		2 (16.7%)	—
<input type="checkbox"/> B-lymphocyte decrease		—	2 (16.7%)
<input type="checkbox"/> Lymphocyte count decrease		—	2 (16.7%)
<input type="checkbox"/> Monocyte count decrease		—	2 (16.7%)
<input type="checkbox"/> Neutrophil count increase		—	2 (16.7%)
<input type="checkbox"/> Myalgia		—	2 (16.7%)
<input type="checkbox"/> Pruritus		2 (16.7%)	1 (8.3%)
<input type="checkbox"/> Rhinorrhea		1 (8.3%)	1 (8.3%)
<input type="checkbox"/> Tooth abscess		2 (16.7%)	—
<input type="checkbox"/> Toothache		2 (16.7%)	—
Efgartigimod deemed related TEAEs		3 (25.0%)	8 (66.7%)
<input type="checkbox"/> Headache		1 (8.3%)	3 (25.0%)
<input type="checkbox"/> Monocyte count decrease		0 (0.0%)	2 (16.7%)
<input type="checkbox"/> Rhinorrhea		1 (8.3%)	1 (8.3%)

The secondary endpoint measures relating to efficacy showed efgartigimod treatment resulted in a strong clinical improvement over placebo as measured by all four predefined clinical efficacy scales during the entire duration of the trial. Patients in the treatment arm showed rapid onset of disease improvement, with clear separation from placebo one week after the first infusion.

83% of patients treated with efgartigimod achieved a clinically meaningful response (MG-ADL>2). 75% of patients treated with efgartigimod had a clinically meaningful and statistically significant improvement in MG-ADL scores (at least a two-point reduction from baseline) for a period of at least six consecutive weeks versus 25% of patients on placebo (p = 0.0391).

Clinical benefit in the efgartigimod treatment group maximized as of one week after the administration of the last dose, achieving statistical significance over the placebo group (p = 0.0356) on the MG-ADL score. Increasing differentiation was observed between the efgartigimod treatment group versus placebo with increasing MG-ADL and QMG thresholds at day 29 (1 week after last dosing) as shown in *Figure 7*.

Figure 7: Increasing differentiation in patient MG-ADL and QMG thresholds (treatment group vs. placebo)



* Missing data point in one patient

Analysis of the pharmacokinetic and pharmacodynamic endpoints was generally consistent with the findings from the Phase 1 clinical trial. We observed disease improvement to be correlated with reduction in pathogenic IgG levels. Total IgG reduction in patients was consistent with the Phase 1 healthy volunteer trial showing a mean maximum IgG reduction of up to 70.7% among treated patients. Reduction of IgG levels was consistent across IgG subtypes, including AChR autoantibodies (IgG1 and IgG3).

In line with findings in the Phase 1 healthy volunteer trial, positive anti-drug antibody, or ADA, titers were detected in a limited number of patients. In the Phase 2 clinical trial, positive post-dosing ADA titers were detected in four out of 12 patients receiving efgartigimod and in three out of 12 patients receiving placebo. In one active-treated patient, positive post-dose ADA titers were detected as of two weeks after the last infusion, and these titers may have the tendency to slightly increase over the course of the trial. In line with the results obtained in the Phase 1 healthy volunteer trial, the majority of ADA signals in active-treated patients were just above the detection limit of the assay and were typically only found once or twice during the course of the trial. Positive post-dose ADA titers had no apparent effect on efgartigimod pharmacokinetics or pharmacodynamics.

Phase 2 Clinical Trial in ITP

We completed a randomized, double-blind, placebo-controlled Phase 2 clinical trial to evaluate the safety, efficacy and pharmacokinetics of efgartigimod in 38 adult primary ITP patients, who have platelet counts lower than $30 \times 10^9/L$ while being on a stable dose of standard-of-care treatments consisting of corticosteroids, permitted immunosuppressants or thrombopoietin receptor agonists, or after having undergone a splenectomy or while being monitored under a “watch & wait” approach. We conducted the clinical trial at 19 clinical centers across eight countries in the European Union. Patients were randomly assigned to three arms of 12 or 13 patients for the placebo or efgartigimod arms, respectively. All patients in this clinical trial on a drug standard-of-care treatment were to continue to receive their stable dose of standard-of-care treatment as per the protocol. One treatment arm received 5 mg/kg efgartigimod, the second arm received 10 mg/kg efgartigimod and the third arm received placebo. Dosing took place in a three-week period, which included four weekly doses of efgartigimod or placebo. Patient follow-ups continued for 21 weeks after treatment. Patients from all three cohorts were eligible to enroll in a one-year open-label extension study at the 10 mg/kg dose of efgartigimod, subject to meeting enrollment criteria, including platelet counts lower than $30 \times 10^9/L$.

Phase 2 Topline Results

The primary objectives of this Phase 2 clinical trial were to evaluate safety and tolerability of efgartigimod with primary endpoints evaluating the incidence and severity of adverse events and serious adverse events, and evaluating vital signs, electrocardiogram and laboratory assessments. Secondary objectives included evaluation of efficacy, based on platelet count, use of rescue treatment and bleeding events, pharmacokinetics, pharmacodynamics, and immunogenicity.

We announced full data from this Phase 2 clinical trial in December 2018. The primary endpoint analysis demonstrated efgartigimod to be well-tolerated in all patients, with most TEAEs observed characterized as mild (CTCAE Grading 1 and 2). Two serious TEAEs were reported for 2 (15.4%) out of 13 patients both in the efgartigimod 10 mg/kg treatment group (1 case of bronchitis and 1 case of thrombocytopenia); both serious TEAE were considered not related to the trial treatment, and both serious TEAEs were downgraded after the study database locked. No deaths were reported during the study. The observed tolerability profile was consistent with the Phase 1 healthy volunteer trial as well as our Phase 2 clinical trial in MG.

All non-bleeding TEAEs reported, as well as non-bleeding TEAEs deemed to be drug-related by the investigator in at least two patients, are summarized in Table 2.

Table 2: Overview of TEAEs and drug-related TEAEs reported in at least two patients in efgartigimod Phase 2 Clinical Trial in ITP

Bleeding TEAEs not included

Treatment Emergent Adverse Events (TEAEs) Reported in ≥ 2 subjects	Placebo (N = 12)	Efgartigimod 5 mg/kg (N = 13)	Efgartigimod 10 mg/kg (N = 13)
Most common TEAEs N (%)			
□ Headache	2 (16.7)	1 (7.7)	—
□ Hypertension	1 (8.3)	—	2 (15.4)
□ Vomiting	—	—	2 (15.4)
□ Cystitis	—	1 (7.7)	1 (7.7)
□ Rash	—	1 (7.7)	1 (7.7)
□ Productive cough	1 (8.3)	1 (7.7)	—
TEAEs deemed related to study intervention N (%)			
□ Headache	1 (8.3)	—	—
□ Vomiting	—	—	1 (7.7)
□ Pubic pain	1 (8.3)	—	—
□ Vaginal discharge	1 (8.3)	—	—
□ Amenorrhoea	1 (8.3)	—	—

Clinically meaningful improvements in platelet counts were seen across ITP classifications and standard of care. 46% of patients demonstrated improved platelet count to $\geq 50 \times 10^9/L$ during two or more visits in each of the 5 mg/kg and 10 mg/kg dosing cohorts, compared to 25% in the placebo cohort. 67% of patients in the OLE trial demonstrated improved platelet counts to $\geq 50 \times 10^9/L$ during two or more visits following the first dosing cycle. Responders from the 10 mg/kg arm in the primary trial all responded again upon retreatment in the OLE trial. Onset of platelet counts reaching $50 \times 10^9/L$ for the first time ranged from week 1 to week 10, consistent with disease heterogeneity. For efgartigimod-treated patients with clinically meaningful platelet responses ($\geq 50 \times 10^9/L$ during two or more visits), the mean duration of platelet response was 40 days versus 16 days for placebo treated patients, with responses lasting the trial duration.

38% of efgartigimod-treated patients showed durable platelet count improvements to clinically meaningful and statistically significant levels of $\geq 50 \times 10^9/L$ for at least 10 cumulative days, compared to 0% of placebo patients ($p=0.03$). These data are summarized in Figures 8 and 9.

Figure 8: Patients achieving platelet counts of $\geq 50 \times 10^9/L$ at least two times

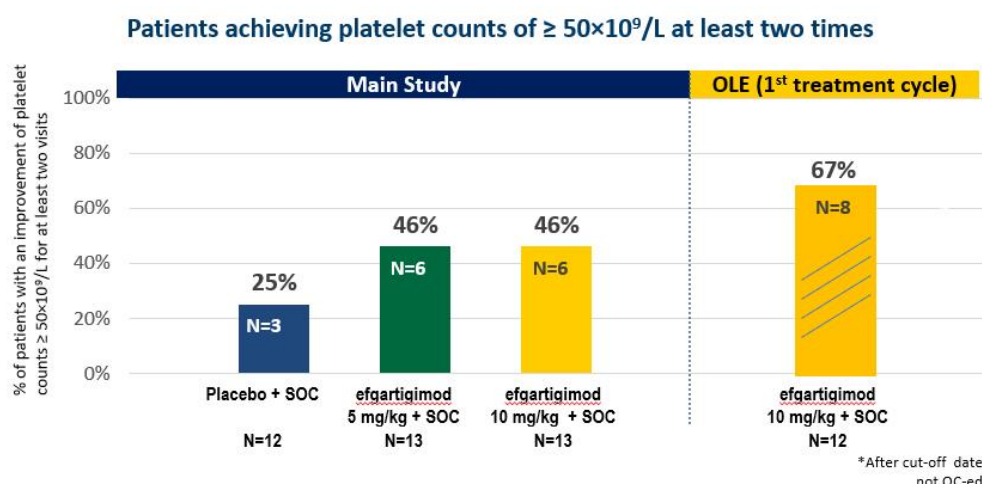
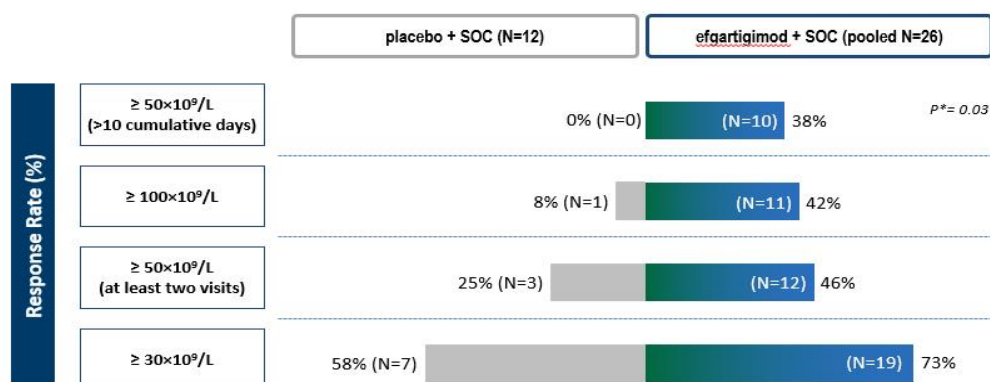


Figure 9: Post-hoc analysis of increasing thresholds of efficacy



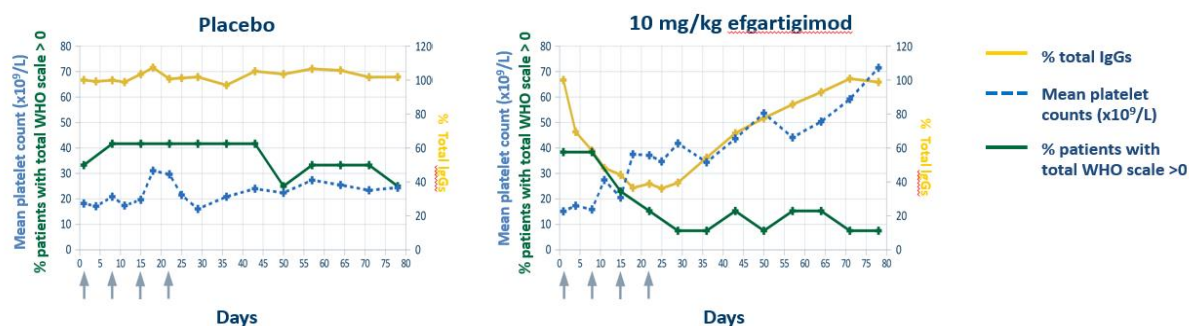
Note: Increasing threshold analysis based exact logistic regression model with the baseline result as a factor

The frequency of bleeding related events, as defined in the protocol, was evaluated separately. This was done due to the nature of the disease, as low platelet levels in ITP patients may induce bleeding events in a proportion of patients, and signs and symptoms vary widely. Bleeding events were assessed using three metrics—adverse event reporting, the WHO scale and the ITP-BAT scale—and showed that efgartigimod reduced bleeding events across each scale. Adverse event reporting showed no severe bleeding events in any patient, mild bleeding events only were reported in the 10 mg/kg arm and mild and moderate in the 5 mg/kg and placebo arm. Incidence of bleeding events was reduced by efgartigimod treatment as assessed by the WHO bleeding scale, with separation from placebo as early as the third dose in the 10 mg/kg arm. Incidence of bleeding events in the skin was reduced

by efgartigimod treatment as assessed by the ITP-BAT bleeding scale, with no clear signal of bleeding events in the mucosa or organs in either treatment arm. Efgartigimod treatment resulted in a correlation between IgG reduction, platelet count improvement and bleeding event reduction.

Analysis of the pharmacokinetic and pharmacodynamic endpoints was generally consistent with the findings from the Phase 1 clinical trial as well as the MG Phase 2 clinical trial. Lasting IgG reductions were consistent with levels achieved in previous studies. All efgartigimod-treated patients showed a rapid and deep reduction of total IgG levels, consistent with the pharmacodynamic effects observed in previous clinical trials. Reduction of IgG levels was consistent across IgG subtypes. Reduction in platelet-associated autoantibodies were observed in the majority of patients with a clinically meaningful platelet increase. Low titer of anti-drug antibodies was detected in 16.7% of placebo patients and 30.8% of treated patients in the 10 mg/kg arm with no apparent effect on pharmacokinetics or pharmacodynamics.

Figure 10: Reduction of total IgGs correlates with increased platelet counts and reduced bleeding event



Phase 2 Clinical Trial in PV

We are conducting an open-label, non-controlled Phase 2 clinical trial to evaluate the safety, efficacy, pharmacodynamics and pharmacokinetics of efgartigimod in a minimum of 12 patients with mild to moderate PV who are either newly diagnosed or relapsing. We conduct the clinical trial at 12 sites across Europe, Ukraine and Israel. The trial design comprises three cohorts of a minimum of four patients each. The first cohort will receive 10 mg/kg of efgartigimod in four weekly doses as induction therapy, followed by five weeks of maintenance therapy with efgartigimod dosed at 10 mg/kg at week 1 and week 5 of the maintenance period, followed by an eight-week follow-up period with no dosing of efgartigimod. In newly diagnosed patients and relapsing patients off-therapy, efgartigimod will be dosed as monotherapy, in absence of standard of care therapy. In relapsing patients on prednisone, efgartigimod will be dosed on top of a stable dose of prednisone during the induction phase. The prednisone dose may be changed (decreased or increased) from the beginning of the maintenance phase up to study end according to standard of care (i. e., corticosteroids, immunosuppressants, IVIg, plasma exchange and rituximab). An Independent Data Monitoring Committee (IDMC) may recommend adapting the dose during both the induction and the maintenance period, or the dosing frequency at maintenance, or the duration of dosing during the maintenance period with a maximum of two extra doses per cohort for a following cohort based on the outcome of the previous cohort. In case of a dose increase, the maximum dose would be 25 mg/kg.

The primary objectives of this Phase 2 clinical trial are to evaluate safety and tolerability of efgartigimod, with primary endpoints evaluating the incidence and severity of adverse events and serious adverse events and evaluating vital signs, electrocardiogram, physical examination abnormalities and laboratory assessments. Secondary objectives include evaluation of pharmacodynamics including assessment of total IgG and pathogenic IgG levels, efficacy based on the PDAI score, pharmacokinetics, and immunogenicity.

Phase 2 Interim Results

In the first cohort of the Phase 2 trial, six mild to moderate PV patients with no or low-dose corticosteroid therapy were treated with efgartigimod. Disease control was reached in three out of six patients in one week, which was characterized by patients having signs of healing of existing lesions and the absence of new lesions forming. One patient reached disease control after four weeks. Two patients had progression of disease. In all patients exhibiting disease control, a mean maximum reduction in Pemphigus Disease Area Index (PDAI) of 55% correlated with a mean maximum decrease in pathogenic autoantibodies levels of 57%. No meaningful anti-drug antibody signals were reported.

Efgartigimod was well-tolerated in all treated PV patients with no severe or serious study drug-related adverse events reported.

The IDMC evaluated the results of the first patient cohort and determined the tolerability profile to be favorable. The IDMC recommended maintaining the dose at 10 mg/kg, but adjusted the dosing frequency and duration of the maintenance phase for the next cohort. The second patient cohort will dose every two weeks during the maintenance phase and will add two additional administrations for a period of eight total weeks of maintenance, up from six weeks in cohort 1.

Phase 1 Clinical Trial for Subcutaneous Formulation of efgartigimod

In addition to the IV product formulation of efgartigimod that we are currently using in our clinical trials, we are also developing a SC product formulation designed to enable administration of efgartigimod to larger patient populations, including patients requiring chronic therapy, potentially outside the hospital setting.

We evaluated the IV and SC formulations of efgartigimod head-to-head in a preclinical cynomolgus monkey model. The results suggest that both formulations result in comparable half-life in circulation of efgartigimod, a favorable bioavailability of 75% of the SC formulation and a comparable pharmacodynamic effect shown by reduction of total IgG antibodies.

We initiated a Phase 1 clinical trial in healthy volunteers for a SC formulation for the treatment of chronic autoimmune diseases. The open-label, Phase 1 trial enrolled 32 healthy volunteers and included three treatment arms: one each of single dose SC and IV efgartigimod, and one evaluating an IV induction followed by a SC maintenance dose. In the single dose treatment arms, the data showed the SC formulation to have comparable half-life, pharmacodynamics and tolerability to the IV formulation, and a bioavailability of approximately 50%. In addition, initial IV dosing followed by weekly 300 mg (2 ml) SC administration of efgartigimod provided sufficient exposure to maintain IgG suppression at a steady state IgG reduction of approximately 50%. The data also suggested a favorable tolerability profile and no meaningful anti-drug antibody signals were reported. The SC formulation supports key manufacturing improvements, including a high product concentration (150mg/ml), low viscosity and optimal stability.

Phase 1 Clinical Data

We have completed enrollment in a double-blind, placebo-controlled Phase 1 clinical trial in healthy volunteers to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and immunogenicity of single and multiple doses of ARGX-113. In the first part of the clinical trial, 30 subjects were randomized to receive a single dose of ARGX-113 or placebo ranging from 0.2 mg/kg to 50 mg/kg. In the second part of the clinical trial, 32 subjects were randomized to receive multiple ascending doses of ARGX-113 or placebo up to a maximum of 25 mg/kg.

We announced interim data from this Phase 1 clinical trial in June 2016 and at a workshop we sponsored in conjunction with the American Society of Hematology annual meeting in December 2016. We expect that the full results from this clinical trial will be published in a peer-reviewed journal during the first half of 2017.

Single Ascending Dose

We observed that a single two-hour infusion of 10 mg/kg ARGX-113 was associated with an approximate 50% reduction of circulating IgG antibody levels. We observed that a reduction of circulating IgG antibody levels persisted for more than four weeks after the last dose, as shown in *Figure 8*. We believe this sustained reduction would be clinically meaningful if replicated with respect to pathogenic IgG antibodies because IVIg and plasmapheresis typically result in a 30% to 60% reduction in pathogenic IgG antibody levels.

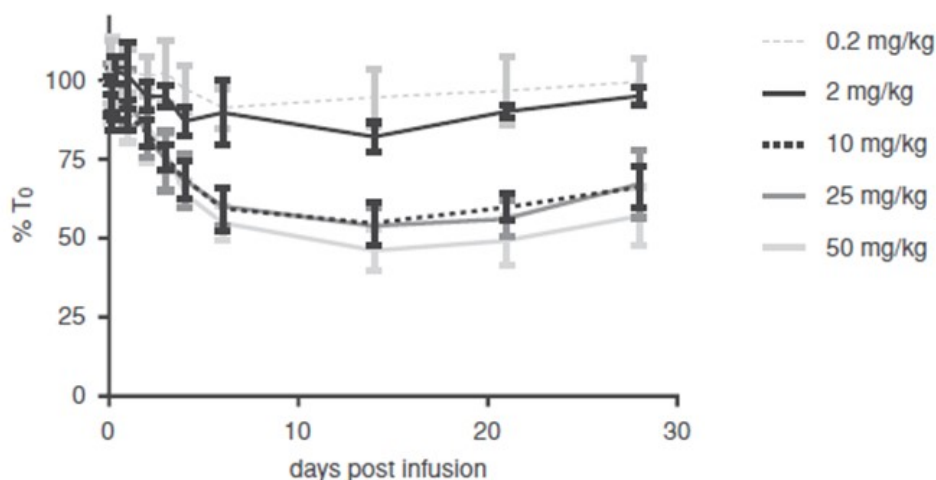


Figure 8. Selective reduction of IgG by administration of ARGX-113 to healthy volunteers in the single ascending dose part of our Phase 1 clinical trial

Administration of ARGX-113 at single doses up to 25 mg/kg was reported to be well-tolerated and administration of a single dose of 50 mg/kg was reported to be moderately tolerated. There were no drug- or infusion-related serious adverse events associated with doses up to 50 mg/kg. The most frequently reported drug-related adverse events included abnormal white blood cell count, increased C-reactive protein levels, headache, dizziness and chills. All of these adverse events were mild or moderate and reported only in the two highest dose groups (25 mg/kg and 50 mg/kg). While ARGX-113 was associated with a decrease in the levels of IgG antibodies, there were no observed changes in IgM or IgA levels or serum albumin observed in the clinical trial, suggesting that ARGX-113 has the potential to be a highly selective immunosuppressant.

Multiple Ascending Dose

In the multiple ascending dose part of the Phase 1 clinical trial, repeat administration of both 10 mg/kg and 25 mg/kg of ARGX-113 every seven days, four doses in total, and 10 mg/kg every four days, six doses in total, was associated with a gradual reduction in levels of all four classes of IgG antibodies by 60% to 85%, with 10 mg/kg dose results shown in *Figure 9*. For all doses, we observed the reduction in circulating IgG antibody levels to persist for more than four weeks after the last dose with levels below 50% at approximately three weeks, and did not return to baseline levels for more than one month. Pharmacokinetic analysis of serum baseline levels of ARGX-113 indicates that it has a half-life of approximately three to four days with no drug accumulation following subsequent weekly dosing. The prolonged activity on the levels of IgG antibodies is consistent with the mechanism of action of ARGX-113 and the effect of the ABDEG™ technology on increasing the intracellular recycling of

ARGX-113. Similar to the single ascending dose part, no significant reductions in IgM, IgA or serum albumin were observed.

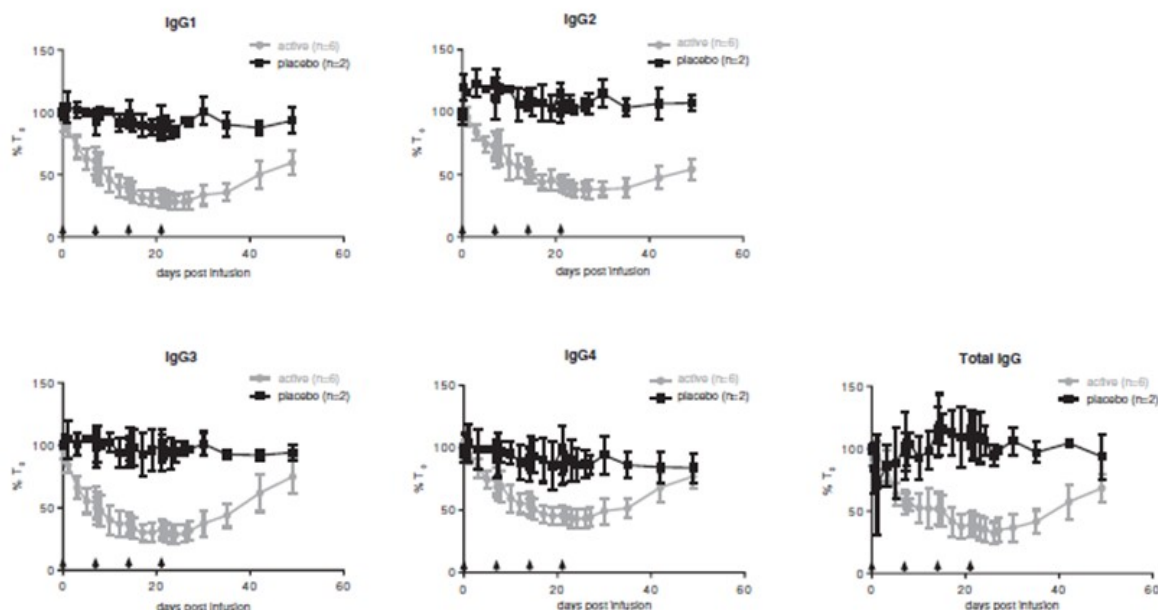


Figure 9. Reduction in the levels of four IgG antibody classes and total IgG levels in the multiple ascending dose part of our Phase 1 clinical trial of ARGX-113 in healthy volunteers at a dose of 10 mg/kg every seven days

Administration of multiple ARGX-113 doses of 10 mg/kg and 25 mg/kg were reported to be well-tolerated. One serious adverse event, hyperventilation, was observed in the multiple ascending dose part. This event, which occurred six days after drug administration, was considered by the clinical investigator as unlikely to be related to ARGX-113. Some patients had changes to C-reactive protein levels that were considered clinically significant. The most frequently reported drug-related adverse events included headache, feeling cold, chills and fatigue, all of which were mild or moderate and reported only in the highest dose group of 25 mg/kg.

In a limited number of pre- and post-dose samples originating from both active- and placebo-treated individuals, positive ADA titers were detected. During the single ascending dose part of the clinical trial, three out of 20 subjects on drug and one out of 10 subjects on placebo showed positive post-dose ADA titers. During the multiple ascending dose part of the clinical trial, one out of 23 subjects on drug and two out of eight subjects on placebo showed positive post-dose ADA titers. Signals typically were just above the detection limit of the assay and were only found once during the clinical trial for the majority of subjects. No increase of ADA titers over time for individual subjects was observed, nor had any of the subjects with at least one positive ADA sample an apparent different pharmacokinetic/pharmacodynamic profile.

Cusatuzumab (formerly referred to as ARGX-110)

We are developing cusatuzumab in hematological cancer indications, currently AML, as well as high-risk MDS. We are developing cusatuzumab with our collaborator Janssen. See “—Collaborations.”

AML is a rare and aggressive hematological cancer for which significant unmet medical needs exist. MDS, a rare bone marrow disorder, is often a precursor to AML. cusatuzumab is a SIMPLE Antibody™ designed to potently block the CD70/CD27 interaction and kill CD70-positive cells via its potent antibody effector functions through the use of POTELLIGENT® technology.

Cusatuzumab is currently being evaluated in an open-label Phase 1/2 clinical trial, in combination with azacytidine, in newly diagnosed AML patients who are unfit for intensive chemotherapy or in patients with high-risk MDS.

We reported interim results for the first 12 patients from the dose-escalation part of the Phase 1/2 clinical trial in combination with azacytidine in AML or high-risk MDS in December 2018, which demonstrated a favorable tolerability profile of the combination therapy and suggested evidence of biological activity across the evaluated doses. In addition, we reported results of the Phase 2 part of the Phase 1/2 clinical trial in CTCL for 26 evaluable patients.

Cusatuzumab is also being evaluated in an open-label Phase 1/2 clinical trial in relapsed or refractory CD70-positive CTCL patients and an open-label Phase 1 clinical trial in patients with nasopharyngeal carcinoma.

Overview of Acute Myeloid Leukemia and Myelodysplastic Syndrome

AML is a hematologic cancer characterized by excessive proliferation of myeloid stem cells and their failure to properly differentiate into mature white blood cells. AML is the second most common subtype of leukemia in adults. In the United States, AML has an incidence of approximately 22,000 new cases annually. AML is generally a disease of elderly people, with more than 60% of diagnosed patients being older than 60 years, and AML is uncommon before the age of 45. The average five-year survival rate for patients with AML is 27%, but there are significant differences in prognosis depending on several factors, including the age of the patient at diagnosis. For patients under the age of 45, the five-year survival rate is approximately 57%, while for those over the age of 65 it is only 6%. There are likely multiple reasons for this discrepancy, including the ability of younger patients to tolerate more aggressive therapy.

Current first-line treatments in AML typically involve aggressive chemotherapy, including alkylating agents and cytarabine potentially followed by stem cell transplantation, for younger patients with the aim to induce remission. This therapy is not recommended for older patients or patients with comorbidities, who are often treated with hypomethylating agents. We believe there is a significant need for safer, more effective AML treatments that can also be used in elderly patients. Because relapse is often due to leukemic stem cells present next to the malignant AML cells, or blasts, therapies targeting both blasts and leukemic stem cells may be more efficacious than chemotherapy only and could increase survival rates.

MDS also affects bone marrow cells, reducing their ability to produce red and white blood cells or platelets. In the United States, MDS has an incidence of approximately 13,000 new cases annually. There are currently an estimated 60,000 MDS patients in the United States. Approximately 75% of MDS patients are older than 60 years of age when diagnosed, and, like with AML, as the population ages the disease prevalence is expected to rise. Some MDS patients are at high risk to develop AML and are treated in a similar way as AML patients.

Our Solution: cusatuzumab

We developed cusatuzumab using our SIMPLE Antibody™ Platform and the POTELLIGENT® Fc engineering technology. Cusatuzumab binds to the cell surface protein CD70 with high affinity, blocking the interaction between CD70 and its receptor CD27 and targeting CD70 expressing cells for destruction by multiple immune pathways. CD70 is a cell surface protein that is highly expressed in cancer, including in T-cell and B-cell lymphomas, leukemias and certain solid tumors. In normal tissues, CD70 expression is either low or absent. Binding of CD70 to its receptor, CD27, initiates a cascade of intracellular events leading to cell proliferation and survival. As a byproduct of CD70 binding to CD27, the extracellular portion of CD27 is cleaved, creating a soluble

form of CD27 known as sCD27, which can easily be measured. sCD27 may serve as a biomarker for CD70 activity, potentially allowing us to identify target patients based on the likelihood of response to treatment, monitor disease progression and measure the impact of anti-CD70 therapy. In AML, CD70 is also expressed on leukemic stem cells. Leukemic stem cells are demonstrated to give rise to a large population of more mature leukemic blasts which lack self-renewal capacity in AML. Leukemic stem cells reside in the bone marrow and are considered difficult to target specifically. Preliminary data from the first set of patients in our clinical trial suggest cusatuzumab could be active both at the circulating and bone marrow blast level and at the leukemic stem cell level. Cusatuzumab exhibits potent ADCC and antibody dependent cellular phagocytosis potential through the use of POTELLIGENT® technology as well as complement-dependent cytotoxicity leading to the killing of cells expressing CD70.

Clinical Development Plan

In December 2016, we initiated an open-label Phase 1/2 clinical trial of cusatuzumab at three sites in Switzerland for the treatment of newly diagnosed AML or high-risk MDS patients. We expect the majority of patient enrollment in this clinical trial to be AML patients. We reported interim results from the dose-escalation part of this clinical trial in December 2018. Patient recruitment is currently ongoing for the Phase 2 part of this clinical trial.

In addition, cusatuzumab is being evaluated in an open-label Phase 1/2 clinical trial in relapsed or refractory CD70-positive CTCL patients and an open-label Phase 1 clinical trial in patients with nasopharyngeal carcinoma. By December 2018, 27 and 11 patients have been enrolled in these clinical trials, respectively, and recruitment has been completed. Prior to this, cusatuzumab was evaluated in an extensive Phase 1 clinical trial in patients with advanced malignancies expressing CD70, following a step-wise adaptive clinical trial design enrolling a total of 86 patients (of whom 85 patients have been treated).

Phase 1/2 Clinical Trial in Combination with Azacytidine in Patients with AML or High-Risk MDS (ongoing)

We are evaluating cusatuzumab in an open-label, dose-escalating Phase 1/2 clinical trial to evaluate its safety, tolerability and efficacy in combination with azacytidine in newly diagnosed AML patients unfit for chemotherapy or high-risk MDS patients. The clinical trial was initiated in December 2016. All patients in this clinical trial are receiving cusatuzumab in combination with 75 mg/m² azacytidine (standard of care for AML). Patients receive two weeks of cusatuzumab monotherapy prior to starting the combination dosing. During the Phase 1 dose-escalation part of the clinical trial, four doses of cusatuzumab, 1 mg/kg, 3 mg/kg, 10 mg/kg and 20 mg/kg administered bi-weekly are being evaluated. We enrolled 12 patients in the Phase 1 part.

We are currently enrolling an initial 21 AML patients in the Phase 2 part of its Phase 1/2 clinical trial using a 10 mg/kg dose of cusatuzumab. The number of total Phase 2 patients may be expanded further. This is a multi-center clinical trial conducted in Europe and the U.S.

We reported interim results for the 12 evaluable patients from the Phase 1 dose-escalation part of this clinical trial in December 2018, representing the data as of October 15, 2018. Six out of twelve Phase 1 patients were still on treatment at the time of the interim data. These interim results showed for the first 12 patients that no dose-limiting toxicity was observed for cusatuzumab and that cusatuzumab was overall reported to be well-tolerated with signs of clinical activity. To date, the tolerability profile of cusatuzumab in this Phase 1/2 clinical study in combination with azacytidine appears to be similar to what we observed in the other cusatuzumab clinical trials. We believe that the observed Grade 3 and 4 hematological toxicity for cusatuzumab in combination with azacytidine corresponds to the reported safety profile of azacytidine monotherapy and can be seen in Table 2 below.

Table 2. Grade 3 and 4 treatment emergent adverse events of cusatuzumab in combination with azacytidine open-label, Phase 1 dose-escalation part (first 12 evaluable patients, ongoing, uncleaned data as of October 15, 2018*)

	Grade 3 # events (# of patients)**	Grade 4 # events (# of patients)**	Grade 5 # events (# of patients)**
Anemia	16 (5)	1 (1)	—
Thrombocytopenia	6 (4)	7 (4)	—
Neutropenia	3 (2)	3 (3)	—
Febrile neutropenia	4 (4)	—	—
Leukopenia	—	2 (2)	—
Hypertension	2 (1)	—	—
Multi-Organ Failure	—	—	1 (1)
Atrial Flutter	—	1 (1)	—

* The collection of safety data for the Phase 2 part is ongoing. Through October 15, 2018, the observed tolerability profile in the Phase 2 part appeared to be in line with the other dose cohorts.

** Only if reported in at least two cases.

More specifically, at the time of the interim data, 11 out of 12 AML (92%) patients showed a response, including complete remission in seven out of 12 patients, complete remission with incomplete blood count recovery in two out of 12 patients and partial response in one out of 12 patients. One of the patients who achieved a complete remission successfully bridged to allogeneic stem cell transplant after five cycles. One patient discontinued from the study following an adverse event. Three patients responded during cusatuzumab monotherapy in the first two weeks.

In December 2018, we entered into a collaboration agreement with Cilag GmbH International, an affiliate of Janssen, to jointly develop and commercialize Cusatuzumab. See “—Collaborations.”

Phase 2 Part of Clinical Trial in Patients with Relapsed or Refractory CD70-positive CTCL and Phase 1 Safety-Expansion Cohorts in Patients with CD70-positive CTCL (ongoing, completed enrollment)

The Phase 1/2 clinical trial in relapsed or refractory CD-70 positive CTCL patients completed enrollment, consisting of 27 heavily pre-treated patients with CD70-positive CTCL.

The primary endpoint of the Phase 2 part of the clinical trial is efficacy, and secondary endpoints include safety and characterization of pharmacokinetics and immunogenicity. As of December 2018, of the 26 evaluable patients (out of 27 recruited patients) under analysis, we observed an overall response rate of 23% (one complete response, five partial responses and eight patients with stable disease). Patients received a 1 mg/kg or 5 mg/kg dose of cusatuzumab. One patient was still on the study at a 5 mg/kg dose. As of December 2018, cusatuzumab has continued to show a favorable tolerability profile in these patients. One patient experienced a Grade 3 adverse event, namely QTc prolonged. No dose limiting toxicities or Grade 4 drug-related toxicities were observed among this patient population.

Phase 1 Part of Phase 1/2 Clinical Trial in Patients with Advanced Malignancies Expressing CD70

Cusatuzumab was evaluated in an extensive Phase 1 part of a Phase 1/2 clinical trial in patients with advanced malignancies expressing CD70, following a step-wise adaptive clinical trial design enrolling a total of 86 patients (of whom 85 patients have been treated). No dose-limiting toxicities were observed. The most frequent grade 3 and 4 drug-related adverse events were fatigue in 48.2% of patients and mild (Grade 1–2) infusion-related reactions in 34.1% of patients. Other monoclonal antibodies engineered using POTEILLIGENT® or similar third-party products that augment ADCC such as mogamulizumab, obinutuzumab and imgatuzumab also have infusion-

related reaction rates of 24% to 77%. Premedication with acetaminophen, antihistamines and/or corticosteroids are used to reduce the impact of infusion-related reactions.

There were 83 serious adverse events seen in 42 of these pre-treated patients. Many patients who enrolled in this study have failed more than one prior therapy. All drug-related adverse events referenced in this paragraph were evaluated by the investigators according to the Common Terminology Criteria for Adverse Events guidelines (CTCAE v4.03). One Grade 1 (pyrexia), seven Grade 2 (infusion-related reactions), four Grade 3 (febrile neutropenia, anaemia, thrombocytopenia and fatigue—included in *Table 6*) and no Grade 4 serious adverse events were reported by the investigator as being drug-related. 23 patient deaths were reported in the phase 1 clinical trial, of which 17 deaths were attributed to disease progression. One patient death (Grade 5), which was deemed drug-related by the investigator, occurred in a heavily pre-treated patient with Waldenstrom Macroglobulinemia and was attributed to sepsis and general condition deterioration.

Table 6. Grade 3 and 4 drug-related adverse events (including serious adverse events), in ARGX-110 in open-label, Phase 1 clinical trial

Dose-escalation Part and Cohorts 1-4	0.1 mg/kg	1 mg/kg	2 mg/kg	5 mg/kg	10 mg/kg
<i>Number of patients</i>	6	15	7	42	5
Fatigue	1	—	—	3	—
Anaemia	—	—	—	1	—
Decreased appetite	1	—	—	—	—
Electrocardiogram qt prolonged	—	1	—	—	—
Febrile neutropenia	—	—	—	1	—
Hypoxia	1	—	—	—	—
Infusion related reactions	—	—	—	1	—
Thrombocytopenia	—	—	—	1	—

Note: All Grade 3 drug-related adverse events. No Grade 4 drug-related adverse events reported.

All other serious adverse events were considered non-drug-related by the treating investigator.

In the dose-escalation part of this clinical trial, the half-life of ARGX-110 was observed to be approximately 13 days. Anti-drug antibodies were detected in 50% of all patients, the majority of which were seen at the 0.1 mg/kg and 1 mg/kg doses.

Phase 1 Clinical Trial in Nasopharyngeal Carcinoma (ongoing, completed enrollment)

Cusatuzumab is being evaluated in an open-label Phase 1 clinical trial in patients with nasopharyngeal carcinoma at various stages of its natural history (adjuvant vs. metastatic). To date, 11 patients have been enrolled in this clinical trial. Patients receive a 5 mg/kg dose of cusatuzumab, which can be administered as monotherapy or in combination with chemotherapy agents, including cisplatin, carboplatin, 5-fluorouracil, gemcitabine and paclitaxel. The clinical trial is currently ongoing, enrollment has been completed and no Grade 3 or 4 drug-related adverse events have been reported to date.

ARGX-117

We are developing ARGX-117 with therapeutic potential in both orphan and large autoimmune inflammatory diseases. ARGX-117 is a highly differentiated therapeutic antibody equipped with our proprietary Fc engineering technology NHance® that addresses a novel target in the classic pathway of the complement cascade. With a potentially differentiated mechanism of action, ARGX-117 represents a broad pipeline opportunity across several autoantibody-mediated indications and may have a synergistic effect with lead autoimmune compound efgartigimod.

The classical pathway of the complement system is composed of a series of proteins that are activated when IgG or IgM autoantibodies bind to their targets. This mechanism contributes to tissue damage and organ dysfunction in a number of autoimmune inflammatory diseases. The ARGX-117 target is key in the lysis of antibody-decorated cells and is active when an immune reaction is taking place.

We obtained the rights to ARGX-117 as part of our Innovative Access Program through which we identified the work on this antibody with Broteio Pharma. argenx and Broteio launched a collaboration in 2017 to conduct research, with support from the University of Utrecht, to demonstrate preclinical proof-of-concept of the mechanism of ARGX-117. Based on promising preclinical data generated under this collaboration agreement, argenx has exercised the exclusive option to license the program and assumed responsibility for further development and commercialization.

ARGX-111

We are developing ARGX-111 for the treatment of patients with certain solid tumors that overexpress c-Met, a receptor associated with tumor growth and metastasis, or tumors that are mesenchymal-epithelial transition factor, or MET, amplified. MET-amplified tumors possess multiple copies of the MET gene, resulting in elevated c-Met levels. While c-Met overexpression and MET amplification both result in elevated c-Met levels, clinical and preclinical evidence suggests c-Met from MET-amplified tumors is a disease driver in some cancers. ARGX-111 employs our SIMPLE Antibody™, NHance® and POTELLIGENT® technologies to drive tissue penetration in the body and to increase its ability to enhance ADCC. ARGX-111 binds to c-Met with high affinity and does not cause dimerization of the c-Met receptor, which differentiates it from other, earlier attempts to direct antibodies against c-Met. Dimerization is a process which can result in receptor activation, undermining the intended therapeutic effect of antibodies blocking hepatocyte growth factor, or HGF, binding to c-Met. By blocking both HGF-dependent and independent c-Met activation, ARGX-111 is able to block c-Met receptor activation which could trigger survival, proliferation and metastasis of tumor cells. Thus, we believe ARGX-111 may have a differentiated clinical profile.

Clinical Development Plan

Phase 1b Clinical Trial in Patients with Advanced Cancer Overexpressing the c-Met Protein

We conducted a Phase 1 clinical trial in Europe consisting of a dose-escalation part in 19 treatment-refractory patients whose tumors overexpress c-Met and a safety-expansion part in five treatment-refractory patients whose tumors were MET-amplified. We chose to focus the safety-expansion part on MET-amplified tumors, rather than c-Met overexpressing tumors, because of the accumulating preclinical and clinical evidence suggesting MET amplification is an oncogenic driver. The primary objective of this Phase 1 clinical trial was to determine the recommended Phase 2 dose of ARGX-111, with the primary endpoint evaluating the incidence of dose-limiting toxicity. As a secondary objective, safety, immunogenicity, pharmacokinetics and pharmacodynamics were characterized, with secondary endpoints being the pharmacokinetics and pharmacodynamics profile of ARGX-111, as well as tumor response.

Dose-Escalation Part

In the dose-escalation part of the Phase 1 clinical trial, ARGX-111 was dosed every three weeks at 0.3 mg/kg, 1 mg/kg, 3 mg/kg and 10 mg/kg in treatment-refractory patients whose tumors overexpress c-Met. Dose-limiting infusion-related reactions were observed at 10 mg/kg, and it was determined to continue further clinical testing at a dose of 3 mg/kg. Nineteen serious adverse events were seen in 12 patients (four events in two patients at a dose of 0.3 mg/kg, two events in one patient at a dose of 1 mg/kg, seven events in six patients at a dose of 3 mg/kg and six events in three patients at a dose of 10 mg/kg). Except for six events of infusion-related reactions and one event of bone pain, no drug-related serious adverse events were observed. Seven patient deaths were reported (one at a dose of 0.3 mg/kg, one at a dose of 1 mg/kg, four at a dose of 3 mg/kg and one at a dose of 10 mg/kg), all of which were due to underlying disease and disease progression and were not deemed to be drug-related according to the investigator.

Safety-Expansion Part

One safety-expansion cohort has been completed in five treatment-refractory MET-amplified cancer patients using a 3 mg/kg dose of ARGX-111 every two weeks. Eight serious adverse events were seen in four of these patients. Except for one case of infusion-related reaction, none of those were deemed drug-related according to the investigator. One patient death attributed to disease progression and pneumonia was reported and was not deemed to be drug-related according to the investigator.

Although neither the dose-escalation part nor the safety-expansion part were designed to evaluate the efficacy of ARGX-111, we anecdotally observed reduced tumor burden at various sites and stable disease in a gastric cancer patient with bone metastases who was refractory to multiple rounds of prior treatment and in a MET-amplified renal cancer patient with metastases and progressive disease. Overall, we observed signs of biological activity for ARGX-111 in seven out of 19 patients in the dose-escalation part, including one partial response, and in three out of five patients in the safety-expansion cohort.

Preclinical Data

In preclinical orthotopic breast cancer models in mice, ARGX-111 was observed to reduce circulating tumor cells and cancer metastasis both in the adjuvant and the neo-adjuvant setting.

Intent to Partner

Given the size of the potential patient populations and the costs of clinical development for ARGX-111, we intend to begin Phase 2 development only if and when we have entered into a collaboration with an appropriate partner.

Our Partnered Programs

The following is the pipeline for our partnered product candidates and discovery programs. For more information on our collaborations, see “—Collaborations.”

Product Candidate	Target	Indication	Preclinical	Phase 1	Phase 2	Phase 3	BLA	Next Milestone / Commentary
Partnered Product Candidates								
ARGX-112 	IL-22R	Skin Inflammation						Eligible for up to ~€100mm in milestones; tiered royalties
ARGX-115 	GARP	Cancer Immunotherapy						Received \$60mm in upfront and preclinical milestone payments Eligible for up to \$625mm milestones; tiered royalties
ARGX-116 	ApoC3	Dyslipidemia						Eligible for double-digit royalties and exclusive option to license the program; collaboration with Novo Nordisk

ARGX-112 (partnered with LEO Pharma)

We are developing ARGX-112 for the treatment of dermatologic indications involving inflammation, together with our collaboration partner LEO Pharma. See- “—Collaborations.”

ARGX-112 employs our SIMPLE Antibody™ technology and blocks the interleukin-22 receptor, or IL-22R, in order to neutralize the signaling of interleukin-22, or IL-22, and interleukin-20, or IL-20, both of which are cytokines involved in the proliferation and differentiation of skin cells. When overexpressed, IL-22 and IL-20 are

implicated in autoimmune diseases of the skin, including atopic dermatitis, psoriasis and pustular psoriasis. In preclinical studies, ARGX-112 was observed to have high neutralization potency for IL-22R and favorable *in vivo* pharmacokinetics and distribution to the skin.

Under the collaboration, LEO Pharma will fund more than half of all product development costs up to approval of a clinical trial application, or CTA, in Europe for a first product in a Phase 1 clinical trial. After CTA approval of a first product in a Phase 1 clinical trial, LEO Pharma will be solely responsible to fund the clinical development of the program.

ARGX-115 (ABBV-151) (partnered with AbbVie)

ARGX-115 (ABBV-151) is being developed as a cancer immunotherapy against the novel target GARP by our collaborator AbbVie. See “—Collaborations.”

ARGX-115 (ABBV-151) employs our SIMPLE Antibody™ technology and works by stimulating a patient's immune system after a tumor has suppressed the immune system by co-opting immunosuppressive cells such as Tregs. While the normal function of Tregs is to suppress portions of the immune system to prevent a self-directed immune response through the release of active transforming growth factor beta, or TGF- β , Tregs can also prevent the immune system from recognizing and suppressing pathogenic cells including cancer cells. By binding to GARP, which plays a key role in the regulation of production and release of active TGF- β , ARGX-115 (ABBV-151) works to limit the immunosuppressive activity of Tregs and thereby stimulate the immune system to attack cancer cells. We believe this specific inhibition of TGF- β release by Tregs is potentially superior as a therapy to systemic inhibition of TGF- β activity or the depletion of Tregs, the presumed mode of action of ipilimumab (Yervoy), and that its specificity has the potential to provide an improved safety profile.

ARGX-115 (ABBV-151) was observed to be active in a mouse model of graft-versus-host disease, or GVHD, where it was able to completely block the activity of Tregs, suggesting its potential to re-activate the immune system against cancer cells. In this model, human peripheral blood lymphocytes, or PBMCs, are introduced into mice leading to a rapid onset of disease, caused by these PBMCs attacking the mouse host. When human Tregs are added to the human PBMCs, they can significantly delay disease onset and reduce disease severity. However, the addition of ARGX-115 (ABBV-151) completely neutralized the effect of human Tregs, resulting in a rapid onset of the disease again. The purpose of the experiment was to show that when ARGX-115 (ABBV-151) binds to GARP on Tregs, the normal immune suppressive function of Tregs is itself suppressed so that the immune system is free to act. In this experiment, the PBMCs represent the human immune system. The Tregs suppress the PBMCs when they are added (illustrated by lower PBMC activity—in this case represented by less activity against the mouse host). ARGX-115 (ABBV-151) suppresses the Tregs, allowing the immune system to act (as represented by the PBMCs once again attacking the mouse host). A prototype of ARGX-115 (ABBV-

151) devoid of cell-killing ability was as effective as ARGX-115 (ABBV-151) with cell-killing ability as shown in Figure 10, leading us to believe the effect of ARGX-115 (ABBV-151) is mainly due to blocking Treg activity.

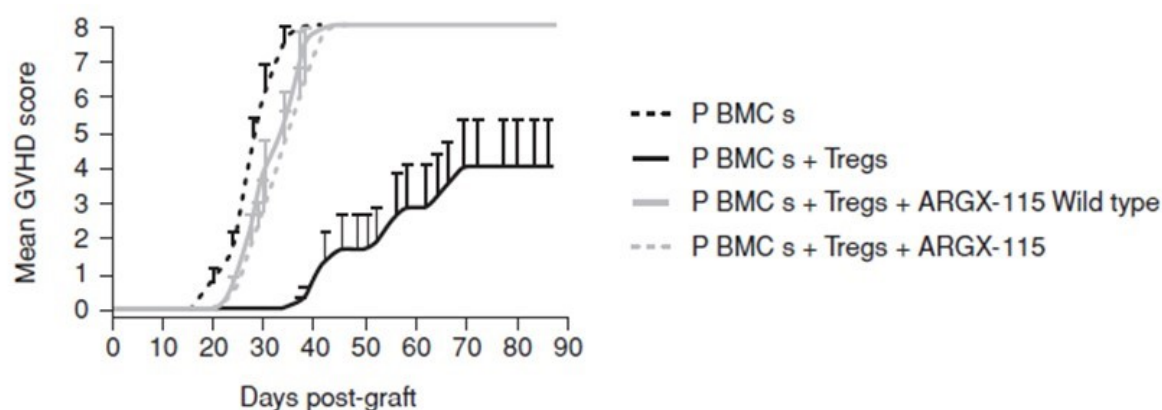


Figure 10. Preclinical data of ARGX-115 (ABBV-151) in a graft-versus-host disease model

We have advanced ARGX-115 (ABBV-151) through preclinical studies up to completion of IND-enabling studies. In August 2018, AbbVie exercised its exclusive license option to develop and commercialize ARGX-115 (ABBV-151).

ARGX-116 (partnered with Staten Biotechnology)

We are developing ARGX-116 for the treatment of dyslipidemia, together with our collaboration partner Staten Biotechnology. See “—Collaborations.”

ARGX-116 employs our SIMPLE Antibody™ technology and blocks APOC3, a metabolic target involved in triglyceride metabolism. APOC3 is supported as a therapeutic target by human genetic evidence suggesting that deactivating mutations in the APOC3 gene results in a favorable lipoprotein profile, lower insulin sensitivity, longevity and protection from cardiovascular disease.

ARGX-116 is the first of up to three research programs under the collaboration. Under the terms of the collaboration, the parties are jointly responsible for conducting research under a mutually agreed research program, with Staten reimbursing us for all costs of carrying out our research responsibilities under each research program.

In December 2018, Staten Biotechnology announced that it will collaborate with Novo Nordisk A/S to co-develop ARGX-116.

ARGX-109 (partnered with Bird Rock Bio)

ARGX-109 (gerilimzumab) is being developed for the treatment of rheumatoid arthritis, or RA, by our collaboration partner Bird Rock Bio. See “—Collaborations.”

ARGX-109 employs our SIMPLE Antibody™ and NHance® technologies and blocks interleukin 6, or IL-6, a cell-signaling protein that is an important driver of inflammatory response implicated in the transition from acute to chronic inflammation. Chronic inflammation is a notable feature of several diseases, including RA, psoriatic arthritis and chronic kidney disease. In particular, IL-6 has been shown to stimulate the immune system to increase tissue destruction and joint damage in RA patients. By targeting a unique epitope, ARGX-109 potentially

enables blocking of IL-6 with high potency, with the goal of mitigating inflammatory responses at lower and less frequent doses than current therapies directed at IL-6.

Bird Rock Bio has completed two Phase 1 clinical trials of ARGX-109 in 50 healthy volunteers to assess the safety and tolerability of the compound in single and multiple ascending doses compared to placebo. The clinical trials also explored the pharmacokinetics of ARGX-109. In these clinical trials, ARGX-109 was reported to be well-tolerated with no serious adverse events. Further, ARGX-109 was observed to have a prolonged half-life in circulation. In January 2017, Bird Rock Bio announced that it had received approval for the initiation of a Phase 2 clinical trial in Brazil in approximately 200 patients with RA.

Bird Rock Bio and argenx have mutually agreed to terminate Bird Rock Bio's license agreement to develop and commercialize ARGX-109. Genor, a sublicensee of Bird Rock Bio, will continue to develop ARGX-109 for the Chinese market. Hence, we will not be entitled to receive some or all of the milestone or other payments under this exclusive license agreement with Bird Rock Bio.

Innovative Access Program

We have developed a program designed to secure access to early, cutting edge targets, which we call our Innovative Access Program. Through our Innovative Access Program, we are able to serially collaborate with leading academic labs by providing them access to our SIMPLE Antibody™ Platform technology with the goal of expediting the validation of new targets and accelerating the addition of new product candidates to our pipeline. In return, we receive early access to these targets and provide academic groups or biotechnology companies a simple path to clinical validation and future commercialization of promising ideas in which we and the academic lab or biotechnology company both share in the upside potential.

One example of the value of the Innovative Access Program is ARGX-115 (ABBV-151), which was developed in collaboration with the de Duve Institute / Université Catholique de Louvain. We provided antibodies to the academic groups to help validate the target. This in turn, allowed the groups to advance their work successfully, including the facilitation of supportive publications. Subsequently, this program formed the basis of our collaboration with AbbVie. ARGX-115 (ABBV-151) exemplifies how our Innovative Access Program enables us to generate product candidates against novel targets that may be of high interest for collaboration with biopharmaceutical partners. Another example is ARGX-116, which was discovered in close collaboration with disease biology experts from Staten Biotechnology, an emerging biotechnology company specialized in the field of dyslipidemia.

In March 2017, we entered into a collaboration under our Innovative Access Program with Broteio Pharma B.V. to develop an antibody against a novel target in the complement cascade, ARGX-117, with therapeutic potential in autoantibody- and complement-mediated indications including autoimmune haemolytic anemia and antibody mediated rejection following organ transplantation. Under the terms of the agreement, we and Broteio jointly developed the complement-targeted antibody to seek to establish preclinical proof-of-concept using our proprietary suite of technologies. Upon successful completion of these studies, we exercised an exclusive option to license the program in March 2018 and assumed responsibility for further development and commercialization.

Manufacturing and Supply

We utilize third-party contract manufacturers who act in accordance with the FDA's good laboratory practices, or GLP, and current good manufacturing practices, cGMP, for the manufacture of drug substance and product. Currently, we contract with Lonza Sales AG, or Lonza, based in Slough, UK and Singapore, for all activities relating to the development of our cell banks, development of our manufacturing processes and the production of all drug substance, thereby using validated and scalable systems broadly accepted in our industry. We use additional contract manufacturers to fill, label, package, store and distribute investigational drug products.

Efgartigimod, cusatuzumab, ARGX-111 and ARGX-112 are each manufactured using an industry-standard mammalian cell culture of a Chinese hamster ovary cell line that expresses the product, followed by multiple purification and filtration steps typically used in producing monoclonal antibodies.

All of our antibodies are manufactured by starting with cells, which are stored in a cell bank. We have one master cell bank for each product manufactured in accordance with cGMP. Half of each master cell bank is stored at a separate site with the goal that, in case of a catastrophic event at one site, sufficient vials of the master cell bank would remain at the alternative storage site to continue manufacturing.

For a description of the sources and availability of raw materials, see section of this annual report titled “Item 3.D. —Risk Factors—Risks Related to Our Business and Industry.”

Competition

We participate in a highly innovative industry characterized by a rapidly growing understanding of disease biology, quickly changing technologies, strong intellectual property barriers to entry, a multitude of companies involved in the creation, development and commercialization of novel therapeutics. These companies are highly sophisticated and often strategically collaborate with each other.

We compete with a wide range of pharmaceutical companies, biotechnology companies, academic institutions and other research organizations for novel therapeutic antibody targets, new technologies for optimizing antibodies, talent, financial resources, intellectual property rights and collaboration opportunities. Many of our competitors and potential competitors have substantially greater scientific, research and product development capabilities as well as greater financial, manufacturing, marketing and sales and human resources than we do. In addition, there is intense competition for establishing clinical trial sites and registering patients for clinical trials. Many specialized biotechnology firms have formed collaborations with large, established companies to support the research, development and commercialization of products that may be competitive with ours. Accordingly, our competitors may be more successful than we may be in developing, commercializing and achieving widespread market acceptance.

Competition in the autoimmune field is intense and involves multiple monoclonal antibodies, other biologics and small molecules either already marketed or in development by many different companies including large pharmaceutical companies such as AbbVie Inc. (Humira/rheumatoid arthritis); Amgen Inc. (Enbrel/rheumatoid arthritis); Biogen, Inc. (Tysabri/multiple sclerosis); GlaxoSmithKline plc, or GSK, (Benlysta/lupus); F. Hoffman-La Roche AG, or Roche, (Rituxan/often used off label); and Janssen (Remicade/rheumatoid arthritis and Stelara/psoriasis). In some cases, these competitors are also our collaborators. In addition, these and other pharmaceutical companies have monoclonal antibodies or other biologics in clinical development for the treatment of autoimmune diseases. In addition to the current standard of care, we are aware that Alexion Pharmaceuticals, Inc. is selling Soliris for the treatment of adult patients with generalized MG who are anti-acetylcholine receptor antibody positive and that GSK; Roche; Novartis AG; CSL Behring; Grifols, S. A.; BioMarin Pharmaceutical Inc.; Curavac; Millennium Pharmaceuticals, Inc., UCB S.A.; Ra Pharmaceuticals; Momenta Pharmaceuticals, among others, are developing drugs that may have utility for the treatment of MG. We are aware that Rigel Pharmaceuticals, Inc.; Dova Pharmaceuticals; Bristol-Myers Squibb; Shire; Immunomedics; Protalex Inc. Principia Biopharma and others are developing drugs that may have utility for the treatment of ITP. We are aware that Roche is selling Rituxan for the treatment of moderate to severe PV and Principia; Alexion and others are developing drugs that may have utility for the treatment of PV. Furthermore, we are aware of competing products specifically targeting FcRn and being developed by UCB S. A.; Momenta, Inc.; Alexion; Immunovant; and Affibody.

Competition in the leukemia and lymphoma space is intense, with many compounds in clinical trials by large multinational pharmaceutical companies and specialized biotech companies. Rituxan (Roche), Adcetris (Seattle Genetics, Inc. /Takeda Pharmaceutical Company Ltd), Darzalex (Janssen), Poteligeo (Kyowa Hakko Kirin Co., Ltd.) are some examples of monoclonal antibodies approved for the treatment of Hodgkin's lymphoma, non-Hodgkin's lymphoma, multiple myeloma or other blood cancers. We are aware of AML drugs recently

approved by the FDA, such as Daurismo (Pfizer), Mylotarg (Pfizer), Rydapt (Amgen), Vyxos (Jazz Pharmaceuticals, Inc.) and IDHIFA (Agiros, Inc. and Celgene). In addition, we are aware of a number of other companies with development stage programs that may compete with cusatuzumab in the future if it is approved. We anticipate that we will face intense and increasing competition as new treatments enter the market and advanced technologies become available.

There are several monoclonal antibody drug discovery companies that may compete with us in the search for novel therapeutic antibody targets, including Adimab LLC; Merus N.V.; Regeneron Pharmaceuticals, Inc.; Xencor Inc. and MorphoSys AG. We are aware that a product candidate in development by Scholar Rock, Inc. may compete with ARGX-115 (ABBV-151) and a product candidate in development by Ionis Pharmaceuticals, Inc. may compete with ARGX-116, if they are approved.

Our commercial opportunity could be reduced or eliminated if our competitors' products prove to be safer and more tolerable, more effective, more convenient to dose, less expensive, faster to approve, or more effectively marketed and reimbursed than any of our product candidates that may gain regulatory approval. In addition, the level of generic competition and the availability of reimbursement from government and other third-party payors will impact the commercial viability of our programs.

Collaborations

We have entered into multiple collaboration agreements with pharmaceutical partners. We expect to continue to collaborate selectively with pharmaceutical and biotechnology companies to leverage our discovery platform and accelerate product candidate development.

Our Strategic Partnership with Janssen (for cusatuzumab)

In December 2018, we entered into a collaboration agreement with Cilag GmbH International, an affiliate of Janssen, to jointly develop and commercialize cusatuzumab.

We have granted Janssen a license to the cusatuzumab program to develop, manufacture and commercialize cusatuzumab. For the US, the granted commercialization license is co-exclusive with argenx, while outside the US, the granted license is exclusive to Janssen. Janssen and argenx will assume certain development obligations, and will be jointly responsible for all research, development and regulatory costs relating to cusatuzumab.

Under the terms of the collaboration agreement, we agreed to a joint global clinical development plan to develop cusatuzumab in AML, MDS and other potential indications in the future. Unless otherwise determined by the parties, Janssen shall be responsible for conducting the development activities specified in the global clinical development plan, subject to certain diligence obligations. The parties have equal decision-making authority and shall make consensus decisions regarding the global clinical development plan, with certain exceptions related to the territory outside of the US. Development costs shall be borne by both parties based on a cost sharing arrangement.

With respect to commercialization activities in the US, argenx shall have the right, but not the obligation, to elect to perform certain of the commercial efforts. Janssen has sole responsibility, at its sole cost and expense, to commercialize cusatuzumab outside of the US, subject to certain diligence obligations.

In January 2019, we received an upfront, non-refundable, non-creditable payment of \$300.0 million from Janssen. We are also eligible to receive potentially up to \$1.3 billion in development, regulatory and commercial milestone payments as well as tiered royalties on sales for the territory outside of the US at percentages ranging from the low double digits to the high teens, subject to customary reductions. For the US, the parties have agreed to share royalties with on a 50/50 basis.

In conjunction with the collaboration agreement, we entered into an investment agreement with Johnson & Johnson Innovation – JJDC, Inc., or JJDC, an affiliate of Johnson & Johnson. At the closing of the transaction in January 2019, JJDC purchased 1,766,899 newly issued shares, representing 4.68% of our then outstanding shares at a price of €100.02 per share (\$113.19 based on the exchange rate in effect as of the date the investment agreement was signed), for a total of €176.7 million (approximately \$200.0 million based on the exchange rate in effect as of the date the payment was received).

Unless earlier terminated upon mutual agreement, for material breach or as otherwise specified in the agreement, the collaboration term ends on a product-by-product, country-by-country basis, upon the expiration of all payment obligations in such country. With respect to the US, the agreement shall survive so long as any product covered by the agreement is being sold in the US. For the outside of U.S. territory, the royalty term expires on a product-by-product and country-by-country basis on the date that is the later of (i) 10 years after the first commercial sale of such product sold in that country, (ii) such time as there are no valid claims covering such product or (iii) the expiration of regulatory exclusivity for such product in such country.

Our Strategic Partnership with AbbVie (for ARGX-115 (ABBV-151))

In April 2016, we entered into a collaboration agreement with AbbVie S.À.R.L., or AbbVie, to develop and commercialize ARGX-115 (ABBV-151). Under the terms of the collaboration agreement, we were responsible for conducting and funding all ARGX-115 (ABBV-151) research and development activities up to completion of IND-enabling studies.

We have granted AbbVie an exclusive option, for a specified period following completion of IND-enabling studies, to obtain a worldwide, exclusive license to the ARGX-115 (ABBV-151) program to develop and commercialize products. Following the exercise of the option, AbbVie will assume certain development obligations, and will be solely responsible for all research, development and regulatory costs relating to the products. We received an upfront, non-refundable, non-creditable payment of \$40.0 million (€35.1 million based on the exchange rate in effect as of the date the payment was received) from AbbVie for the exclusive option to license ARGX-115 (ABBV-151), and we achieved the first of two preclinical milestones, triggering a \$10.0 million (€8.9 million based on the exchange rate in effect as of the date the payment was received) payment, and are eligible to receive a second preclinical milestone of \$10.0 million. We are also eligible, if AbbVie exercises its option and develops a product, to receive additional development, regulatory and commercial milestone payments in aggregate amounts of up to \$110.0 million, \$190.0 million and \$325.0 million, respectively, as well as tiered royalties on sales at percentages ranging from the mid-single digits to the lower teens, subject to customary reductions.

We have the right, on a product-by-product basis to co-promote ARGX-115-based products in the European Economic Area and Switzerland and combine the product with our own future immuno-oncology programs. The co-promotion effort would be governed by a co-promotion agreement negotiated in good faith by the parties. In addition to the ARGX-115 (ABBV-151) program, and upon reaching a predetermined preclinical stage milestone, AbbVie will fund further GARP-related research by us for an initial period of two years. AbbVie will have the right to license additional therapeutic programs emerging from this research, for which we could receive associated milestone and royalty payments.

In August 2018, AbbVie exercised its option to develop and commercialize ARGX-115 (ABBV-151).

Unless earlier terminated upon mutual agreement, for material breach or as otherwise specified in the agreement, the term of the option and license agreement ends, with respect to the ARGX-115 (ABBV-151) program, upon the earliest of (i) a technical failure of the IND-enabling studies which is outside of our control, (ii) AbbVie's election to not exercise its option, or (iii) following AbbVie's exercise of the option, fulfillment of all payment obligations under the agreement. AbbVie may terminate the agreement for any reason upon prior written notice to us. AbbVie's royalty payment obligations expire, on a product-by-product and country-by-country basis, on the date that is the later of (i) such time as there are no valid claims covering such product, (ii) expiration of

regulatory or market exclusivity in respect of such product or (iii) 10 years after the first commercial sale of such product sold in that country under the agreement.

Our Collaboration with Bird Rock Bio (for ARGX-109)

In October 2012, we entered into an exclusive license agreement with Bird Rock Bio, Inc. (formerly known as RuiYi, Inc. and Anaphore, Inc.), or Bird Rock Bio, to develop and commercialize ARGX-109. Under the terms of the collaboration, Bird Rock Bio is solely responsible for and bears all costs incurred in the research, development and commercialization of ARGX-109.

We have granted Bird Rock Bio an exclusive, worldwide, royalty-bearing license to develop and commercialize ARGX-109. Bird Rock Bio has certain diligence obligations with regard to development and commercialization of ARGX-109 and must report their progress in achieving these milestones on an annual basis. We received a non-refundable, non-creditable upfront payment from Bird Rock Bio of €0.5 million in cash plus shares of Bird Rock Bio stock, and we are eligible to receive additional development milestone payments of up to approximately €10.0 million in cash and additional shares of Bird Rock Bio stock, regulatory milestone payments of up to €10.0 million in cash and commercial milestone payments of up to €12.0 million in cash. We are eligible to receive tiered royalties on Bird Rock Bio's commercial sales of ARGX-109 at percentages ranging from the low to high single digits and a tiered percentage of Bird Rock Bio's sublicensing income ranging from the mid-teens to high twenties, subject to customary reductions. In connection with the collaboration, we also granted Bird Rock Bio a sublicense under our license agreement with the University of Texas with respect to our NHance® Fc engineering technology, which is incorporated into ARGX-109.

In the event that Bird Rock Bio fails to achieve a certain performance milestone within a designated period after entering the agreement, we have the right to terminate the agreement, unless Bird Rock Bio pays us an amount equal to the milestone payment that would have been payable had the milestone event occurred. In addition, in the event that Bird Rock Bio does not meet certain sublicensing objectives with respect to a product, we have the option to enter a profit sharing arrangement with Bird Rock Bio, under which we have the option to fund 50% of remaining program costs for a product and waive future milestone and royalty payments in return for a 50% share of all profits with respect to that product.

Unless earlier terminated upon mutual agreement, for material breach or as otherwise specified in the agreement, the collaboration term ends with the expiry of the last royalty term under the agreement. Each royalty term expires, on a product-by-product and country-by-country basis, on the date that is the later of (i) 10 years after the first commercial sale of such product sold in that country under the agreement or (ii) such time as there are no valid claims covering such product. Bird Rock Bio may terminate the agreement upon prior written notice to us in the event of a technical failure in product development.

Bird Rock Bio and argenx have mutually agreed to terminate Bird Rock Bio's license agreement to develop and commercialize ARGX-109. Genor, a sublicensee of Bird Rock Bio, will continue to develop ARGX-109 for the Chinese market. Hence, we will not be entitled to receive some or all of the milestone or other payments under this exclusive license agreement with Bird Rock Bio.

Our Strategic Partnership with LEO Pharma (for ARGX-112)

In May 2015, we entered into a collaboration agreement with LEO Pharma A/S, or LEO Pharma, to develop and commercialize ARGX-112. Under the terms of the collaboration, LEO Pharma funded more than half of all product development costs up to CTA approval of a first product in a Phase 1 clinical trial, with our share of such costs capped. Now that CTA approval of a first product in a Phase 1 clinical trial has been received (in April 2018), LEO Pharma will be solely responsible for funding the clinical development of the program.

We received a non-refundable, non-creditable upfront payment from LEO Pharma of €3.0 million in cash. In February 2016, June 2017 and April 2018, we achieved preclinical milestones under this collaboration for which we received milestone payments. Up through specified periods following the latest to occur of (i) submission of an

application to commence a Phase 2b dose finding trial (or Phase 3 clinical trial if a Phase 2b is not conducted) or (ii) the availability of an International Preliminary Examination report for ARGX-112 patent rights after completion of a Phase 2a clinical trial, LEO Pharma may exercise an option to obtain an exclusive, worldwide license to further develop and commercialize products. Following the exercise of the option, LEO Pharma would assume full responsibility for the continued development, manufacture and commercialization of such product, subject to certain diligence obligations. If LEO Pharma elects to exercise this option, it must pay us an option fee. We are also eligible to receive additional development, regulatory and commercial milestone payments in aggregate amounts of up to €11.5 million, €6.0 million and €102.5 million, respectively, as well as tiered royalties on product sales at percentages ranging from the low single digits to the low teens, subject to customary reductions.

If LEO Pharma does not exercise its option prior to expiration of the applicable option period, if it does not meet certain development diligence obligations within a specified time, or if the agreement is terminated other than for reasons of our breach or insolvency, then we have the right to develop and commercialize ARGX-112 alone, subject to our obligation to pay LEO Pharma low-single digit percentage royalties on net sales of any product covered by any LEO Pharma patents, know-how or rights in research results generated under the collaboration. If the agreement is terminated for reasons of our breach or insolvency, rights to product candidates in development at the time of such termination will be allocated to the parties through a mechanism specified in the agreement.

Unless earlier terminated upon mutual agreement, for material breach or as otherwise specified in the agreement, the term of the agreement ends upon the later of (i) the expiration of the option period, (ii) the expiration of the last license which has been granted under the agreement, and (iii) the fulfilment of all payment obligations which may arise under the agreement. LEO Pharma may terminate the agreement for any reason upon prior written notice to us. LEO Pharma's royalty payment obligations expire, on a product-by-product and country-by-country basis, on the date that is the later of (i) such time as there are no valid claims covering such product, (ii) in major market countries in which no composition of matter patent has been issued covering such product, the expiration of the data exclusivity period or (iii) in countries that are not major market countries, a double-digit number of years after the first commercial sale of such product sold in that country under the agreement.

Our Research Collaboration with Staten (for ARGX-116)

In January 2015, we entered into a collaboration agreement with Staten Biotechnology B.V., or Staten, to develop and commercialize products in the area of dyslipidemia therapy. Under the collaboration agreement, the parties sought to discover and characterize antibodies against a human target with therapeutic relevance in the field of dyslipidemia and/or cardiovascular disease. The parties may also commence two further research programs for targets with therapeutic relevance in these areas. Each research program will last no more than 24 months from commencement unless the parties agree otherwise. The first research program under this agreement proceeded as planned and was extended to December 2017, with ARGX-116 identified as the initial product candidate. Staten exercised its exclusive option to license ARGX-116 in March 2017. Under the terms of the collaboration, the parties were and are jointly responsible for conducting research under a mutually agreed research plan, with Staten reimbursing us for all costs of carrying out our research responsibilities under each research program. Staten is also responsible for additional clinical development.

On a research program-by-research program basis, up through a specified period within such research program, we have granted Staten an option to obtain an exclusive, worldwide, permanent license to research, develop and commercialize products identified in that program. If Staten elects to exercise this option for a product (as it has for ARGX-116), it would be obligated to pay us a percentage of any payments payable to or on behalf of Staten's shareholders in the event of (i) a change of control of Staten, (ii) any licensing, sale, disposition or similar transaction relating to any such product, or (iii) otherwise from the research, development or commercialization of that product. This percentage varies by stage of development for an applicable product and ranges up to the low-twenties, subject to downward proportional adjustment in the event a portion of the proceeds from the applicable transaction does not include payment for the product candidate we developed with Staten. Staten has certain diligence obligations to develop and commercialize at least one product during the term of the agreement and must report on their progress in doing so on an annual basis.

In December 2018, Staten announced that it had entered into a collaboration and exclusive option agreement with Novo Nordisk to develop novel therapeutics for the treatment of hypertriglyceridemia. Specifically, Novo will provide research and development funding and support to Staten to develop its lead asset STT-5058 (formerly ARGX-116) for the treatment of dyslipidemia. Novo has the right under the agreement to acquire Staten and gain worldwide rights to STT-5058. Staten and its shareholders will potentially receive signing and exercise fees, research and development funding, and milestone payments of up to €430 million.

If Staten does not exercise its option with respect to a research program prior to expiration of the applicable option period, then we have the right to research, develop and commercialize product candidates in relation to the relevant target at our sole cost and expense.

Unless earlier terminated upon mutual agreement, for material breach or as otherwise specified in the agreement, the collaboration term ends on the later of (i) January 2020, (ii) expiration of the last license granted by us under the agreement, (iii) expiration of last option period for Staten and (iv) fulfillment of all payment obligations which have arisen or may arise pursuant to the agreement. In addition, we may terminate the agreement in whole or with respect to a research program if no targets have been selected within 24 months of the effective date of the agreement, other than the target selected for the ARGX-116 research program.

Our Strategic Collaboration with Shire

In February 2012, we entered into a collaboration agreement with Shire AG (now known as Shire International GmbH), or Shire, to discover, develop and commercialize novel human therapeutic antibodies against up to three targets to address diverse, rare and unmet diseases. Under the terms of the collaboration, for any target selected for study under the collaboration, the parties worked together to conduct research and development through discovery of antibodies with certain specificity for and functional activity against those targets.

Up through a specified period following completion of each study for a target, we have granted Shire an exclusive option to obtain all right, title and interest in any antibodies discovered under a study and to obtain an exclusive, worldwide license under our intellectual property which is necessary to further develop and commercialize products incorporating such antibodies. Following exercise of its exclusive option, Shire has certain diligence obligations to develop and commercialize at least one product. To exercise this option with respect to antibodies discovered against any of the three initial targets named in the agreement, Shire paid us a one-time option fee.

In May 2014, we expanded the collaboration agreement to accommodate research and development of additional novel targets implicated in multiple disease areas to provide Shire with a sublicense under our license agreement with the University of Texas with respect to our NHance® and ABDEG™ engineering technologies and to provide an option to a sublicense to the POTELLIGENT® technology of BioWa, Inc. The initial three year term of this expanded agreement expired on May 30, 2017, and Shire opted to extend the collaboration term for a further year until May 30, 2018, but no further beyond May 2018.

Shire may exercise exclusive options to develop and commercialize programs arising under our expanded agreement, in which case an option fee is due on a per program basis. In July 2018, Shire exercised such an exclusive option to in-license an antibody discovered and developed using our licensed technologies, which exercise triggered a milestone payment by Shire to argenx, in an amount undisclosed due to contractual obligations of confidentiality.

In addition to option fees, Shire would also be obligated to pay us on a per-product basis upon achievement of specified development, regulatory and commercial milestones and a percentage of net sales as a royalty. Milestones are paid on a first product per indication per study target basis, and we are eligible to receive payments in aggregate amounts of up to \$3.8 million, \$4.5 million and \$22.5 million, upon achievement of development, regulatory and commercial milestones, respectively, for a product generated against one of the three initial targets named in the 2012 agreement. For products generated against additional targets nominated under the 2014 agreement, development and regulatory milestone payments remain the same, and we are eligible to receive

payments in aggregate amounts of up to \$60.0 million for achievement of commercial milestones. The royalties payable to us are tiered, single digit and are subject to customary reductions. Through December 31, 2018, pursuant to the agreement Shire has paid us an aggregate total of (i) €3.4 million in upfront payments, (ii) €0.3 million in milestone payments and (iii) \$12.6 million in research and development funding. In addition, Shire purchased €12.0 million of our ordinary shares in July 2014 by participating in our initial public offering on Euronext Brussels.

If Shire does not exercise its option with respect to any discovered antibody within a specified period, then we are free to research, develop and commercialize antibodies in relation to the applicable study target, subject to negotiation of a license from Shire for the use of any antibodies that were discovered during the applicable study, or any Shire confidential information, Shire intellectual property or Shire's interest in any joint intellectual property. If (a) Shire (i) does not exercise its option with respect to any discovered antibody, or (ii) exercises its option but later abandons development of such antibody or (iii) the agreement is terminated other than for our breach or insolvency, and (b) Shire is no longer pursuing a development program with respect to the applicable study target, then we may elect to continue the development of such antibody at our sole cost and expense, subject to negotiation of a license from Shire under which Shire will receive either specified royalties, if we commercialize the program ourselves, or a percentage of sublicensing revenues, if the program is subsequently sublicensed to a third party.

Unless earlier terminated upon mutual agreement, for material breach or as otherwise specified in the agreement, the collaboration term ends with the expiry of the last royalty term under the agreement. Each royalty term expires, on a product-by-product and country-by-country basis, on the date that is the later of (i) such time as there are no valid claims covering such product or (ii) 10 years after the first commercial sale of such product sold in that country under the agreement. Shire may terminate the agreement for any reason upon prior written notice to us.

License Agreements

We are a party to a number of license agreements under which we license patents, patent applications and other intellectual property from third parties. We enter into these agreements to augment our proprietary intellectual property portfolio. The licensed intellectual property covers some of our product candidates and some of the Fc engineering technologies that we use. These licenses impose various diligence and financial payment obligations on us. We expect to continue to enter into these types of license agreements in the future.

Our Exclusive License with Halozyme (ENHANZE)

In February 2019, we entered into a license agreement with Halozyme Inc., or Halozyme, for the use of certain patents, materials and know-how owned by Halozyme and relating to its ENHANZE® Technology, for application in the field of prevention and treatment of human diseases. ENHANZE® Technology is referred to herein as ENHANZE. Under the terms of the license, we were granted exclusive rights to apply ENHANZE to biologic products against pre-specified targets, in order to research, develop and commercialize SC formulations of our therapeutic antibody-based product candidates.

Our first therapeutic target for which we have received an exclusive license from Halozyme is FcRn, which allows us to apply ENHANZE to efgartigimod and any other product candidate selective and specific for FcRn. Moreover, the breadth of our exclusive license to FcRn precludes either Halozyme itself or any of its current or future partners from utilizing ENHANZE in the context of an FcRn-targeted product. Under the license terms, we also have the right to nominate future targets – again, for an exclusive ENHANZE license if the target in question has not already been licensed by Halozyme, or is not already being pursued by Halozyme. From the effective date of the license agreement, we have a four-year period in which to conduct research and preclinical studies on other target-specific molecules in combination with ENHANZE and may nominate a maximum of two targets for an exclusive commercial license during the four-year term.

In return for the FcRn exclusive license, we have made a \$30 million upfront payment to Halozyme. Upon the nomination of any future target for an exclusive commercialization license and confirmation by Halozyme that such a license is available, we will pay \$10 million to Halozyme per target. We will be obligated to pay clinical development, regulatory and commercial milestones totaling \$160 million for the first product that uses ENHANZE and is specific for a given target. Throughout the term of the agreement, we must provide Halozyme on an annual basis a guidance forecast setting out all projected milestone payments for products for the following four calendar quarters. We are also obligated to pay Halozyme a percentage of net sales as a royalty of any licensed product that uses ENHANZE. This royalty varies with net sales volume, ranging from the low to mid-single digits, and it is reduced by a maximum of 50% if following 10 years from the first commercial sale of the product in a country, the last valid claim within the licensed ENHANZE patent(s) expires. Throughout the term of the agreement, we must provide Halozyme on an annual basis an estimate of royalty payments anticipated for the following four calendar quarters. We have certain diligence requirements with respect to development and commercialization of product candidates, but we are not obligated to utilize ENHANZE for every product candidate directed to a given exclusive target(s).

Under the terms of the license and subject to certain restrictions, we have the right to grant sublicenses to third parties both for research/preclinical work (for example, to subcontractors) and for development and commercialization. Halozyme has no rights to any of our current or future product candidates which use the ENHANZE technology. Halozyme provides dedicated specialist support to us which it has accrued over ten years of licensing ENHANZE to its collaborators.

We may terminate the license agreement at any time, either in its entirety or on a target-by-target basis, by sending Halozyme prior written notice. Absent early termination, the agreement will automatically expire upon the expiry of our royalty payment obligations under the agreement. In the event the agreement is terminated for any reason, the license granted to us would terminate, but Halozyme would grant our sublicensees a direct license following such termination. In the event the agreement is terminated other than for our breach, we would retain the right to sell licensed products then on hand for a certain period of time post-termination.

As also set out in “Item 6.A.—Directors, Senior Management and Employees”, our non-executive director James M. Daly is also a non-executive member of the board of directors of Halozyme. Despite this, our entering into the license agreement with Halozyme was not a related party transaction in accordance with IAS 24 – Related Party Disclosures, since Mr. Daly, in his role as non-executive director, does not control or have significant influence over our company or Halozyme. Mr. Daly did not participate in any discussions and decision making relating to the Halozyme license agreement. Consequently, no further disclosures regarding Halozyme have been added in “Item 7.B.—Related Party Transactions”.

Our Exclusive License with the University of Texas (NHance® and ABDEG™)

In February 2012, we entered into an exclusive license with The Board of Regents of The University of Texas System, or UoT, for use of certain patents rights relating to the NHance® platform, for any use worldwide. The agreement was amended on December 23, 2014 to also include certain additional patent rights relating to the ABDEG™ platform.

Upon commercialization of any of our products that use the in-licensed patent rights, we will be obligated to pay UoT a percentage of net sales as a royalty until the expiration of any patents covering the product. This royalty varies with net sales volume and is subject to an adjustment for royalties we receive from a sublicensee of our rights under this agreement, but in any event does not exceed 1%. In addition, we must make annual license maintenance payments to UoT until termination of the agreement. We have assumed certain development and commercial milestone payment obligations and must report on our progress in achieving product sales on a quarterly basis. The maximum milestone payments we would be required to make is approximately \$0.5 million in total. Through December 31, 2018, we have paid UoT an aggregate of \$0.75 million, which includes reimbursement for UoT's patent prosecution and maintenance costs and development milestones on products using the in-licensed patent rights. We also have certain diligence requirements with respect to development and commercialization of products which use the in-licensed patent rights.

Under the terms of the license, we have the right to grant sublicenses to third parties, subject to certain restrictions. If we receive any non-royalty income in connection with such sublicenses we must pay UoT a percentage of such income varying from low-middle single digits to middle-upper single digits depending on the nature of the sublicense. Such fees are waived if a sublicensee agrees to pay the milestone payments as set forth in our agreement with UoT.

We may unilaterally terminate the license agreement for convenience upon prior written notice. Absent early termination, the agreement will automatically expire upon the expiration of all issued patents and filed patent applications within the patent rights covered by the agreement. Our royalty payment obligations expire, on a product-by-product and country-by-country basis, at such time as there are no valid claims covering such product.

Our Non-Exclusive License with BioWa (POTELLIGENT®)

In October 2010, we entered into a non-exclusive license agreement with BioWa, Inc., or BioWa, for use of certain patents and know-how owned by BioWa and relating to its POTELLIGENT® Technology, for use in the field of prevention and treatment of human diseases. POTELLIGENT® Technology is referred to herein as POTELLIGENT®. Under the terms of the license, we are granted a non-exclusive right to use POTELLIGENT® to research, develop and commercialize antibodies and products containing such antibodies using POTELLIGENT®. BioWa retains a right of first negotiation for the exclusive right to develop and commercialize, in certain countries only, any product we develop using POTELLIGENT®. We successfully applied POTELLIGENT® to cusatuzumab, an anti-CD70 mAb, and ARGX-111, an anti-c-Met mAb, under this license.

Upon commercialization of our products developed using POTELLIGENT®, we will be obligated to pay BioWa a percentage of net sales of a licensed product as a royalty. This royalty varies with net sales volume, ranging in the low single digits, and it is reduced by half if during the following 10 years from the first commercial sale of the product in a country the last valid claim within the licensed patent(s) that covers the product expires or ends. In addition, we must make annual research license maintenance payments which cease with commencement of our royalty payments to BioWa. We have certain diligence requirements with respect to development and commercialization of products. We have also assumed certain development, regulatory and commercial milestone payment obligations and must report on our progress toward achieving these milestones on an annual basis. Milestones are to be paid on a commercial target-by-commercial target basis, and we are obligated to make milestone payments in aggregate amounts of up to \$36.0 million per commercial target should we achieve annual global sales of over \$1.0 billion.

Under the terms of the license, we have the right to grant sublicenses to third parties, subject to certain restrictions.

We may terminate the license agreement at any time by sending BioWa prior written notice. Absent early termination, the agreement will automatically expire upon the expiry of our royalty obligations under the agreement. In the event the agreement is terminated for any reason, the license granted to us would terminate but BioWa would grant our sublicensees a direct license following such termination. In the event the agreement is terminated other than for our breach or insolvency, we would retain the right to sell licensed products then on hand for a certain period of time post-termination.

Our Non-Exclusive Licenses with BioWa and Lonza (POTELLIGENT® CHOK1SV)

To scale up production of our product candidates cusatuzumab and ARGX-111 for clinical trial and commercial supply, we required a license to a GMP cell line in which POTELLIGENT® antibodies could be expressed. This cell line, POTELLIGENT® CHOK1SV, was jointly developed by BioWa and Lonza. In December 2013 and August 2014, respectively, we entered non-exclusive commercial license agreements for cusatuzumab and ARGX-111 with BioWa and Lonza Sales AG, or Lonza, for use of certain patents and know-how relating to the POTELLIGENT® CHOK1SV Technology, which is a combination of Lonza's GS System and BioWa's POTELLIGENT® Technology, for use in the field of prevention and treatment of human diseases. Under the terms of each commercial license, we received a non-exclusive right to research, develop and commercialize products

containing an antibody generated specifically against a specific target using POTE LLIGENT® CHOK1SV, namely the target CD70 in the case of cusatuzumab and c-Met in the case of ARGX-111. Both targets are designated as reserved targets under our 2010 license agreement with BioWa, which continues to govern our research, development and commercialization of products utilizing BioWa's POTE LLIGENT® Technology. Under the terms of each commercial license, BioWa retains a right of first negotiation for the exclusive right to develop and commercialize, in certain countries only, any product we develop using POTE LLIGENT® CHOK1SV. This right of first negotiation is not applicable in cases where we intend to grant a global license to a third party to develop and commercialize a product - as was the case with our exclusive, global collaboration and license agreement for cusatuzumab with Cilag GmbH International, an affiliate of Janssen, which was entered into on December 3, 2018. BioWa retains a right of first negotiation for the exclusive right to develop and commercialize our anti-c-Met antibody ARGX-111 in certain countries only.

Upon commercialization of our products developed using POTE LLIGENT® CHOK1SV, we will be obligated to pay both BioWa and Lonza a percentage of net sales as a royalty. We are required to pay a royalty to BioWa on net sales for any specific licensed product under only one license—either the POTE LLIGENT® agreement or the POTE LLIGENT® CHOK1SV agreement, but not both. The BioWa royalty is tiered, ranging in the low single digits and is reduced by half if during the following 10 years from the first commercial sale of the product in a country the last valid claim within the licensed BioWa patent(s) that covers the product expires or ends. The Lonza royalty varies based on whether the product is manufactured by Lonza, us or a third party, but in any event is in the low single digits and is reduced by half if during the following 10 years from the first commercial sale of the product in a country the last valid claim within the licensed Lonza patent(s) that covers the product expires or ends. In addition, we must make annual commercial license maintenance payments to BioWa on a per product basis which cease with commencement of payment of the BioWa royalty for the respective product, and annual payments to Lonza in the event that any product is manufactured by a party other than Lonza, us or one of our affiliates or strategic partners named in the agreement.

We have assumed certain development, regulatory and commercial milestone payment obligations to both BioWa and Lonza and must report on our progress toward achieving these milestones on an annual basis. We are required to pay such milestones to BioWa under only one license—either the POTE LLIGENT® agreement or the POTE LLIGENT® CHOK1SV agreement, but not both. Payments related to the development and commercialization of cusatuzumab and ARGX-111 are foreseen under their respective POTE LLIGENT® CHOK1SV agreements. Milestones are to be paid on a product-by-product basis, and we are obligated to make development, regulatory and commercial milestone payments to BioWa in aggregate amounts of up to \$36.0 million per product should we achieve global annual sales of \$1.0 billion. We are obligated to make development, regulatory and commercial milestone payments to Lonza in aggregate amounts of up to approximately £1.1 million per product, if such product is manufactured by Lonza, us or one of our affiliates or strategic partners, or £3.1 million per product, otherwise. Through December 31, 2018, we have paid BioWa an aggregate amount of \$1.625 million, which includes target reservation fees and annual research license fees under our POTE LLIGENT® agreement and commercial license fees and milestone payments under our POTE LLIGENT® CHOK1SV agreement. Through December 31, 2018, we have paid Lonza an aggregate amount of £0.52 million, which includes milestone payments under our POTE LLIGENT® CHOK1SV agreement.

Under the terms of both cusatuzumab and ARGX-111 commercial licenses, we have the right to grant sublicenses to certain pre-approved third parties, but otherwise must obtain BioWa and Lonza's prior written consent. No prior written consent was required from either BioWa or Lonza for our exclusive global collaboration and license agreement for cusatuzumab with Cilag GmbH International, an affiliate of Janssen.

We may terminate the non-exclusive commercial license agreements at any time by sending BioWa and Lonza prior written notice. Absent early termination, the agreements will automatically expire upon the expiry of our royalty obligations under the respective agreement. In the event an agreement is terminated for any reason, the license granted to us would terminate but BioWa and Lonza would grant our sublicensees a direct license following such termination. In the event an agreement is terminated other than for our failure to make milestone or royalty payments, we would retain the right to sell the respective products then on hand for a certain period of time post-termination. Our royalty payment obligations expire, on a product-by-product and country-by-country basis, on the

date that is the later of (i) 10 years after the first commercial sale of such product sold in that country under the agreement or (ii) such time as there are no valid claims covering such product.

Our Collaboration with UCL and Sopartec (GARP)

In January 2013, we entered into a collaboration and exclusive product license agreement with Université Catholique de Louvain, or UCL, and its technology transfer arm Sopartec S.A., or Sopartec, to discover and develop novel human therapeutic antibodies against GARP. Under the terms of the collaboration with UCL, each party was responsible for all of its own costs and in connection with the activities assigned to it under a mutually agreed research plan.

In January 2015, we exercised the option we had been granted to enter into an exclusive, worldwide commercial license for use of certain GARP-related intellectual property rights owned by UCL and the Ludwig Institute for Cancer Research to further develop and commercialize licensed products, including the GARP-neutralizing antibody ARGX-115 (ABBV-151) which was discovered under the original collaboration. Upon the expiration of the agreement, this license would become a fully paid up, perpetual worldwide exclusive license under the GARP intellectual property for any purpose, subject to UCL's retention of non-commercial research rights.

Under the terms of the license, we obtained the right to grant sublicenses to third parties, subject to certain restrictions. From any income we receive in connection with these sublicenses, such as from our collaboration with AbbVie (see "Our Strategic Partnership with AbbVie" above), we must pay Sopartec a percentage of that income in the lower teen digit range. Royalty payment obligations expire on a product-by-product and country-by-country basis when there are no valid claims covering the ARGX-115 (ABBV-151) product. We also have certain diligence obligations with respect to development and commercialization of ARGX-115 (ABBV-151) products. Through December 31, 2018, we were due an aggregate amount of €4.0 million (of which €3.6 million has been paid and €0.4 million accrued) to Sopartec, as a result of the upfront and milestone payments we received from AbbVie.

Intellectual Property

We strive to protect the proprietary technologies that we believe are important to our business, including pursuing and maintaining patent protection intended to cover the platform technologies incorporated into, or used to produce, our product candidates, the compositions of matter of our product candidates and their methods of use, as well as other inventions that are important to our business. In addition to patent protection, we also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection, including certain aspects of our llama immunization and antibody affinity maturation approaches.

Our commercial success depends in part upon our ability to obtain and maintain patent and other proprietary protection for commercially important technologies, inventions and know-how related to our business, defend and enforce our intellectual property rights, particularly our patent rights, preserve the confidentiality of our trade secrets and operate without infringing valid and enforceable intellectual property rights of others.

The patent positions for biotechnology companies like us are generally uncertain and can involve complex legal, scientific and factual issues. In addition, the coverage claimed in a patent application can be significantly reduced before a patent is issued, and its scope can be reinterpreted and even challenged after issuance. As a result, we cannot guarantee that any of our platform technologies and product candidates will be protectable or remain protected by enforceable patents. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

As of January 10, 2019, our patent estate (which includes both owned and in-licensed patent rights) included 21 issued U.S. patents, over 20 pending U.S. patent applications, 84 issued foreign patents (including six

granted European patents that have been validated into 69 national patents) and 86 pending foreign patent applications (including 7 pending European patent applications).

Platform Technologies

With regard to our platform technologies, we own or have rights in patents and patent applications directed to our SIMPLE Antibody™ discovery platform, the ABDEG™ and NHance® platforms and the POTE LLIGENT® platform.

With regard to our SIMPLE Antibody™ discovery platform, we own a patent family containing six issued U.S. patents with composition of matter claims directed to chimeric antibodies containing variable domains comprising CDRs obtained from conventional heterotetrameric llama antibodies fused to one or more domains of a human antibody, polynucleotides encoding such chimeric antibodies, libraries of expression vectors comprising cDNA sequences encoding camelid antibodies, method claims directed to the preparation of such chimeric antibodies, and methods of modulating the binding of a human target antigen to its ligand or receptor by administering such a chimeric antibody. The U.S. patents are expected to expire in 2029 to 2033. In addition, the patent family contains patents that have been granted in Australia, Europe and Israel, and at least five patent applications pending in various other countries and regions in North America, Europe and Asia. In addition, we have a second patent family containing patents granted in the United States and Australia, and eight patent applications pending in the United States and other countries in North America, Europe and Asia, with composition of matter claims directed to a chimeric antibody containing variable regions with CDRs derived from a llama antibody and certain amino acid substitutions corresponding to amino acids present in a human germline variable region. The granted U.S. patent and the pending U.S. patent application, if issued as a patent, are expected to expire in 2029.

With regard to the ABDEG™ platform, we co-own with, and exclusively license from, the University of Texas, a patent family containing a pending U.S. patent application with composition of matter claims directed to an isolated FcRn-antagonist comprising a variant immunoglobulin Fc region having an increased affinity for an Fc gamma receptor relative to a wild-type IgG1 Fc region, and method of use claims directed to a method of using such an FcRn-antagonist to treat certain antibody mediated disorders. The U.S. patent application, if issued as a U.S. patent, is expected to expire in 2034. In addition, we have at least 10 patent applications pending in various other countries and regions in North America, South America, Europe and Asia. In addition, we own a second patent family containing pending patent applications in the United States and 14 other jurisdictions with claims directed to methods of reducing the serum levels of an Fc-containing agent in a subject by administering to the subject an FcRn-antagonist containing a variant immunoglobulin Fc region containing certain amino acid substitutions. A U.S. patent, if issued from the U.S. patent application, is expected to expire in 2036.

With regard to the NHance® platform, we have exclusively licensed from the University of Texas two U.S. patents with composition of matter claims directed to an IgG molecule comprising a variant human Fc domain, and method of use claims directed to a method of blocking FcRn function in a subject by providing to the subject such an IgG molecule. The U.S. patents are expected to expire in 2027 to 2028. The patent family also includes a granted European patent.

With regard to the POTE LLIGENT® platform, which is currently used in the production of our cusatuzumab and ARGX-111 product candidates, we have non-exclusively licensed from BioWa certain patent rights that relate to different aspects of the POTE LLIGENT® platform.

Product Candidates: Wholly-Owned Programs

With regard to the efgartigimod product candidate, efgartigimod incorporates the ABDEG™ technology platform, the coverage of which is discussed above under “Platform Technologies.” It is expected that U.S. patents, if they were to issue from the two patent families directed to the ABDEG™ technology platform are expected to expire in 2034 or 2036, without taking a potential patent term extension into account.

With regard to the cusatuzumab product candidate, we have three issued U.S. patents, one with composition of matter claims directed to the cusatuzumab antibody, one with claims directed to the epitope cusatuzumab binds to, and one with claims directed to a polynucleotide that encodes antibodies that bind to the epitope cusatuzumab binds to and one U.S. patent application with method of use claims directed to the treatment of cancer with the cusatuzumab antibody. The issued U.S. patents expire in 2032 and 2033, and the U.S. patent application, if issued as a U.S. patent, is expected to expire in 2032, without taking a potential patent term extension into account. In addition, we have patents that have been granted in Japan and Russia and at least nine patent applications pending in various other countries and regions in North America, South America, Europe and Asia. Furthermore, cusatuzumab incorporates or employs the SIMPLE Antibody™ and POTELLIGENT® technology platforms, which are covered by one or more of the patents and patent applications discussed above under “Platform Technologies.”

With regard to the ARGX-111 product candidate, we have three issued U.S. patents, one with composition of matter claims directed to the ARGX-111 antibody, one with method of use claims directed to the use of the ARGX-111 antibody in the treatment of cancer, and one with claims directed to polynucleotides that encode the ARGX-111 antibody and one U.S. patent application with composition of matter claims directed to ARGX-111. The issued U.S. patents and the U.S. patent application, if issued as a U.S. patent, are expected to expire in 2031, without taking a potential patent term extension into account. In addition, we have patents that have been granted in Australia, Europe, Japan and Russia, and at least eight patent applications pending in various other countries and regions in North America, South America, Europe and Asia. Furthermore, ARGX-111 also incorporates or employs the SIMPLE Antibody™, POTELLIGENT® and NHance® technology platforms, which are covered by one or more of the patents and patent applications discussed above under “Platform Technologies.” In addition, we have one U.S. patent, patents granted in Australia and Europe, and eight patent applications pending in various other countries and regions in North America, South America and Asia with composition of matter claims directed to a combination of antibodies or a multi-specific antibody, where one of the antigen binding regions in the combination of antibodies or the multi-specific antibody binds the epitope bound by the ARGX-111 antibody. The U.S. patent is expected to expire in 2033.

Product Candidates: Partnered Programs

With regard to the ARGX-115 (ABBV-151) product candidate, we co-own with, and exclusively license from, the Ludwig Institute for Cancer Research and Université Catholique de Louvain, a pending U.S. patent application with composition of matter claims directed to an antibody that binds GARP the presence of TGF-β and method of use claims directed to the use of such an antibody in the treatment of cancer. A U.S. patent, if issued from the U.S. patent application, is expected to expire in 2034, without taking a potential patent term extension into account. In addition, the patent family contains at least 10 patent applications pending in various other countries and regions in North America, South America, Europe and Asia. In addition, we co-own with, and exclusively license from, the Université Catholique de Louvain patent applications pending in the United States and Europe with composition of matter claims directed to an antibody that binds an epitope of a complex formed by human GARP and TGF-β and method of use claims directed to the use of such an antibody in the treatment of cancer. A U.S. patent, if issued from the U.S. patent application, is expected to expire in 2034. Furthermore, ARGX-115 (ABBV-151) incorporates or employs the SIMPLE Antibody™ technology platform, which is covered by one or more of the patents and patent applications discussed above under “Platform Technologies.”

With regard to the ARGX-109 product candidate, we have a pending U.S. patent application with composition of matter claims directed to ARGX-109. A U.S. patent, if it were to issue, would be expected to expire in 2033, without taking a potential patent term extension into account. We also have counterpart patents and pending patent applications in various jurisdictions, including North America, Europe and Asia. Furthermore, ARGX-109 incorporates or employs the SIMPLE Antibody™ technology and the NHance® technology, which is covered by one or more of the patents and patent applications discussed above under “Platform Technologies.”

With regard to the ARGX-112 product candidate, we have a pending international application with composition of matter claims directed to an antibody that binds human IL-22R. A U.S. patent, if it were to issue, that claims priority to the international application would be expected to expire in 2037, without taking a potential

patent term extension into account. Furthermore, ARGX-112 incorporates the SIMPLE Antibody™ technology, which is covered by one or more of the patents and patent applications discussed above under “Platform Technologies.”

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application.

In the United States, the term of a patent covering an FDA-approved drug may be eligible for a patent term extension under the Hatch-Waxman Act as compensation for the loss of patent term during the FDA regulatory review process. The period of extension may be up to five years beyond the expiration of the patent, but cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent among those eligible for an extension may be extended. Similar provisions are available in Europe and in certain other jurisdictions to extend the term of a patent that covers an approved drug. It is possible that issued U.S. patents covering each of our product candidates may be entitled to patent term extensions. If our product candidates receive FDA approval, we intend to apply for patent term extensions, if available, to extend the term of patents that cover the approved product candidates. We also intend to seek patent term extensions in any jurisdictions where they are available, however, there is no guarantee that the applicable authorities, including the FDA, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions.

In addition to patent protection, we also rely on trade secret protection for our proprietary information that is not amenable to, or that we do not consider appropriate for, patent protection, including, for example, certain aspects of our llama immunization and antibody affinity maturation approaches. However, trade secrets can be difficult to protect. Although we take steps to protect our proprietary information, including restricting access to our premises and our confidential information, as well as entering into agreements with our employees, consultants, advisors and potential collaborators, third parties may independently develop the same or similar proprietary information or may otherwise gain access to our proprietary information. As a result, we may be unable to meaningfully protect our trade secrets and proprietary information.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in the European Union and other countries and jurisdictions, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products, including biological products. In addition, some jurisdictions regulate the pricing of pharmaceutical products. The processes for obtaining marketing approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

Licensure and Regulation of Biologics in the United States

In the United States, our product candidates are regulated as biological products, or biologics, under the Public Health Service Act, or PHSA, and the Federal Food, Drug, and Cosmetic Act, or FDCA, and their implementing regulations. The failure to comply with the applicable U.S. requirements at any time during the product development process, including nonclinical testing and clinical testing, the approval process or post-approval process may subject an applicant to delays in the conduct of a study, regulatory review and approval, and/or administrative or judicial sanctions. These sanctions may include, but are not limited to, the FDA's refusal to allow an applicant to proceed with clinical testing, refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, warning or untitled letters, adverse publicity, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines and civil or criminal investigations and penalties brought by the FDA or the Department of Justice or other governmental entities.

An applicant seeking approval to market and distribute a new biologic in the United States generally must satisfactorily complete each of the following steps:

- nonclinical laboratory tests, animal studies and formulation studies all performed in accordance with the FDA's GLP regulations;
- submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may begin;
- approval by an institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials to establish the safety, potency and purity of the product candidate for each proposed indication, in accordance with Good Clinical Practices, or GCP;
- preparation and submission to the FDA of a Biologic License Application, or BLA, for a biologic product requesting marketing for one or more proposed indications, including submission of detailed information on the manufacture and composition of the product in clinical development and proposed labeling;
- review of the product by an FDA advisory committee, if applicable;
- one or more FDA inspections of the manufacturing facility or facilities, including those of third parties, at which the product, or components thereof, are produced to assess compliance with current Good Manufacturing Practices, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- FDA audits of the clinical study sites to assure compliance with GCPs, and the integrity of clinical data in support of the BLA;
- payment of user fees and securing FDA approval of the BLA and licensure of the new biologic product; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, and any post-approval studies required by the FDA.

Nonclinical Studies and Investigational New Drug Application

Before testing any biologic product candidate in humans, the product candidate must undergo nonclinical testing. Nonclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as animal studies to evaluate the potential for activity and toxicity. The conduct of the nonclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the nonclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an Investigational New Drug, or IND, application. The IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about the product or conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns before the clinical trial can begin.

As a result, submission of the IND may result in the FDA not allowing the trial to commence or on the terms originally specified by the sponsor in the IND. If the FDA raises concerns or questions either during this

initial 30-day period, or at any time during the IND process, it may choose to impose a partial or complete clinical hold. This order issued by the FDA would delay either a proposed clinical study or cause suspension of an ongoing study, or in the case of a partial clinical hold place limitations on the conduct of the study such as duration of treatment, until all outstanding concerns have been adequately addressed and the FDA has notified the company that investigation may proceed and then only under terms authorized by the FDA. This could cause significant delays or difficulties in completing planned clinical trials in a timely manner. The FDA may impose clinical holds on a biologic product candidate at any time before or during clinical trials due to safety concerns or non-compliance.

Human Clinical Trials in Support of a BLA

Clinical trials involve the administration of the investigational product candidate to healthy volunteers or patients with the disease to be treated under the supervision of a qualified principal investigator in accordance with GCP requirements. Clinical trials are conducted under study protocols detailing, among other things, the objectives of the study, inclusion and exclusion criteria, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND.

A sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of the BLA so long as the clinical trial is well-designed and well-conducted in accordance with GCP, including review and approval by an independent ethics committee, and the FDA is able to validate the study data through an onsite inspection, if necessary.

Further, each clinical trial must be reviewed and approved by an institutional review board, or IRB, either centrally or individually at each institution at which the clinical trial will be conducted. The IRB will consider, among other things, clinical trial design, patient informed consent, ethical factors and the safety of human subjects. An IRB must operate in compliance with FDA regulations. The FDA, IRB, or the clinical trial sponsor may suspend or discontinue a clinical trial at any time for various reasons, including a finding that the clinical trial is not being conducted in accordance with FDA requirements or the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive GCP rules and the requirements for informed consent. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group may recommend continuation of the study as planned, changes in study conduct, or cessation of the study at designated check points based on access to certain data from the study. Information about certain clinical studies must be submitted within specific timeframes to the National Institutes of Health for public dissemination at www.clinicaltrials.gov.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Additional studies may be required after approval.

- Phase 1 clinical trials are initially conducted in a limited population to test the product candidate for safety, including adverse effects, dose tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics in healthy humans or, on occasion, in patients, such as cancer patients.
- Phase 2 clinical trials are generally conducted in a limited patient population to identify possible adverse effects and safety risks, evaluate the efficacy of the product candidate for specific targeted indications and determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger Phase 3 clinical trials.
- Phase 3 clinical trials proceed if the Phase 2 clinical trials demonstrate that a dose range of the product candidate is potentially effective and has an acceptable safety profile. Phase 3 clinical trials are undertaken within an expanded patient population to gather additional information about safety and effectiveness necessary to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling.

In some cases, the FDA may approve a BLA for a product candidate but require the sponsor to conduct additional clinical trials to further assess the product candidate's safety and effectiveness after approval. Such post-approval trials are typically referred to as Phase 4 clinical trials. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of biologics approved under accelerated approval regulations. If the FDA approves a product while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any Phase 4 clinical trial requirement or to request a change in the product labeling. Failure to exhibit due diligence with regard to conducting required Phase 4 clinical trials could result in withdrawal of approval for products.

A drug being studied in clinical trials may be made available to individual patients in certain circumstances. Pursuant to the 21st Century Cures Act, as amended, the manufacturer of an investigational drug for a serious disease or condition is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for individual patient access to such investigational drug. This requirement applies on the earlier of the first initiation of a Phase 2 or Phase 3 trial of the investigational drug, or as applicable, 15 days after the drug receives a designation as a breakthrough therapy, fast track product, or regenerative advanced therapy.

Compliance with cGMP Requirements

Before approving a BLA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in full compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The PHSA emphasizes the importance of manufacturing control for products like biologics whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency, and purity of the final biological product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

Manufacturers and others involved in the manufacture and distribution of products must also register their establishments with the FDA and certain state agencies. Both domestic and foreign manufacturing establishments must register and provide additional information to the FDA upon their initial participation in the manufacturing process. Any product manufactured by or imported from a facility that has not registered, whether foreign or domestic, is deemed misbranded under the FDCA. Establishments may be subject to periodic unannounced inspections by government authorities to ensure compliance with cGMPs and other laws. Manufacturers may have to provide, on request, electronic or physical records regarding their establishments. Delaying, denying, limiting, or refusing inspection by the FDA may lead to a product being deemed to be adulterated.

Review and Approval of a BLA

The results of product candidate development, nonclinical testing and clinical trials, including negative or ambiguous results as well as positive findings, are submitted to the FDA as part of a BLA requesting a license to market the product. The BLA must contain extensive manufacturing information and detailed information on the composition of the product and proposed labeling as well as payment of a user fee.

The FDA has 60 days after submission of the application to conduct an initial review to determine whether the BLA is sufficient to accept for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission has been accepted for filing, the FDA begins an in-depth review of the application. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or the PDUFA, the FDA has ten months in which to complete its initial review of a standard application and respond to the applicant, and six months for a priority review of an application. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs. The review process may often be significantly extended by FDA requests for additional information or clarification. The review process and the

PDUFA goal date may be extended by three months if the FDA requests or if the applicant otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

On the basis of the FDA's evaluation of the application and accompanying information, including the results of the inspection of the manufacturing facilities and any FDA audits of clinical trial sites to assure compliance with GCPs, the FDA may issue an approval letter, denial letter, or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. Under the PHSA, the FDA may approve a BLA if it determines that the product is safe, pure and potent and the facility where the product will be manufactured meets standards designed to ensure that it continues to be safe, pure and potent. If the application is not approved, the FDA may issue a complete response letter, which will contain the conditions that must be met in order to secure final approval of the application, and when possible will outline recommended actions the sponsor might take to obtain approval of the application. Sponsors that receive a complete response letter may submit to the FDA information that represents a complete response to the issues identified by the FDA, or withdraw the application or request a hearing. The FDA will not approve an application until issues identified in the complete response letter have been addressed. The FDA issues a denial letter if it determines that the establishment or product does not meet the agency's requirements.

The FDA may also refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. In particular, the FDA may refer applications for novel biologic products or biologic products that present difficult questions of safety or efficacy to an advisory committee. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

If the FDA approves a new product, it may limit the approved indications for use of the product. It may also require that contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may call for post-approval studies, including Phase 4 clinical trials, to further assess the product's safety after approval. The agency may also require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, to help ensure that the benefits of the product outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patent registries. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Fast Track, Breakthrough Therapy and Priority Review Designations

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are referred to as fast track designation, breakthrough therapy designation and priority review designation.

The FDA may designate a product for fast track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For fast track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for

reviewing a fast track application does not begin until the last section of the application is submitted. Fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

The FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from 10 months to six months.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a product, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a product.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of products for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements,

including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Post-Approval Regulation

If regulatory approval for marketing of a product or new indication for an existing product is obtained, the sponsor will be required to comply with all regular post-approval regulatory requirements as well as any post-approval requirements that the FDA has imposed as part of the approval process. The sponsor will be required to report certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling. Manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP regulations, which impose certain procedural and documentation requirements upon manufacturers. Accordingly, the sponsor and its third-party manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMP regulations and other regulatory requirements.

A biologic product may also be subject to official lot release, meaning that the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official lot release, the manufacturer must submit samples of each lot, together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot, to the FDA. The FDA may in addition perform certain confirmatory tests on lots of some products before releasing the lots for distribution. Finally, the FDA will conduct laboratory research related to the safety, purity, potency and effectiveness of pharmaceutical products.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, untitled letters or warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Pharmaceutical products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Orphan Drug Designation

Orphan drug designation in the United States is designed to encourage sponsors to develop products intended for rare diseases or conditions. In the United States, a rare disease or condition is statutorily defined as a condition that affects fewer than 200,000 individuals in the United States or that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available the product for the disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation qualifies a company for tax credits and market exclusivity for seven years following the date of the product's marketing approval if granted by the FDA. An application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. A product becomes an orphan when it receives orphan drug designation from the Office of Orphan Products Development, or OOPD, at the FDA based on acceptable confidential requests made under the regulatory provisions. The product must then go through the review and approval process like any other product.

A sponsor may request orphan drug designation of a previously unapproved product or new orphan indication for an already marketed product. In addition, a sponsor of a product that is otherwise the same product as an already approved orphan drug may seek and obtain orphan drug designation for the subsequent product for the same rare disease or condition if it can present a plausible hypothesis that its product may be clinically superior to the first drug. More than one sponsor may receive orphan drug designation for the same product for the same rare disease or condition, but each sponsor seeking orphan drug designation must file a complete request for designation.

The period of exclusivity begins on the date that the marketing application is approved by the FDA and applies only to the indication for which the product has been designated. The FDA may approve a second application for the same product for a different use or a second application for a clinically superior version of the product for the same use. The FDA cannot, however, approve the same product made by another manufacturer for the same indication during the market exclusivity period unless it has the consent of the sponsor or the sponsor is unable to provide sufficient quantities.

Pediatric Studies and Exclusivity

Under the Pediatric Research Equity Act of 2003, as amended, a BLA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests and other information required by regulation. The applicant, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent and orphan exclusivity. This six-month exclusivity may be granted if a BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric

studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

Biosimilars and Exclusivity

The Biologics Price Competition and Innovation Act, or BPCIA, established a regulatory scheme authorizing the FDA to approve biosimilars and interchangeable biosimilars. To date, while biosimilar products have been approved by the FDA for use in the United States, no interchangeable biosimilars have been approved.

Under the BPCIA, a manufacturer may submit an application for licensure of a biologic product that is “biosimilar to” or “interchangeable with” a previously approved biological product or “reference product.” In order for the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product, and (for products administered multiple times) that the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date of approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor's own nonclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. However, to rely on such exclusivities for establishing or protecting our market position is not without risk, as such laws are subject to changes by the legislature. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed “interchangeable” by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

Regulation and Procedures Governing Approval of Medicinal Products in the European Union

In order to market any product outside of the United States, a company also must comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can initiate clinical trials or marketing of the product in those countries or jurisdictions. Specifically, the process governing approval of medicinal products in the European Union generally follows the same lines as in the United States. It entails satisfactory completion of pharmaceutical development, nonclinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the medicinal product for each proposed indication. It also requires the submission to relevant competent authorities for clinical trials authorization and to the EMA or to competent authorities in European Union Member States for a marketing authorization application, or MAA, and granting of a marketing authorization by these authorities before the product can be marketed and sold in the European Union.

Clinical Trial Approval

Pursuant to the currently applicable Clinical Trials Directive 2001/20/EC and the Directive 2005/28/EC on GCP, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states. Under this system, an applicant must obtain approval from the competent national authority of an European Union member state in which the clinical trial is to be conducted or in multiple member states if the clinical trial is to be conducted in a number of member states. Furthermore, the applicant may only

start a clinical trial at a specific study site after the independent ethics committee has issued a favorable opinion. The clinical trial application, or CTA, must be accompanied by an investigational medicinal product dossier with supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and corresponding national laws of the member states and further detailed in applicable guidance documents.

In April 2014, the European Union adopted a new Clinical Trials Regulation (EU) No 536/2014, which is set to replace the current Clinical Trials Directive 2001/20/EC. It is expected that the new Clinical Trials Regulation will enter into force in 2020 with a three-year transition period. It will overhaul the current system of approvals for clinical trials in the European Union. Specifically, the new regulation, which will be directly applicable in all member states, aims at simplifying and streamlining the approval of clinical trials in the European Union. For instance, the new Clinical Trials Regulation provides for a streamlined application procedure via a single entry point and strictly defined deadlines for the assessment of clinical trial applications.

Orphan Drug Designation and Exclusivity

Regulation (EC) No. 141/2000 and Regulation (EC) No. 847/2000 provide that a product can be designated as an orphan drug by the European Commission if its sponsor can establish: that the product is intended for the diagnosis, prevention or treatment of (1) a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the European Union when the application is made, or (2) a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the drug in the European Union would generate sufficient return to justify the necessary investment. For either of these conditions, the applicant must demonstrate that there exists no satisfactory method of diagnosis, prevention, or treatment of the condition in question that has been authorized in the European Union or, if such method exists, the drug has to be of significant benefit compared to products available for the condition.

An orphan drug designation provides a number of benefits, including fee reductions, regulatory assistance and the possibility to apply for a centralized European Union marketing authorization. Marketing authorization for an orphan drug leads to a ten-year period of market exclusivity. During this market exclusivity period, neither the EMA nor the European Commission or the member states can accept an application or grant a marketing authorization for a “similar medicinal product.” A “similar medicinal product” is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The market exclusivity period for the authorized therapeutic indication may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation because, for example, the product is sufficiently profitable not to justify market exclusivity.

Marketing Authorization

To obtain a marketing authorization for a product under the European Union regulatory system, an applicant must submit an MAA, either to EMA using the centralized procedure or to competent authorities in European Union Member States using the other procedures (decentralized procedure, national procedure, or mutual recognition procedure). A marketing authorization may be granted only to an applicant established in the European Union. Regulation (EC) No. 1901/2006 provides that prior to obtaining a marketing authorization in the European Union, an applicant must demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan, or PIP, covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, class waiver, or a deferral for one or more of the measures included in the PIP.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all European Union member states. Pursuant to Regulation (EC) No. 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of cancer and auto-immune diseases. For products with a new active substance indicated for the

treatment of other diseases and products that are highly innovative or for which the centralized procedure is in the interest of public health, the centralized procedure may be optional.

Under the centralized procedure, the Committee for Medicinal Products for Human Use, or the CHMP, established at the EMA is responsible for conducting the assessment of a product to define its risk/benefit profile. Under the centralized procedure, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated evaluation may be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts such a request, the time limit of 210 days will be reduced to 150 days, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that it is no longer appropriate to conduct an accelerated assessment.

Periods of Authorization and Renewals

A marketing authorization is valid for five years, in principle, and it may be renewed after five years on the basis of a reevaluation of the risk benefit balance by the EMA or by the competent authority of the authorizing member state. To that end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any authorization that is not followed by the placement of the drug on the European Union market (in the case of the centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid.

Regulatory Requirements after Marketing Authorization

Following approval, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of the medicinal product. These include compliance with the European Union's stringent pharmacovigilance or safety reporting rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed. In addition, the manufacturing of authorized products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the EMA's GMP requirements and comparable requirements of other regulatory bodies in the European Union, which mandate the methods, facilities and controls used in manufacturing, processing and packing of drugs to assure their safety and identity. Finally, the marketing and promotion of authorized products, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the European Union under Directive 2001/83EC, as amended.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may obtain regulatory approval. Even if our product candidates are approved for marketing, sales of such product candidates will depend, in part, on the extent to which third-party payors, including government health programs in the United States (such as Medicare and Medicaid), commercial health insurers, and managed care organizations, provide coverage and establish adequate reimbursement levels for such product candidates. Moreover, increasing efforts by governmental and third-party payors in the European Union, the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products, and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general,

particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

In the United States and markets in other countries, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered, and patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use any product candidates we may develop unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of such product candidates. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse health care providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services and imposing controls to manage costs, especially drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidate and other therapies as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidate, pricing of existing drugs may limit the amount we will be able to charge for our product candidate. These payors may deny or revoke the reimbursement status of a given drug product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates, and may not be able to obtain a satisfactory financial return on products that we may develop. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, and the cost of these studies would be in addition to the costs required to obtain FDA or other comparable marketing approvals. Even after pharmacogenomic studies are conducted, product candidates may not be considered medically necessary or cost-effective. A decision by a third-party payor not to cover any product candidates we may develop could reduce physician utilization of such product candidates once approved and have a material adverse effect on our sales, results of operations and financial condition. Additionally, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. For example, the payor may require co-payments that patients find unacceptably high. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor. Third-party reimbursement and coverage may not be adequate to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. The insurance coverage and reimbursement status of newly-approved products for orphan diseases is particularly uncertain, and failure to obtain or maintain adequate coverage and reimbursement for any such product candidates could limit our ability to generate revenue.

The containment of healthcare costs also has become a priority of U.S. federal, state and international governments and the prices of pharmaceuticals have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our potential revenue from the sale of any products for which we may obtain approval. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more of our products for which a we or our collaborators

receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Obtaining and maintaining reimbursement status is time-consuming and costly. No uniform policy for coverage and reimbursement for drug products exists among third-party payors in the United States. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

Outside the United States, we will face challenges in ensuring obtaining adequate coverage and payment for any product candidates we may develop. Pricing of prescription pharmaceuticals is subject to governmental control in many countries. Pricing negotiations with governmental authorities can extend well beyond the receipt of regulatory marketing approval for a product and may require us to conduct a clinical trial that compares the effectiveness of any product candidates we may develop to other available therapies to support cost-effectiveness. The conduct of such a clinical trial could be expensive, involve additional risk and result in delays in our commercialization efforts.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies (so called health technology assessments, or HTAs) in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its member states to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other member states allow companies to fix their own prices for products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. The downward pressure on health care costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel trade (arbitrage between low-priced and high-priced member states) can further reduce prices. Special pricing and reimbursement rules may apply to orphan drugs. Inclusion of orphan drugs in reimbursement systems tend to focus on the medical usefulness, need, quality and economic benefits to patients and the healthcare system as for any drug. Acceptance of any medicinal product for reimbursement may come with cost, use and often volume restrictions, which again can vary by country. In addition, results based rules of reimbursement may apply. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products, if approved in those countries.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of healthcare and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most European Union member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing European Union and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize any products for which we obtain marketing approval.

Healthcare Law and Regulation

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of pharmaceutical products that are granted marketing approval. Our current and future arrangements with providers, researchers, consultants, third-party payors and customers are subject to broadly applicable federal and state fraud and abuse, anti-kickback, false claims, transparency and patient privacy laws and regulations and other healthcare laws and regulations that may constrain our business and/or financial arrangements. Restrictions under applicable federal and state healthcare laws and regulations include, without limitation, the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;
- the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false, fictitious, or fraudulent or knowingly making, using, or causing to be made or used a false record or statement to avoid, decrease, or conceal an obligation to pay money to the federal government;
- HIPAA, which created additional federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by HITECH, and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without the appropriate authorization by entities subject to the law, such as healthcare providers, health plans and healthcare clearinghouses and their respective business associates;
- the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively the ACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or CMS, within the U.S. Department of Health and Human Services, information related to payments and other transfers of value made by that entity to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring pharmaceutical manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

We will be required to spend substantial time and money to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations. Recent healthcare reform legislation has strengthened these federal and state healthcare laws. For example, the ACA amends the intent requirement of the federal Anti-Kickback Statute and criminal healthcare fraud statutes to clarify that liability under these statutes does not require a person or entity to have actual knowledge of the statutes or a specific intent to violate them. Moreover, the ACA provides that the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

Violations of these laws can subject us to criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment and exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm, and we may be required to curtail or restructure our operations. Moreover, we expect that there will continue to be federal and state laws and regulations, proposed and implemented, that could impact our future operations and business.

Healthcare Reform

In the United States, the European Union and other foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the ACA became law. The ACA is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the ACA of importance to our potential product candidates are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic products, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices and extending rebate liability to prescriptions for individuals enrolled in Medicare Advantage plans;

- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for products that are inhaled, infused, instilled, implanted or injected;
- expanding the types of entities eligible for the 340B drug discount program;
- establishing the Medicare Part D coverage gap discount program, which requires manufacturers to provide a 50% point-of-sale-discount off the negotiated price of applicable products to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient products to be covered under Medicare Part D;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of the Center for Medicare and Medicaid Innovation within Centers for Medicare & Medicaid, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription product spending (funding has been allocated to support the mission of the CMS Innovation through 2019).

Since its enactment, some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial, congressional, and executive challenges. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the ACA. The U.S. Supreme Court has upheld certain key aspects of the legislation, including a tax-based shared responsibility payment imposed on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly known as the “individual mandate.” However, as a result of tax reform legislation passed in December 2017, the individual mandate has been eliminated effective January 1, 2019. According to the Congressional Budget Office, the repeal of the individual mandate will cause 13 million fewer Americans to be insured in 2027 and premiums in insurance markets may rise.

Since January 2017, President Trump has signed several executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. One such Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. The loss of the cost share reduction payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. Further, on June 14, 2018, the U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than \$12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known.

Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed repeal legislation, it has enacted laws that modify certain provisions of the ACA, such as removing or delaying penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance, delaying the implementation of certain ACA-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. On December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseparable feature of the ACA, and therefore because the mandate was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. The Trump administration and CMS have both stated that the ruling will have no immediate effect, and on December 30, 2018, the same judge issued an order staying the judgment pending appeal. It is unclear how this decision and any subsequent appeals and other efforts to repeal and replace the ACA will impact the ACA and our business. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. We will continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These new laws may result in additional reductions in Medicare and other healthcare funding. For example, on August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2012 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including without limitation the Bipartisan Budget Act of 2015, will remain in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. The Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

CMS may develop new payment and delivery models, such as bundled payment models. CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. On November 30, 2018, CMS announced a proposed rule that would amend the Medicare Advantage and Medicare Part D prescription drug benefit regulations to reduce out of pocket costs for plan enrollees and allow Medicare plans to negotiate lower rates for certain drugs. Among other things, the proposed rule changes would allow Medicare Advantage plans to use pre authorization (PA) and step therapy (ST) for six protected classes of drugs and, with certain exceptions, permit plans to implement PA and ST in Medicare Part B drugs; and change the definition of "negotiated prices" as well as add a definition of "price concession" in the regulations. It is unclear whether these proposed changes will be accepted, and if so, what effect such changes will have on our business.

In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Specifically, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Further, legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional

legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals, if any, of our product candidates, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing conditions and other requirements.

Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our current or any future products. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most European Union member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing European Union and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize any products for which we obtain marketing approval. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or our collaborators are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

C. ORGANIZATIONAL STRUCTURE

As of December 31, 2018, we had two subsidiaries. The following table sets out for each of our principal subsidiaries, the country of incorporation, and percentage ownership and voting interest held by us (directly or indirectly through subsidiaries).

Company	Country of incorporation	Percentage ownership and voting interest	Main activity
argenx BVBA	Belgium	100.00 %	Biotechnical research on drugs and pharma processes
argenx US, Inc.	United States	100.00 %	Pharmaceuticals and pharmacy supplies merchant wholesalers

D. PROPERTY, PLANTS AND EQUIPMENT

We lease our operational offices and laboratory space, which consists of approximately 1,500 square meters, located in Zwijnaarde, Belgium. The lease for this facility expires in 2026. In January 2019, we signed an agreement to lease additional office space in a building adjacent to our current facility. We also lease an office in Breda, the Netherlands.

We lease office space in Boston, Massachusetts. The lease runs on a yearly basis. In January 2019, we signed an agreement to lease additional office space to accommodate the anticipated growth of our U.S. activities in line with our business plan.

We have a total of three facilities worldwide owned or leased as of December 31, 2018, as set forth in the following table:

Facility location	Use	Approx. size (m ²)	Lease expiry
Zwijnaarde, Belgium (leased)	Operations and Laboratory Space	1,500	April 1 st , 2026
Breda, the Netherlands (leased)	Headquarters	12	July 31 st , 2019
Boston, Massachusetts (leased)	Office Space	163	September 30 th , 2019

Environment, Health and Safety

Our research and development activities take place in our facilities in Zwijnaarde, Belgium. For these activities we have obtained the necessary environmental and biohazard permits from the responsible governments. See “Item 3.D.—Risk Factors—Risks Related to Our Business and Industry.”

ITEM 4A. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**A. OPERATING RESULTS****Overview**

We are a clinical-stage biotechnology company developing a deep pipeline of differentiated antibody-based therapies for the treatment of severe autoimmune diseases and cancer. Utilizing our suite of technologies, we are focused on developing product candidates with the potential to be either first-in-class against novel targets or best-in-class against known, but complex, targets in order to treat diseases with a significant unmet medical need. Our SIMPLE Antibody™ Platform, based on the powerful llama immune system, allows us to exploit novel and complex targets, and our three antibody Fc engineering technologies are designed to enable us to expand the therapeutic index of our product candidates. Together with our antibody discovery and development expertise, this suite of technologies has enabled our pipeline of eight product candidates. Two of our product candidates are in Phase 2 and Phase 3 trials for multiple indications, one of which has achieved clinical proof-of-concept in two indications and is in Phase 3 clinical development for the first indication.

In September 2018, we launched our first Phase 3 trial for efgartigimod, our most advanced product candidate for the treatment of the rare autoimmune disease myasthenia gravis, or MG. The full data from the Phase

2 trial in myasthenia gravis were reported in April 2018. In addition, we recently completed a Phase 2 clinical trial for efgartigimod in immune thrombocytopenia, or ITP, where we reported for the second time a proof-of-concept of our lead product candidate with strong clinical improvement over placebo. In both Phase 2 studies, efgartigimod was observed to have a favorable tolerability profile consistent with that observed in our Phase 1 clinical trial. In September 2017, we initiated a Phase 2 clinical trial of efgartigimod for the treatment of a third rare autoimmune disease, pemphigus vulgaris, or PV. In June 2018, we reported interim data from the first cohort of this Phase 2 proof-of-concept clinical trial where rapid disease control was observed with a favorable tolerability profile. For efgartigimod, we are also developing a subcutaneous (SC) product formulation designed to enable administration potentially outside the hospital setting. In June 2018, we reported that at the same dose level the SC formulation was comparable across key measures, including half-life, pharmacodynamics and tolerability, to the intravenous (IV) formulation used in clinical studies to date.

We continued to develop our second lead product candidate, cusatuzumab, for the rare and aggressive hematological cancer acute myeloid leukemia, or AML, as well as high-risk myelodysplastic syndrome, or MDS. In December 2016, we commenced the dose-escalation part of the Phase 1/2 clinical trial of cusatuzumab in combination with azacytidine. In December 2018, we reported a 92% response rate in the treated newly diagnosed AML patients. The transition into the Phase 2 part of this clinical trial was announced in August 2018.

We have a disciplined strategy to maximize the value of our pipeline whereby we plan to retain development and commercialization rights to those product candidates that we believe we can ultimately commercialize successfully on our own if they are approved. We plan to collaborate on product candidates that we believe have promising utility in disease areas or patient populations that are better served by the resources of larger biopharmaceutical companies. We have entered into collaborations with a number of biopharmaceutical companies, including our collaboration with Cilag GmbH International, an affiliate of Janssen. In January 2019, we received a \$300 million upfront payment and Johnson & Johnson Innovation Inc. (JJDC) made a €176.7 million equity investment in argenx. In addition, in August 2018, our collaborator AbbVie S. A. R. L., or AbbVie has exercised its exclusive option to license ARGX-115 (ABBV-151), a cancer immunotherapy-focused product candidate against the novel target glycoprotein A repetitions predominant, or GARP.

Since our inception in 2008, we have focused most of our financial resources and efforts towards developing our SIMPLE Antibody™ Platform and antibody engineering technologies, identifying potential product candidates, establishing process, development and manufacturing capabilities for our product candidates and advancing multiple discovery programs into the clinic. We have advanced six internally developed product candidates into clinical development—efgartigimod, cusatuzumab, ARGX-111, ARGX-109, ARGX-112 and ARGX-115 (ABBV-151)—two into the preclinical stage—ARGX-116 and ARGX-117—and currently have multiple programs in the discovery stages. Through December 31, 2018, we have raised an aggregate gross proceeds of €735.9 million, including (i) an aggregate of €46.0 million from the private placement of equity securities in 2008, 2009 and 2011, (ii) €41.8 million from our initial public offering on the Euronext Brussels in 2014, (iii) €46.0 million from the private placement of equity securities, primarily to U.S.-based institutional investors, in 2016, (iv) \$114.7 million from our initial U.S. public offering on the Nasdaq Global Select Market in May 2017, (v) \$265.5 million from our second U.S. public offering on the Nasdaq Global Select Market in December 2017 and (vi) \$300.6 million from our third U.S. public offering on the Nasdaq Global Select Market in September 2018. In addition, as of December 31, 2018, we have received upfront payments, milestone payments and research and development service fees from our collaborators totaling €88.2 million and have received €18.7 million in grants and incentives from governmental bodies. As of December 31, 2018, we had cash, cash equivalents and current financial assets of €564.6 million.

Since our inception, we have incurred significant operating losses. We do not currently have any approved products and have never generated any revenue from product sales. Our ability to generate revenue sufficient to achieve profitability will depend significantly upon the successful development and eventual commercialization of one or more of our product candidates, which may never occur. For the years ended December 31, 2017 and 2018, we incurred total comprehensive losses of €28.1 million and €66.6 million, respectively. As of December 31, 2018, we had accumulated losses of €169.6 million.

We expect our expenses to increase substantially in connection with our ongoing development activities related to our preclinical and clinical programs. In addition, we expect to continue to incur significant costs associated with operating as a public company in the United States. We anticipate that our expenses will increase substantially if and as we:

- execute the Phase 3 clinical trials of efgartigimod in MG and, potentially, ITP and PV;
- complete the Phase 2 clinical trials of efgartigimod in ITP and PV and launch a Phase 2 clinical trial in CIDP;
- complete the Phase 2 clinical trials of cusatuzumab in AML / high risk MDS;
- execute a Phase 2 clinical trial in ITP with the subcutaneous formulation of efgartigimod;
- jointly develop and commercialize cusatuzumab with Janssen as per the collaboration agreement signed in December 2018;
- continue the research and development of our other clinical- and preclinical-stage product candidates and discovery stage programs;
- seek to enhance our technology platform and discover and develop additional product candidates;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- potentially establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize any product candidates for which we may obtain regulatory approval;
- maintain, expand and protect our intellectual property portfolio, including litigation costs associated with defending against alleged patent infringement claims;
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts; and
- experience any delays or encounter any issues any of the above, including failed studies, ambiguous trial results, safety issues or other regulatory challenges.

We expect that the costs of development and commercialization will significantly increase due to the extended product development roadmap for cusatuzumab as part of our collaboration with Janssen. Although this collaboration agreement provides for a joint decision process to approve the development plan as well as the budget, we will not control the actual amounts spent within such approved budget, and we cannot control or guarantee that these funds are spent in the most efficient way.

As a result of the above uncertainty, we will need additional financing to support our continuing operations. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity or debt financings or other sources, which may include collaborations with third parties. Adequate additional financing may not be available to us on acceptable terms, or at all. Our ability to raise additional funds will depend on financial, economic and market conditions and other factors, over which we may have no or limited control. Our inability to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy and as a result we may be forced to delay, reduce or terminate the development or commercialization of all or part of our research programs or product candidates or we may be unable to take advantage of future business opportunities.

Collaboration Agreements

We have a disciplined strategy to maximize the value of our pipeline whereby we plan to retain all development and commercialization rights to those product candidates that we believe we can ultimately commercialize successfully, if approved. We have partnered, and plan to continue to partner, product candidates that we believe have promising utility in disease areas or patient populations that are better served by resources of larger biopharmaceutical companies. Below are summaries of our key collaborations. See "Item 4.B.—Business Overview—Collaborations" for a more detailed description of these agreements.

Janssen. In December 2018, we entered into a collaboration agreement with Cilag GmbH International, an affiliate of Janssen, to jointly develop and commercialize cusatuzumab. We have granted Janssen a license to the cusatuzumab program to develop, manufacture and commercialize products. For the U.S., the granted commercialization license is co-exclusive with argenx, while outside the U.S., the granted license is exclusive. Janssen and argenx will assume certain development obligations, and will be jointly responsible for all research, development and regulatory costs relating to the products.

Under the terms of the agreement, Janssen has paid argenx \$300 million in an upfront payment and JJDC has purchased €176.7 million (\$200 million based on the exchange rate as of the date the agreement was signed) in newly issued shares, for a total of 1,766,899 shares representing 4.68% of our outstanding shares at a price of €100.02 per share (\$113.17 based on the exchange rate in effect as of the date the agreement was signed) in January 2019. argenx will be eligible to receive potentially up to \$1.3 billion in development, regulatory and sales milestones, in addition to tiered royalties, ranging from the low double digits to the high teens. Janssen will be responsible for commercialization worldwide. argenx retains the option to participate in commercialization efforts in the U.S., where the companies have agreed to share royalties on a 50/50 basis, and outside the U.S., Janssen will pay double-digit sales royalties to argenx. The agreement stipulates customary standstill and lock-up provisions.

AbbVie. In April 2016, we entered into a collaboration agreement with AbbVie to develop and commercialize ARGX-115 (ABBV-151). Under the terms of the collaboration agreement, we were responsible for conducting and funding all ARGX-115 (ABBV-151) research and development activities up to completion of IND-enabling studies.

We granted AbbVie an exclusive option, for a specified period following completion of IND-enabling studies, to obtain a worldwide, exclusive license to the ARGX-115 (ABBV-151) program to develop and commercialize products. We received an upfront, non-refundable, non-creditable payment of \$40.0 million (€35.1 million based on the exchange rate in effect as of the date the payment was received) from AbbVie for the exclusive option to license ARGX-115 (ABBV-151). During the course of the collaboration, we achieved two pre-defined preclinical milestones, each of which triggered a \$10.0 million payment (€8.9 million based on the exchange rate in effect as of the date the first preclinical milestone payment was received, and €8.7 million based on the exchange rate in effect as of the date the second preclinical milestone payment was received). In addition, in March 2019 we have achieved the first pre-defined clinical milestone, triggering a \$30 million payment.

In August 2018, AbbVie exercised its option and has now assumed certain development obligations, being solely responsible for all research, development and regulatory costs relating to ARGX-115-based products. Subject to the continuing progress of ARGX-115 (ABBV-151) by AbbVie, we are eligible to receive development, regulatory and commercial milestone payments in aggregate amounts of up to \$110.0 million, \$190.0 million and \$325.0 million, respectively, as well as tiered royalties on product sales at percentages ranging from the mid-single digits to the lower teens, subject to customary reductions.

Bird Rock Bio. In October 2012, we entered into an exclusive license agreement with Bird Rock Bio, Inc. (formerly known as RuiYi, Inc. and Anaphore, Inc.), or Bird Rock Bio, under which we granted Bird Rock Bio an exclusive, worldwide, royalty-bearing license to develop and commercialize ARGX-109. We received a non-refundable, non-creditable upfront payment from Bird Rock Bio of €0.5 million in cash plus shares of Bird Rock Bio stock, and we are eligible to receive additional development milestone payments of up to approximately €10.0 million in cash and additional shares of Bird Rock Bio stock, regulatory milestone payments of up to

€10.0 million in cash and commercial milestone payments of up to €12.0 million in cash. We are eligible to receive tiered royalties on Bird Rock Bio's commercial sales of ARGX-109 at percentages ranging from the low to high single digits and a tiered percentage of Bird Rock Bio's sublicensing income ranging from the mid teens to high twenties, subject to customary reductions. Bird Rock Bio and argenx have mutually agreed to terminate Bird Rock Bio's license agreement to develop and commercialize ARGX-109. Genor, a sublicensee of Bird Rock Bio, will continue to develop ARGX-109 for the Chinese market. Hence, we will not be entitled to receive some or all of the milestone or other payments under this exclusive license agreement with Bird Rock Bio.

LEO Pharma. In May 2015, we entered into a collaboration agreement with LEO Pharma A/S, or LEO Pharma, to develop and commercialize ARGX-112. Under the terms of the collaboration, LEO Pharma funded more than half of all product development costs up to CTA approval of a first product in a Phase 1 clinical trial, with our share of such costs capped. Since CTA approval of a first product in a Phase 1 clinical trial was received in April 2018, LEO Pharma is solely responsible for funding the clinical development of the program.

We received a non-refundable, non-creditable upfront payment from LEO Pharma of €3.0 million in cash. In February 2016, June 2017 and April 2018, we achieved preclinical milestones under this collaboration for which we received milestone payments. LEO Pharma may exercise an option to obtain an exclusive, worldwide license to further develop and commercialize products. Following the exercise of the option, LEO Pharma would assume full responsibility for the continued development, manufacture and commercialization of such products, subject to certain diligence obligations. If LEO Pharma elects to exercise this option, it must pay us an option fee. We are also eligible to receive additional development, regulatory and commercial milestone payments in aggregate amounts of up to €11.5 million, €6.0 million and €102.5 million, respectively, as well as tiered royalties on product sales at percentages ranging from the low single digits to the low teens, subject to customary reductions.

Staten. In January 2015, we entered into a collaboration agreement with Staten Biotechnology B.V., or Staten, to develop and commercialize products in the area of dyslipidemia therapy. Under the collaboration agreement, the parties sought to discover and characterize antibodies against a human target with therapeutic relevance in the field of dyslipidemia and/or cardiovascular disease. The first research program under this agreement proceeded as planned and was extended to December 2017, with ARGX-116 identified as the initial product candidate. Staten exercised its exclusive option to license ARGX-116 in March 2017. Under the terms of the collaboration, the parties were and are jointly responsible for conducting research under a mutually agreed research plan, with Staten reimbursing us for all costs of carrying out our research responsibilities under each research program. Staten is also responsible for additional clinical development. In December 2018, Staten announced that it will collaborate with Novo Nordisk A/S to co-develop ARGX-116.

Shire. In February 2012, we entered into a collaboration agreement with Shire AG (now known as Shire International GmbH), or Shire, to discover, develop and commercialize novel human therapeutic antibodies against up to three targets to address diverse, rare and unmet diseases. Under the terms of the collaboration, for any target selected for study under the collaboration, the parties worked together to conduct research and development through discovery of antibodies with certain specificity for and functional activity against those targets. In May 2014, we expanded the collaboration agreement to accommodate research and development of additional novel targets implicated in multiple disease areas. The initial three-year term of this expanded agreement expired on May 30, 2017, and Shire opted to extend the collaboration term for a further year until May 30, 2018, but no further beyond May 2018.

Through December 31, 2018, pursuant to the agreement Shire has paid us an aggregate total of (i) €3.4 million in upfront payments, (ii) €0.3 million in milestone payments and (iii) \$12.6 million in research and development funding. In addition, Shire purchased €12.0 million of our ordinary shares in July 2014 by participating in our initial public offering on Euronext Brussels.

Basis of Presentation

Revenue

The company and its subsidiaries, or the Group, generate revenue from collaborations and strategic alliances. The Group applies a five-step model to determine when, how and at what amount revenue is to be recognized depending on whether certain criteria are met.

1. Identify the contracts

In its current arrangements, the Group is licensing its intellectual property, providing research and development services and in the future, selling its products to collaborative entities. Revenue is generated through these arrangements via upfront payments, milestone payments based on development criteria, research and development service fees on an agreed full-time equivalent, or FTE, basis and future sales-based milestones and sales-based royalties.

2. Identify performance obligations

The Group has determined that there is one single performance obligation for certain arrangements in its material ongoing license and collaboration arrangements, that being the transfer of a license combined with the performance of research and development services.

This is because we consider that the license has no stand-alone value without the Group being further involved in the research and development collaboration and that there is interdependence between the license and the research and development services to be provided. We estimate that the Group's activities during the collaboration are going to significantly add to Intellectual Property and thereby the value of the programs.

3. Determine the transaction price

We have analyzed the transaction prices of our material ongoing license and collaboration arrangements, currently composed of upfront payments, milestone payments and research and development service fees being delivered. Sales-based milestones and sales-based royalties are part of certain of our arrangements but are not yet included in our revenues, as our most advanced license and collaboration arrangement is still in the development phase.

4. Allocate the transaction price

In principle, an entity shall allocate the transaction price to each performance obligation identified in the contract on a relative stand-alone selling price. However, the transaction price of certain of our arrangements is allocated to a single performance obligation since the transfer of a license is considered to be combined with the performance of research and development services.

Therefore, research and development milestone payments are variable considerations that are entirely allocated to the single performance obligation.

5. Recognize revenue

Revenue from certain arrangements is recognized over time as the Group satisfies a single performance obligation. Our collaborative entities simultaneously receive the benefits provided by the Group's performance as the Group performs.

The Group recognizes upfront payments and milestone payments, allocated to a single performance obligation over the estimated service period based on a pattern that reflects the transfer of the services. The revenues recognized reflect the level of service during each period. In this case, the Group would use an input model that considers estimates of the percentage of total research and development service costs that are completed each period compared to the total estimated services costs (percentage of completion method).

Research and development service fees are recognized as revenue when costs are incurred and agreed by the parties, as the Group is acting as a principal in the scope of its stake of the research and development activities of its ongoing license and collaboration agreements.

Other Operating Income

As a company that carries extensive research and development activities, we benefit from various grants, research and development incentives and payroll tax rebates from certain governmental agencies. These grants and research and development incentives generally aim to partly reimburse approved expenditures incurred in our research and development efforts. The primary grants, research and development incentives and payroll tax rebates are as follows:

Government Grants

- We have received several grants from agencies of the Flemish government to support various research programs focused on technological innovation in Flanders. These grants require us to maintain a presence in the Flemish region for a number of years and invest according to pre-agreed budgets.

Research and Development Incentives

- Companies in Belgium can benefit from tax savings on amounts spent on research and development by applying a one-time or periodic tax deduction on research and development expenditures for the acquisition or development of patents. This tax credit is a reduction of the corporate income taxes for Belgian statutory purposes and is transferrable to the next four accounting periods. These tax credits are paid to us in cash after five years to the extent they have not been offset against corporate taxes due.

Payroll Tax Rebates

- We also benefit from certain rebates on payroll withholding taxes for scientific personnel.

The government grants and research and development incentives generally aim to partly reimburse approved expenditures incurred in our research and development efforts and are credited to the income statement, under other operating income, when the relevant expenditure has been incurred and there is reasonable assurance that the grant or research and development incentive is receivable.

Research and Development Expenses

Research and development expenses consist principally of:

- personnel expense related to compensation of research and development staff and related expenses, including salaries, benefits and share-based compensation expenses;
- external research and development expenses related to (i) chemistry, manufacturing and control costs for our product candidates, both for preclinical and clinical testing, all of which is conducted by specialized contract manufacturers, (ii) costs associated with regulatory submissions and approvals,

quality assurance and pharmacovigilance and (iii) fees and other costs paid to contract research organizations in connection with preclinical testing and the performance of clinical trials for our product candidates;

- materials and consumables expenses;
- depreciation and amortization of tangible and intangible fixed assets used to develop our product candidates; and
- other expenses consisting of (i) costs associated with obtaining and maintaining patents and other intellectual property and (ii) other costs such as travel expenses related to research and development activities.

We incur various external expenses under our collaboration agreements for material and services consumed in the discovery and development of our partnered product candidates. Under our agreements with Shire, LEO Pharma and Staten, our collaboration partner reimburses us for part or all of these external expenses and compensates us for time spent on the project by our employees. Under our agreement with AbbVie, our own research and development expenses are not reimbursed. Research and development expenses are recognized in the period in which they are incurred. Under our agreement with Janssen, we assume certain development obligations, and are jointly responsible with Janssen for all research, development and regulatory costs relating to the product.

Our research and development expenses may vary substantially from period to period based on the timing of our research and development activities, including the timing of the initiation of clinical trials, production of product batches and enrolment of patients in clinical trials. Research and development expenses are expected to increase as we advance the clinical development of efgartigimod and cusatuzumab and further advance the research and development of our other preclinical and discovery stage programs. The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing and estimated costs of the efforts that will be necessary to complete the development of, or the period, if any, in which material net cash inflows may commence from, any of our product candidates. This is due to numerous risks and uncertainties associated with developing drugs, as fully described in “Item 3.D.—Risk Factors,” and including the uncertainty of:

- the scope, rate of progress and expense of our research and development activities;
- the successful enrollment in, and completion of clinical trials;
- the successful completion of preclinical studies necessary to support IND applications in the United States or similar applications in other countries;
- establishing and maintaining a continued acceptable safety profile for our product candidates;
- the terms, timing and receipt of regulatory approvals from applicable regulatory authorities;
- the expense of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; and
- the ability to market, commercialize and achieve market acceptance for efgartigimod, cusatuzumab or any other product candidate that we may develop in the future, if approved; and
- our current and future collaborators continuing their collaborations with us.

Any of these variables with respect to the development of efgartigimod, cusatuzumab or any other product candidate that we may develop could result in a significant change in the costs and timing associated with, and the viability of, the development of such product candidates. For example, if the FDA, the EMA or other regulatory authority were to require us to conduct preclinical studies or clinical trials beyond those we currently anticipate will be required for the completion of clinical development or if we experience significant delays in enrolment in any clinical trials, we could be required to expend significant additional financial resources and time on the completion of our clinical development programs and the viability of the product candidate in question could be adversely affected.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of (i) personnel expenses relating to salaries and related costs for personnel, including share-based compensation, of our employees in executive, finance, business development, commercial and support functions, (ii) consulting fees relating to professional fees for accounting, business development, IT, audit, commercial, legal services and investor relations costs, (iii) board expenses consisting of directors' fees, travel expenses and share-based compensation for non-executive board members, (iv) allocated facilities costs and (v) other selling, general and administrative expenses, including leasing costs, office expenses, travel costs.

We expect our selling, general and administrative expenses to increase as we continue to support our growth and operate as a public company in the United States. Such costs include increases in our finance and legal personnel, additional external legal and audit fees, and expenses and costs associated with compliance with the regulations governing public companies. We expect our selling expenses to increase significantly with preparatory marketing and pricing activities with respect to the potential future commercialization of one or more of our product candidates, if approved.

Financial Income (Expense)

Financial income reflects interest earned on the financial investments of our cash and cash equivalents and financial assets. Financial expense corresponds to interest expenses.

Exchange Gains (Losses)

Our exchange gains (losses) relate to (i) our transactions denominated in foreign currencies, mainly in U.S. dollars, Swiss francs and British pounds, which generate exchange gains or losses and (ii) the translation at the reporting date of assets and liabilities denominated in foreign currencies into euros, which is our functional and presentation currency. For more information on currency exchange fluctuations on our business, please see "Item 11—Quantitative and Qualitative Disclosures about Market Risk—Foreign Exchange Risk." We have no derivative financial instruments to hedge interest rate and foreign currency risk.

Income Tax

We have a history of losses. We expect to continue incurring losses as we continue to invest in our clinical and pre-clinical development programs and our discovery platform, and as we prepare for the potential future commercial launch of one or more of our product candidates, if approved. Consequently, we do not have any deferred tax asset on our consolidated statement of financial position.

Critical Accounting Policies and Significant Judgments and Estimates

In the application of our accounting policies, we are required to make judgments, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period or in the period of the revision and future periods if the revision affects both current and future periods.

The following elements are areas where key assumptions concerning the future, and other key sources of estimation uncertainty at the end of the reporting period, have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year.

Critical Judgements in Applying Accounting Policies

Revenue Recognition

Revenue from certain arrangements is recognized as the Group satisfies a single performance obligation. The Group recognizes upfront payments and milestone payments, allocated to a single performance obligation over the estimated service period based on a pattern that reflects the transfer of the services. The revenue recognized would reflect the level of service during each period. In this case, the Group would use an input model that considers estimates of the percentage of total research and development service costs that are completed each period compared to the total estimated service costs (percentage of completion method). Research and development service fees are recognized as revenue when costs are incurred and agreed by the parties, as the Group is acting as a principal in the scope of its stake in the research and development activities of its ongoing license and collaboration agreements.

Research and Development Cost Accruals

Research and development costs are charged to expense as incurred and are typically made up of payroll costs, clinical and preclinical activities, drug development and manufacturing costs, including costs for clinical research organizations and investigative sites. Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as information provided by vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid expenses.

Critical Accounting Estimates

Going Concern

The Group has incurred net losses since its inception, and for the year ended December 31, 2018, its consolidated statement of profit and loss and other comprehensive income reflects a net loss, and its consolidated statement of financial position includes a loss carried forward. On March 26, 2019, the Board has reviewed and approved the consolidated financial statements and accounting policies. Taking into account the cash and cash equivalents and current financial asset position of €564.6 million on December 31, 2018, the Board is of the opinion that the Group is operating on a going concern basis.

Measurement of Share-Based Payments

We determine the costs of the share-based payment plan (*i.e.*, our stock option plan) on the basis of the fair value of the equity instrument at grant date in accordance with IFRS 2. For the determination of the fair value we are using the Black Scholes pricing model. This requires the input into the valuation model of amounts that require judgment, like the estimated useful life of the stock options and the volatility of our stock (see also note 4.9 of our consolidated financial statements). Once calculated, the fair value of the stock options granted is recognized as an expense over the service period in our consolidated statement of comprehensive income and not re-measured subsequently.

In accordance with the terms of our stock option plan, as approved by our shareholders, our employees, certain of our consultants and our directors may be granted options to purchase ordinary shares at an exercise price per ordinary share equal to the average of the closing share prices of the last 30 calendar days preceding the date of the grant by the board of directors. Each stock option converts into one ordinary share upon exercise. No amounts are paid or payable by the beneficiary upon receipt of the option. The stock options carry neither rights to dividends nor voting rights. Stock options may be exercised at any time from the date of vesting to the date of their expiry.

The stock options generally vest as follows:

- one third of the stock options vest on the first anniversary of the grant date, and
- one twenty-fourth of the remaining two thirds of the stock options vest on the last day of each of the 24 months following the month of the first anniversary of the grant date.

In addition to the above, the stock options are subject to the terms and conditions of the argenx Employee Stock Option Plan.

On December 31, 2018, the total number of stock options outstanding was 3,536,651, compared to 2,862,216 on December 31, 2017. For the year ended December 31, 2018, no stock options had expired, a total of 319,671 stock options had been exercised and 46,369 stock options had been forfeited.

	Stock options granted in	
	June 2018	December 2018
Number of options granted	178,900	861,575
Average fair value of options	€ 32.12	€ 44.49
Share price	€ 72.00	€ 82.20
Exercise price	€ 80.82	€ 86.32
Expected volatility	45.50 %	46.19 %
Average expected option life (in years)	7.36	10 (1)
Risk-free interest rate	0.72 %	0.77 %
Expected dividends	— %	— %

- (1) The beneficiary can choose between a contractual term of five or ten years. The average expected option life for the December 2018 stock option grant is currently estimated at ten years. This estimate will be reassessed once the acceptance period of 60 days has passed and the beneficiaries will have made a choice between a contractual term of five or ten years. The total fair value of the grant would range from €27.7 million (100% of the stock options at an expected option life of five years) to €38.3 million (100% of the stock options at an expected option life of ten years).

	Stock options granted in	
	June 2017	December 2017
Number of options granted	120,536	653,825
Average fair value of options	€ 7.90	€ 37.10
Share price	€ 17.76	€ 53.50
Exercise price	€ 18.41	€ 21.17
Expected volatility	36.6 %	36.1 %
Average expected option life (in years)	10	10
Risk-free interest rate	0.61 %	0.53 %
Expected dividends	— %	— %

The grant date fair value of the options in the above table is estimated using the following assumptions:

- The expected volatility corresponds to the calculated annual volatility of our shares since our initial public offering on Euronext Brussels on July 10, 2014 until the date of grant of the options.
- The average expected option life is currently the contractual option term of 5 or 10 years.
- Risk-free interest rate equals the Belgium 10-Year Bond Yield at the date of grant.
- Expected dividends is considered 0% as we have no plan for distributing dividends and have no history of distributing dividends to shareholders.

The total share-based payment expense recognized in the consolidated statement of profit and loss and other comprehensive income was €19.2 million for the year ended December 31, 2018 and €4.3 million for the year ended December 31, 2017.

Recognition of Deferred Tax Assets and Liabilities

We are subject to income taxes in the Netherlands, in Belgium and in the United States. Significant judgment is required in determining the use of net loss carry-forwards and taxation of upfront and milestone payments for income tax purposes. There are many transactions and calculations for which the ultimate tax determination is uncertain. Where the final tax outcome of these matters is different from the amounts that were initially recorded, such differences will impact the current and deferred income tax assets and liabilities in the period in which such determination is made.

We had consolidated tax loss carry forwards of €117.1 million as of December 31, 2018 and €113.6 million as of December 31, 2017.

Deferred income tax assets are recognized for tax losses and other temporary differences to the extent that the realization of the related tax benefit through future taxable profits is probable. We recognize deferred tax assets arising from unused tax losses or tax credits only to the extent the relevant fiscal unity has sufficient taxable temporary differences or if there is convincing other evidence that sufficient taxable profit will be available against which the unused tax losses or unused tax credits can be utilized by the fiscal unity. Our judgment is that sufficient convincing other evidence is not available and therefore, a deferred tax asset is not recognized.

Results of Operation

Comparison of Years Ended December 31, 2018 and 2017

	Year ended December 31,		
	2018	2017	% Change
	(In thousands)		
Revenue	€ 21,482	€ 36,415	(41)%
Other operating income	7,749	4,841	60 %
Total operating income	29,231	41,256	(29)%
Research and development expenses	(83,609)	(51,740)	62 %
Selling, general and administrative expenses	(27,471)	(12,448)	121 %
Operating loss	(81,849)	(22,932)	257 %
Financial income	3,694	1,250	195 %
Exchange gains (losses)	12,308	(5,797)	(312)%
Loss before taxes	€ (65,847)	€ (27,479)	140 %
Income tax expense	(794)	(597)	33 %
Loss for the period and total comprehensive loss	€ (66,641)	€ (28,076)	137 %
Weighted average number of shares outstanding	33,419,356	24,609,536	
Basic and diluted loss per share (in €)	(1.99)	(1.14)	

Revenue

	Year ended December 31,		
	2018	2017	% Change
	(In thousands)		
Upfront payments	€ 8,635	€ 20,137	(57)%
Milestone payments	11,440	9,677	18 %
Research and development service fees	1,407	6,601	(79)%
Total	€ 21,482	€ 36,415	(41)%

Our revenue decreased by €14.9 million for the year ended December 31, 2018 to €21.5 million, compared to €36.4 million for the year ended December 31, 2017, primarily related to a €11.5 million decrease in revenue recognized from upfront payments.

The decrease of €11.5 million in upfront payments for the year ended December 31, 2018, compared to the year ended December 31, 2017, was primarily due to the completion in 2018 of the preclinical activities under our collaborations with LEO Pharma and AbbVie.

The milestone payments recognized for the year ended December 31, 2018 and for the year ended December 31, 2017 related to payments received under the AbbVie and LEO Pharma collaborations. On January 1, 2018, the Company adopted IFRS 15, resulting in the reversal of €2.7 million of revenue related to milestone payments that were previously recognized under IAS 18. We refer to note 5.1 of the consolidated financial statements for additional information on the impact of the adoption of IFRS 15.

Both the upfront payments and milestone payments are recognized as revenue over the estimated period of the Company's continuing involvement in the research and development activities provided for under the terms of these agreements.

The decrease of €5.2 million in research and development service fees for the year ended December 31, 2018, compared to the year ended December 31, 2017, is primarily linked with the completion of the preclinical activities under our collaboration agreements with LEO Pharma and Shire in the first half of the year.

Other Operating Income

	Year ended December 31,		
	2018	2017	% Change
	(In thousands)		
Government grants	€ 1,842	€ 422	337 %
Research and development incentives	2,151	983	119 %
Payroll tax rebates	3,756	3,436	9 %
Total	€ 7,749	€ 4,841	60 %

Other operating income increased by €2.9 million for the year ended December 31, 2018 to €7.7 million, compared to €4.8 million for the year ended December 31, 2017. In April and September 2018, we received two new grants from The Flanders Innovation and Entrepreneurship Agency (VLAIO), which resulted in an increase of €1.4 million in government grant income in 2018. For the year ended December 31, 2018, we accrued research and development incentives income of €2.2 million, compared to €1.0 million for the year ended December 31, 2017, corresponding to Belgian research and development incentives with regard to incurred research and development expenses, which will be paid to us in cash after a five-year period, if not offset against the taxable basis over the respective period. The increase in research and development incentives income is due to an extension of the scope, which allows us to take more research and development expenses in consideration for the calculation of the incentive. We accounted for €3.8 million of payroll tax rebates in the year ended December 31, 2018, compared to €3.4 million in the year ended December 31, 2017, for employing certain research and development personnel.

For more information regarding governmental policies that could affect our operations, see “Item 4.B.—Business Overview—Government Regulation.”

Research and Development Expenses

	Year ended December 31,		
	2018	2017	% Change
	(In thousands)		
Personnel expense	€ 26,519	€ 16,473	61 %
External research and development expenses	48,859	27,893	75 %
Materials and consumables	1,464	1,562	(6)%
Depreciation and amortization	494	446	11 %
Other expenses	6,273	5,366	17 %
Total	€ 83,609	€ 51,740	62 %

Our research and development expenses totaled €83.6 million and €51.7 million for the years ended December 31, 2018 and 2017 respectively, primarily as a result of higher external research and development expenses and personnel expenses. The increase of €10.0 million in personnel expense for the year ended December 31, 2018 corresponded principally to (i) an increase of €7.1 million for share-based compensation expenses related to the grant of stock options to our research and development employees and (ii) increased costs associated with additional research and development personnel. We employed 75 employees in our research and development functions on December 31, 2018, compared to 58 employees on December 31, 2017.

Our external research and development expenses for the year ended December 31, 2018 totaled €48.9 million, compared to €27.9 million for the year ended December 31, 2017, reflecting higher clinical trial costs and manufacturing expenses related to the development of our product candidate portfolio. The table below provides additional detail on our external research and development expenses by program:

	Year ended December 31,		
	2018	2017	% Change
	(In thousands)		
efgartigimod	€ 30,944	€ 12,382	150 %
cusatuzumab	9,289	3,144	195 %
Other programs	8,626	12,367	(30)%
Total	€ 48,859	€ 27,893	75 %

External research and development expenses for our lead product candidate efgartigimod totaled €30.9 million for the year ended December 31, 2018, compared to €12.4 million for the year ended December 31, 2017. This increase of €18.5 million of external research and development expenses in 2018 corresponded primarily to increased manufacturing and clinical development activities in relation to the preparation for and initiation of two Phase 3 clinical trials in MG.

External research and development expenses for cusatuzumab totaled €9.3 million for the year ended on December 31, 2018 compared to €3.1 million for the year ended December 31, 2017. This increase of €6.1 million in 2018 resulted principally from increased manufacturing and clinical development activities in relation to the advancement of the Phase 1/2 clinical trial in patients with AML or high-risk MDS.

External research and development expenses on other programs decreased by €3.7 million to €8.6 million for the year ended December 31, 2018, compared to €12.4 million for the year ended December 31, 2017. This decrease was primarily due to the decreased external research and development expenses following the completion of the preclinical work under our collaboration agreements with LEO Pharma and AbbVie.

Selling, General and Administrative Expenses

	Year ended December 31,		
	2018	2017	% Change
	(In thousands)		
Personnel expense	€ 18,292	€ 6,745	171 %
Consulting fees	5,472	3,289	66 %
Supervisory board	1,088	621	75 %
Office costs	2,619	1,793	46 %
Total	€ 27,471	€ 12,448	121 %

Our selling, general and administrative expenses totaled €27.5 million and €12.4 million for the years ended December 31, 2018 and 2017, respectively. The increase of €15.1 million in our selling, general and administrative expenses for the year ended December 31, 2018 was principally due to:

- an increase of €11.5 million of personnel expenses resulting from (i) €8.0 million of increased costs of the share-based payment compensation plans related to the grant of stock options to our general and administrative employees, (ii) increased costs associated with additional employees recruited to strengthen our selling, general and administrative activities and from increases in our executive management's compensation.
- an increase of €2.2 million in consulting fees primarily related to costs for the preparation of a possible future commercialization of our lead product candidate efgartigimod.

- an increase of €0.5 million of our supervisory board expenses primarily due to increased costs for the share-based payment compensation plans related to the grant of stock options to the members of the board of directors.

On December 31, 2018, we employed 30 employees in our selling, general and administrative functions, compared to 15 employees on December 31, 2017.

Financial Income (Expense)

For the year ended December 31, 2018, financial income amounted to €3.7 million compared to €1.3 million for the year ended December 31, 2017. The increase of €2.4 million in 2018 related primarily to an increase in the interest received on our cash, cash equivalents and current financial assets.

Exchange Gains (Losses)

Exchange gains totaled €12.3 million for the year ended December 31, 2018. The increase was mainly attributable to unrealized exchange rate gains on our cash and current financial assets position in U.S. dollars due to the favorable fluctuation of the EUR/USD exchange rate in 2018.

Comparison of Years Ended December 31, 2017 and 2016

	Year ended December 31,		
	2017	2016	% Change
	(In thousands)		
Revenue	€ 36,415	€ 14,713	148 %
Other operating income	4,841	2,439	98 %
Total operating income	41,256	17,152	141 %
Research and development expenses	(51,740)	(31,557)	64 %
Selling, general and administrative expenses	(12,448)	(7,011)	78 %
Operating loss	(22,932)	(21,416)	7 %
Financial income	1,250	73	1,612 %
Exchange gains (losses)	(5,797)	(31)	18,600 %
Loss before taxes	€ (27,479)	€ (21,374)	29 %
Income tax income/(expense)	(597)	—	%
Loss for the period and total comprehensive loss	€ (28,076)	€ (21,374)	31 %
Weighted average number of shares outstanding	24,609,536	18,820,612	
Basic and diluted loss per share (in €)	(1.14)	(1.14)	

Revenue

	Year ended December 31,		
	2017	2016	% Change
	(In thousands)		
Upfront payments	€ 20,137	€ 9,103	121 %
Milestone payments	9,677	500	1,835 %
Research and development service fees	6,601	5,110	29 %
Total	€ 36,415	€ 14,713	148 %

Our revenue increased by €21.7 million for the year ended December 31, 2017 to reach €36.4 million, compared to €14.7 million for the year ended December 31, 2016, primarily related to a €11.0 million increase in upfront payments and a €9.2 million increase in milestone payments.

The increase of €11.0 million in upfront payments for the year ended December 31, 2017 compared to the year ended December 31, 2016 corresponded principally to the payments received in connection with entering into the collaboration agreements with LEO Pharma in May 2015 and with AbbVie in April 2016. These upfront payments were recognized in revenue based on the progress of the research and development programs that are the subject of both collaborations.

The milestone payment recognized for the year ended December 31, 2017 related to payments received under the AbbVie and LEO Pharma collaborations. The milestone payments recognized for the year ended December 31, 2016 related to a payment received under the LEO Pharma collaboration. In 2016, no milestone payment was received from AbbVie.

The increase of €1.5 million in research and development service fees for the year ended December 31, 2017 compared to the year ended December 31, 2016 related to payments under the collaboration agreements with LEO Pharma and Shire.

Other Operating Income

	Year ended December 31,		
	2017	2016	% Change
	(In thousands)		
Government grants	€ 422	€ 779	(46)%
Research and development incentives	983	641	53 %
Payroll tax rebates	3,436	1,019	237 %
Total	€ 4,841	€ 2,439	99 %

Other operating income increased by €2.4 million for the year ended December 31, 2017 to €4.8 million, compared to €2.4 million for the year ended December 31, 2016. For the year ended December 31, 2017, we accrued research and development incentives income of €1.0 million, compared to €0.6 million for the year ended December 31, 2016, corresponding to Belgian research and development incentives with regard to incurred research and development expenses which will be paid to us in cash after a five-year period, if not offset against the taxable basis over the respective period. We accounted for €3.4 million of payroll tax rebates in the year ended December 31, 2017, compared to €1.0 million in the year ended December 31, 2016, for employing certain research and development personnel.

For more information regarding governmental policies that could affect our operations, see “Item 4.B.—Business Overview—Government Regulation.”

Research and Development Expenses

	Year ended December 31,		
	2017	2016	% Change
	(In thousands)		
Personnel expense	€ 16,473	€ 9,844	67 %
External research and development expenses	27,893	17,562	59 %
Materials and consumables	1,562	1,180	32 %
Depreciation and amortization	446	335	33 %
Other expenses	5,366	2,636	104 %
Total	€ 51,740	€ 31,557	64 %

Our research and development expenses totaled €51.7 million and €31.6 million for the years ended December 31, 2017 and 2016, respectively, primarily as a result of higher external research and development expenses. The increase of €6.6 million in personnel expense for the year ended December 31, 2017 corresponded principally to (i) costs associated with additional research and development personnel and (ii) increased

share-based compensation expense related to the grant of stock options to our research and development employees (including an increase of €3.2 million of social security costs on stock options granted to certain Belgian and non-Belgian resident employees). We employed 58 employees in our research and development function on December 31, 2017, compared to 48 employees on December 31, 2016.

Our external research and development expenses for the year ended December 31, 2017 totaled €27.9 million, compared to €17.6 million for the year ended December 31, 2016, reflecting higher clinical trial costs and manufacturing expenses related to the development of our product candidate portfolio. The increase of €2.7 million in other expenses for the year ended December 31, 2017 corresponded to (i) €0.1 million for patent expenses related to the growth of our product candidate portfolio, (ii) €2.3 million for license fees we paid to one of our licensors as a result of the signing of the AbbVie agreement, and (iii) €0.3 million for expenses corresponding principally to travel expenses, clinical trial insurance premiums and recruitment fees for research and development employees. The table below provides additional detail on our external research and development expenses by program:

	Year ended December 31,		
	2017	2016	% Change
	(In thousands)		
efgartigimod	€ 12,382	€ 8,988	38 %
cusatuzumab	3,144	2,914	8 %
Other programs	12,367	5,660	118 %
Total	€ 27,893	€ 17,562	59 %

External research and development expenses for our lead product candidate efgartigimod totaled €12.4 million for the year ended December 31, 2017, compared to €9.0 million for the year ended December 31, 2016. The increase of €3.4 million of external research and development expenses for the year ended December 31, 2017 for efgartigimod corresponded to increased manufacturing and clinical development activities in relation to (i) the advancement of the Phase 2 clinical trials for MG and ITP, (ii) the preparation for and initiation of the Phase 2 clinical trial for PV, and (iii) the Phase 1 clinical trial in healthy volunteers for a subcutaneous formulation.

External research and development expenses for cusatuzumab totaled €3.1 million for the year ended on December 31, 2017, compared to €2.9 million for the year ended December 31, 2016. This increase of €0.2 million related principally to the progression of the Phase 1/2 clinical trial in patients with AML or high-risk MDS.

External research and development expenses on other programs increased by €6.7 million to €12.4 million for the year ended December 31, 2017, compared to €5.7 million for the year ended December 31, 2016. This increase was primarily due to external research and development expenses incurred under our collaboration agreements with LEO Pharma and AbbVie.

Selling, General and Administrative Expenses

	Year ended December 31,		
	2017	2016	% Change
	(In thousands)		
Personnel expense	€ 6,745	€ 3,256	107 %
Consulting fees	3,289	2,563	28 %
Supervisory board	621	446	39 %
Office costs	1,793	746	140 %
Total	€ 12,448	€ 7,011	78 %

Our selling, general and administrative expenses totaled €12.4 million and €7.0 million for the years ended December 31, 2017 and 2016, respectively. The increase of €5.4 million in our selling, general and administrative expenses for the year ended December 31, 2017 was principally due to:

- an increase of €3.5 million of personnel expenses resulting from (i) €2.3 million of increased costs of the share-based payment compensation plans related to the grant of stock options to our selling, general and administrative employees (including an increase of €2.1 million of social security costs on stock options granted to certain Belgian and non-Belgian resident employees), (ii) €1.1 million from the costs of additional employees recruited to strengthen our general and administrative activities and from increases in our executive management's compensation, and (iii) €0.1 million of car lease costs;
- an increase of €0.7 million of consulting fees related to investor relations, business development, IT, legal, commercial and audit activities;
- an increase of €0.2 million of supervisory board expenses due to increases in the remuneration and travel expenses of the non-executive members of our board of directors; and
- an increase of €1.0 million of office costs due to increased operation lease expenses for our offices and laboratory facilities, increased travel expenses and additional costs related to operating as a public company on Nasdaq and Euronext.

On December 31, 2017, we employed 15 employees in our selling, general and administration function, compared to 10 employees on December 31, 2016.

Financial Income (Expense)

For the year ended December 31, 2017, financial income amounted to €1.3 million compared to €0.1 million for the year ended December 31, 2016. The increase of €1.1 million relates to (i) a €0.9 million realized gain on the sale of a participation in FairJourney Biologics LDA in December 2017 and (ii) an increase in the interest received on our cash, cash equivalents and current financial assets.

Exchange Gains (Losses)

Exchange losses totaled €5.8 million for the year ended December 31, 2017. The increase is mainly attributable to unrealized exchange rate losses on our cash and current financial assets position in U.S. dollars due to the unfavorable fluctuation of the EUR/USD exchange rate.

B. LIQUIDITY AND CAPITAL RESOURCES

Sources of Funds

Since our inception in 2008, we have invested most of our resources to developing our product candidates, building our intellectual property portfolio, developing our supply chain, conducting business planning, raising capital and providing general and administrative support for these operations. We do not currently have any approved products and have never generated any revenue from product sales. To date, we have funded our operations through public and private placements of equity securities, upfront, milestone and expense reimbursement payments received from our collaborators, funding from governmental bodies and interest income from the investment of our cash, cash equivalents and financial assets. Through December 31, 2018, we have raised gross proceeds of €735.9 million from private and public offerings of equity securities, received €88.2 million in revenue from our collaborators, and €18.7 million in grants and incentives from governmental bodies.

Our cash flows may fluctuate and are difficult to forecast and will depend on many factors. On December 31, 2018, we had cash, cash equivalents and current financial assets of €564.6 million, compared to €359.8 million on December 31, 2017.

We have no ongoing material financing commitments, such as lines of credit or guarantees, that are expected to affect our liquidity over the next five years, other than operating leases.

For more information as to the risks associated with our future funding needs, see the section of this annual report titled “Item 3.D.—Risk Factors—Risks Related to Our Financial Position and Need for Additional Capital.”

For more information as to our financial instruments, please see “Note 6—Financial instruments and financial risk management—Overview of financial instruments” in our consolidated financial statements which are appended to our annual report for the period ended December 31, 2018 and which are incorporated herein by reference.

Cash Flows

Comparison for the Years Ended December 31, 2018 and 2017

The table below summarizes our cash flows for the years ended December 31, 2018 and 2017.

	Year ended December 31,		
	2018	2017	Variance
	(In thousands)		
Cash and cash equivalents at beginning of the period	€ 190,867	€ 89,897	€ 100,970
Net cash flows (used in) / from operating activities	(53,839)	(36,546)	(17,293)
Net cash flows (used in) / from investing activities	(107,542)	(162,052)	54,510
Net cash flows (used in) / from financing activities	244,671	305,365	(60,694)
Effect of exchange rate differences on cash and cash equivalents	6,883	(5,797)	12,680
Cash and cash equivalents at end of the period	€ 281,040	€ 190,867	€ 90,173

Net Cash Used in Operating Activities

Net cash outflow from our operating activities increased by €17.3 million to a net outflow of €53.8 million for the year ended December 31, 2018, compared to a net outflow of €36.5 million for the year ended December 31, 2017. The increased cash used in operating activities for the years ended December 31, 2018 and December 31, 2017 resulted primarily from increased research and development expenses in relation to the manufacturing and clinical development activities of efgartigimod and cusatuzumab and the advancement of other preclinical and discovery-stage product candidates.

Net Cash Used in Investing Activities

Investing activities consist primarily of the acquisition of current financial assets, purchase of laboratory equipment and interest received from the placements of our cash and cash equivalents and current financial assets. Cash flow used in investing activities represented a net outflow of €107.5 million for the year ended December 31, 2018, compared to a net outflow of €162.1 million for the year ended December 31, 2017. The net outflow for the year ended December 31, 2018 related to (i) the investment of €114.6 million in current financial assets, including money market funds and U.S. dollar term deposit accounts, (ii) the purchase of €0.7 million of office, information technology and laboratory equipment, and less (iii) €3.7 million interest received from the placements of our cash, cash equivalents and current financial assets. The net outflow for the year ended December 31, 2017 related to (i) the acquisition of €162.1 million of current financial assets, including money market funds and a U.S. dollar term deposit account, (ii) the purchase of €0.3 million of office, information technology and laboratory equipment, and

less (iii) €0.4 million interest received from the placements of our cash, cash equivalents and current financial assets.

Net Cash Provided by Financing Activities

Financing activities consist of net proceeds from our private placements and public offerings of our securities and exercise of stock options. The net cash inflow from financing activities was €244.7 million for the year ended December 31, 2018, compared to a net cash inflow of €305.4 million for the year ended December 31, 2017. The net cash inflow for the year ended December 31, 2018 was attributed to (i) €241.1 million net cash proceeds of our follow-on U.S. public offering of ADSs on the Nasdaq Global Select Market in September 2018 (based on the exchange rate in effect of the date the proceeds were received) and (ii) €2.3 million proceeds received from the exercise of stock options in 2018. The net cash inflow for the year ended December 31, 2017 was attributed to (i) €93.2 million net cash proceeds from our initial U.S. public offering of ADSs on the Nasdaq Global Select Market in May 2017 (based on the exchange rate in effect of the date the proceeds were received), (ii) €211.5 million net cash proceeds of our follow on offering of ADSs on the Nasdaq Global Select Market in December 2017 (based on the exchange rate in effect of the date the proceeds were received) and (iii) €0.7 million proceeds received from the exercise of stock options in 2017.

Comparison for the Years Ended December 31, 2017 and 2016

The table below summarizes our cash flows for the years ended December 31, 2017 and 2016.

	Year ended December 31,		
	2017	2016	Variance
	(In thousands)		
Cash and cash equivalents at beginning of the period	€ 89,897	€ 35,514	€ 54,383
Net cash flows (used in) / from operating activities	(36,546)	10,599	(47,145)
Net cash flows (used in) / from investing activities	(162,052)	(806)	(161,246)
Net cash flows (used in) / from financing activities	305,365	44,621	260,744
Effect of exchange rate differences on cash and cash equivalents	(5,797)	(31)	(5,766)
Cash and cash equivalents at end of the period	€ 190,867	€ 89,897	€ 100,970

Net Cash Used in Operating Activities

Net cash outflow from our operating activities increased by €48.1 million to a net outflow of €36.5 million for the year ended December 31, 2017, compared to a net inflow of €10.6 million for the year ended December 31, 2016. The increased cash used in operating activities for the year ended December 31, 2017 resulted primarily from increased research and development expenses in relation to the manufacturing and clinical development activities of efgartigimod and cusatuzumab and the advancement of other preclinical and discovery-stage product candidates (including external research and development expenses incurred under the LEO Pharma and AbbVie collaborations). The net cash inflow for the year ended December 31, 2016 is related to the upfront payment of \$40 million (€35.1 million based on the exchange rate in effect as of the date the payment was received) received from AbbVie in April 2016.

Net Cash Used in Investing Activities

Investing activities consist primarily of the acquisition of current financial assets, purchase of laboratory equipment and interest received from the placements of our cash and cash equivalents and current financial assets. Cash flow used in investing activities represented a net outflow of €162.1 million for the year ended December 31, 2017, compared to a net outflow of €0.8 million for the year ended December 31, 2016. The net outflow for the year ended December 31, 2017 related to (i) the acquisition of €162.1 million of current financial assets, including money market funds and a U.S. dollar term deposit account, (ii) the purchase of € 0.3 million of office, information technology and laboratory equipment, and less (iii) € 0.4 million interest received from the placements of our cash,

cash equivalents and current financial assets. The net outflow for the year ended December 31, 2016 related to €0.7 million to purchase office and laboratory equipment and €0.1 million to purchase information technology equipment.

Net Cash Provided by Financing Activities

Financing activities consist of net proceeds from our private placements and public offerings of our securities and exercise of stock options. The net cash inflow from financing activities was €305.4 million for the year ended December 31, 2017, compared to a net cash inflow of €44.6 million for the year ended December 31, 2016. The net cash inflow for the year ended December 31, 2017 was attributed to (i) €93.2 million net cash proceeds from our initial U.S. public offering of ADSs on the Nasdaq Global Select Market in May 2017 (based on the exchange rate in effect of the date the proceeds were received), (ii) €211.5 million net cash proceeds of our follow-on U.S. public offering of ADSs on the Nasdaq Global Select Market in December 2017 (based on the exchange rate in effect of the date the proceeds were received) and (iii) €0.7 million proceeds received from the exercise of stock options. The net cash inflow for the year ended December 31, 2016 was attributed to two private placements of our ordinary shares issued to institutional investors in January and June 2016 for total gross proceeds of €46.0 million.

Operating and Capital Expenditure Requirements

We have never achieved profitability and, as of December 31, 2018, we had accumulated losses of €169.6 million. We expect to continue to incur significant operating losses for the foreseeable future as we continue our research and development efforts and seek to obtain regulatory approval and commercialization of our product candidates.

On the basis of current assumptions, we expect that our existing cash and cash equivalents and current financial assets will enable us to fund our operating expenses and capital expenditure requirements through at least the next 12 months. Because of the numerous risks and uncertainties associated with the development of efgartigimod, cusatuzumab and our other product candidates and discovery stage programs and because the extent to which we may enter into collaborations with third parties for the development of these product candidates is unknown, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates. Our future capital requirements for efgartigimod, cusatuzumab and our other product candidates and discovery stage programs will depend on many factors, including:

- the progress, timing and completion of preclinical testing and clinical trials for our current or any future product candidates;
- the number of potential new product candidates we identify and decide to develop;
- the costs involved in growing our organization to the size needed to allow for the research, development and potential commercialization of our current or any future product candidates;
- the costs involved in filing patent applications and maintaining and enforcing patents or defending against claims or infringements raised by third parties;
- the maintenance of our existing collaboration agreements and entry into new collaboration agreements;
- the time and costs involved in obtaining regulatory approval for our product candidates and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to any of our product candidates;

- selling and marketing activities undertaken in connection with the potential commercialization of our current or any future product candidates, if approved, and costs involved in the creation of an effective sales and marketing organization; and
- the amount of revenues, if any, we may derive either directly or in the form of royalty payments from future sales of our product candidates, if approved.

For more information as to the risks associated with our future funding needs, see the section of this annual report titled “Item 3.D.—Risk Factors—Risks Related to Our Financial Position and Need for Additional Capital.”

C. RESEARCH AND DEVELOPMENT, PATENTS AND LICENSES

For a discussion of our research and development activities, see the sections of this annual report titled “Item 4.B.—Business Overview” and “Item 5.A.—Operating Results.”

D. TREND INFORMATION

Other than as disclosed elsewhere in this annual report, we are not aware of any trends, uncertainties, demands, commitments or events for the period from January 1, 2018 to December 31, 2018 that are reasonably likely to have a material effect on our net revenues, income, profitability, liquidity or capital resources, or that caused the disclosed financial information to be not necessarily indicative of future operating results or financial conditions. For a discussion of trends, see the sections of this annual report titled “Item 4.B.—Business Overview,” “Item 5.A.—Operating Results,” and “Item 5.B.—Liquidity and Capital Resources.”

E. OFF-BALANCE SHEET ARRANGEMENTS

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC, such as relationships with unconsolidated entities or financial partnerships, which are often referred to as structured finance or special purpose entities, established for the purpose of facilitating financing transactions that are not required to be reflected on our balance sheets.

F. TABULAR DISCLOSURE OF CONTRACTUAL OBLIGATIONS

The table below summarizes our contractual obligations at December 31, 2018.

	Total	Payments due by period			
		Less than 1 year	1–3 years	3–5 years	More than 5 years
		(In thousands)			
Operating lease commitments	€ 3,004	€ 1,028	€ 1,766	€ 210	€ —
Purchase obligation	€ 46,626	€ 13,610	€ 23,179	€ 6,148	€ 3,689

We signed a lease agreement effective April 2016 for laboratory and office space in Zwijnaarde, Belgium. This lease agreement is for a period of nine years starting from April 1, 2016, with the possibility to terminate the lease by giving a notice of at least 12 months in advance at the occasion of the third and sixth anniversary of the agreement. Our operating lease commitments include a lease plan for company cars with maturity dates up to four years.

For our office in the Netherlands, we have a lease agreement renewable on an annual basis. For our office in Boston, Massachusetts, we have a lease agreement renewable on an annual basis.

The purchase obligation described above relates to contractual obligations with our manufacturing contractor, Lonza Sales AG.

The commitment amounts in the table above are associated with contracts that are enforceable and legally binding and that specify all significant terms, including fixed or minimum services to be used, fixed, minimum or variable price provisions and the approximate timing of the actions under the contracts. The table does not include obligations under agreements that we can cancel without a significant penalty.

We have received various governmental grants that may need to be repaid if certain conditions related to these grants are not met. We believe that it is uncertain whether we will be required to repay these grants and, accordingly, have not included them in the table above.

Our manufacturing commitments with our drug substance manufacturing contractor Lonza relate to the ongoing execution of the BLA services for efgartigimod and the ongoing manufacturing activities related to the start-up of Lonza Singapore as a potential future commercial manufacturing site. In December 2018, we signed our first commercial supply agreement with Lonza related to the reservation of commercial drug substance supply capacity for efgartigimod. The total commitment under this commercial supply agreement amounts to a minimum commitment of £25.3 million over a period of five years starting from 2020. In the aggregate, we have outstanding commitments for efgartigimod of approximately €42.2 million. In addition to the obligations for efgartigimod, we also have contractual obligations for cusatuzumab of approximately €4.5 million starting from 2019.

G. SAFE HARBOR

This annual report contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act and as defined in the Private Securities Litigation Reform Act of 1995. See “Cautionary Statement with Respect to Forward Looking Statements” at the beginning of this annual report.

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. DIRECTORS AND SENIOR MANAGEMENT

Our Board of Directors

We have a one-tier board structure consisting of an executive director who is responsible for our day-to-day management and non-executive directors who are responsible for the supervision of the executive directors. Our executive directors and our non-executive directors are collectively responsible for our general affairs. We may be represented by our board of directors or by two executive directors acting jointly. Our board of directors is currently comprised of one executive director and six non-executive directors, who we refer to individually as a director. Less than a majority of the directors of our board of directors are citizens or residents of the United States.

The following table sets forth certain information with respect to the current members of our board of directors, including their ages as of December 31, 2018:

Name	Age	Position	Nationality	Date of appointment	Term expiration
Tim Van Hauwermeiren	46	Executive Director (Chief Executive Officer)	BE	May 8, 2018	2022
Peter K.M. Verhaeghe	60	Non-Executive Director (chairperson)	BE	May 8, 2018	2022
David L. Lacey	66	Non-Executive Director	US	May 8, 2018	2022
Werner Lanthaler	50	Non-Executive Director (vice chairperson)	AT	May 8, 2018	2022
J. Donald deBethizy	68	Non-Executive Director	US	May 13, 2015	2019
Pamela Klein	57	Non-Executive Director	US	April 28, 2016	2020
A.A. Rosenberg	65	Non-Executive Director	UK	April 26, 2017	2021
James M. Daly	57	Non-Executive Director	US	May 8, 2018	2022

The address for our directors is our registered office, Willemstraat 5, 4811 AH, Breda, the Netherlands.

Donald deBethizy is expected to be nominated for re-appointment at the General Meeting to be held in 2019.

Our board of directors has determined that all of the non-executive members of the board of directors are independent under the Nasdaq's listing requirements and that all of the non-executive members of the board of directors are independent under the Dutch Corporate Governance Code, or DCGC.

The following is the biographical information of the members of our board of directors:

Tim Van Hauwermeiren co-founded our company in 2008 and has served as our Chief Executive Officer since July 2008. He has served as a member of our board of directors since July 2014. Mr. Van Hauwermeiren has more than 20 years of general management and business development experience across the life sciences and consumer goods sectors. Mr. Van Hauwermeiren holds a B.Sc. and M.Sc. in bioengineering from Ghent University (Belgium) and an Executive MBA from The Vlerick School of Management.

Peter K.M. Verhaeghe has served as a member and chairperson of our board of directors since July 2014. Mr. Verhaeghe is the managing partner of VVGB Advocaten—Avocats, a corporate finance law and tax law firm, a position he has held since July 1999. He is currently lead counsel to a number of Belgian, Dutch and Swiss biotechnology and diagnostics companies. Mr. Verhaeghe served as the president of the board of directors of Merisant France SAS, as a member of the management board of Merisant Company 2 sàrl and serves as a member of the board of directors of CzechPak Manufacturing s.r.o. He previously served as the chairman of the board of directors of PharmaNeuroBoost NV from December 2006 to January 2013 and as liquidator in charge of KBC Private Equity Fund Biotech NV from April 2009 to December 2012. Mr. Verhaeghe holds a degree in law from the University of Leuven and an LL.M. degree from Harvard Law School.

Dr. David L. Lacey has served as a member of our board of directors since July 2014. Dr. Lacey is a biopharmaceutical consultant at David L. Lacey LLC, where he advises academic institutions, biotechnology companies and venture capital firms, a position he has held since July 2011. He currently serves as a director of Inbiomotion SL, Atreca, Inc. and Nurix, Inc. From 1994 until his retirement in 2011, he held various positions, including head of discovery research, at Amgen Inc., where he played a fundamental scientific role in the discovery of the OPG/RANKL/RANK pathway, which led to the development of the anti-RANKL human mAb denosumab, for both osteoporosis (Prolia) and cancer-related bone diseases (XGEVA). He holds a Bachelor's degree in biology and an M.D. from the University of Colorado, and has his board certification in anatomic pathology.

Dr. Werner Lanthaler has served as a member of our board of directors since July 2014. Dr. Lanthaler is the chief executive officer of Evotec AG, a global drug discovery research organization, a position he has held since March 2009. Dr. Lanthaler previously served on the supervisory boards of Bioxell SpA and Pantec Biosolutions AG. Dr. Lanthaler holds a degree in psychology, a Ph.D. in business administration from Vienna University of Economics and Business and a Master's degree in public administration from Harvard University.

Dr. J. Donald deBethizy has served as a member of our board of directors since May 2015. Dr. deBethizy has 30 years of experience in research and development and financial, business and operating management in the biotechnology and consumer products industry. He is the president of White City Consulting ApS. Previously, Dr. deBethizy served as president and chief executive officer of Santaris Pharma A/S until October 2014, when the company was sold to Roche. From August 2000 to June 2012, Dr. deBethizy was co-founder and chief executive officer of Targacept, Inc., a U.S. biotechnology company listed on Nasdaq. He currently serves on the supervisory boards of Albumedix A/S, Newron Pharmaceuticals SpA, Noxxon Pharma NV and AG, Rigontec GmbH and Proterris, Inc. From May 2013 to November 2014, he served as executive chairman of Contera Pharma ApS. He previously served on the boards of Asceneuron SA, Serendex Pharmaceuticals A/S, Enbiotix Inc., Targacept Inc. and Biosource Inc. Mr. deBethizy has held adjunct appointments at Wake Forest University Babcock School of Management, Wake Forest University School of Medicine and Duke University. Dr. deBethizy holds a B.Sc. in biology from the University of Maryland, and an M.Sc. and a Ph.D. in toxicology from Utah State University.

Dr. Pamela Klein has served as a member of our board of directors since April 2016. Dr. Klein is a principal and founder of PMK BioResearch, which offers strategic consulting in oncology drug development to corporate boards, management teams and the investment community, a position she has held since 2008. She currently serves as a member of various scientific advisor boards. Previously, Dr. Klein spent seven years at the National Cancer Institute as Research Director of the NCI-Navy Breast Center, after which she joined Genentech and was VP, Development until 2001. She served as Chief Medical Officer for Intellikine which was acquired by Takeda. She was previously Vice President, Development for Genentech. Dr. Klein holds a Bachelor's degree in biology from California State University and an M.D. from Stritch School of Medicine, Loyola University Chicago and is trained in internal medicine and medical oncology.

Msc. A.A. Rosenberg has served as a member of our board of directors since April 2017. He currently serves as CEO of TR Advisory Services GmbH, a consultancy firm advising on business development, licensing and mergers and acquisitions. Mr. Rosenberg has also been a Managing Director of MPM Capital, a venture capital firm, since April 2015. From January 2013 until February 2015, he served as Corporate Head of M&A and Licensing at Novartis Pharma. He served as Global Head of Business Development and Licensing at Novartis Pharma from March 2005 to December 2012. Msc. A.A. Rosenberg holds non-executive board memberships in Radius Health Inc., TriNetX, Inc., iOmx Therapeutics AG, Cullinan Oncology Inc. and Oculis SA. Msc. A.A. Rosenberg has a B.Sc. (Hons) from the University of Leicester and a M.Sc. Physiology from the University of London.

James M. Daly has served as a member of our board of directors since May 2018. He holds a Bachelor in Science and a Master in Business Administration from the State of New York University. He joined GlaxoSmithKline in 1985 where he held various positions, including Sr. Vice President – Respiratory Division with full responsibility for sales, marketing and medical affairs. He moved to Amgen in 2002 where he was Sr. Vice President for the North America Commercial Operations 2011. In 2012 he joined Incyte, a publicly traded company focused on oncology and inflammation, where he was chief commercial officer until June 2015. James Michael Daly currently serves as a director of Chimerix Inc, Acadia Pharmaceuticals, Coherus Biosciences, Halozyme Therapeutics and Bellicum Pharmaceuticals, all Nasdaq-listed companies.

Our Executive Management

The following table sets forth certain information with respect to the current members of our executive management, including their ages as of December 31, 2018:

Name	Age	Position	Nationality	Date of appointment
Tim Van Hauwermeiren	46	Chief Executive Officer and Executive Director	BE	July 15, 2008
Eric Castaldi	54	Chief Financial Officer	F	April 1, 2014
Keith Woods	51	Chief Operating Officer	US	April 5, 2018
Nicolas Leupin	45	Chief Medical Officer	CH	February 1, 2016
Hans de Haard	59	Chief Scientific Officer	NL	July 1, 2008
Torsten Dreier	54	Chief Development Officer	G	May 1, 2008
Debbie Allen	59	Senior VP Business Development	UK	November 1, 2010
Dirk Beeusaert	54	General Counsel	BE	April 1, 2017

The address for our executive management is Industriepark Zwijnaarde 7, Building C, 9052 Zwijnaarde (Ghent), Belgium.

The following is a brief summary of the biographical information of those members of our executive management who do not also serve on our board of directors:

Eric Castaldi has served as our Chief Financial Officer since April 2014 and served as a member of our board of directors from July 2014 to April 26, 2017. Mr. Castaldi has 28 years of international financial executive management experience, including 19 years in the biopharmaceutical industry. From 1998 to 2014, Mr. Castaldi served as chief financial officer and a member of the executive committee of Nicox SA, a Euronext-listed biotechnology company. From 2008 to 2012, he served as a member of the board of directors and as chairman of the audit committee of Hybrigenics Services SAS, a Euronext-listed French biopharmaceutical company specializing in oncology. Mr. Castaldi graduated with a degree in finance, accountancy and administration from the University of Nice.

Keith Woods has over 25 years of experience in the biopharmaceutical industry. He most recently served as Senior Vice President of North American Operations for Alexion Pharmaceuticals Inc. (Alexion), where he managed a team of several hundred people in the U.S. and Canada and was responsible for more than \$1 billion in annual sales. Within Alexion, he previously served as Vice President and Managing Director of Alexion UK, overseeing all aspects of Alexion's U.K. business; Vice President of U.S. Operations; and Executive Director of Sales, leading the launch of Soliris in atypical hemolytic uremic syndrome. Prior to joining Alexion, he held various positions of increasing responsibility within Roche, Amgen and Eisai over a span of 20 years. Keith Woods holds a B.S. in Marketing from Florida State University.

Dr. Nicolas Leupin has served as our Chief Medical Officer since February 2016. Dr. Leupin has clinical and industry expertise in medical oncology as well as experience in drug development. He currently lectures at the University of Bern. From 2008 to 2015, Dr. Leupin served in different positions in clinical development at Celgene, including Director of Clinical Development of EMEA Celgene, where he contributed to building the clinical development department in Europe and then led the European lymphoma and myeloma teams, served as clinical lead for several compounds up to phase III clinical trials, and was responsible for running and managing hematology and oncology clinical trials, including both industry-sponsored trials and academic cooperative groups, several of them through to registration. Among other activities, he was responsible for specific clinical documents of registration dossiers that lead to European and American registrations. Dr. Leupin holds an MBA from Jones International University and an M.D. from the University of Bern and was board certified in medical oncology (Switzerland).

Prof. Hans de Haard has served as our Chief Scientific Officer since July 2008. Prof. de Haard has been active in the antibody engineering field since 1989. He also serves as a Professor of Immunology at University of Franche Comté (France). Prof. de Haard holds an M.Sc. in biochemistry from the Higher Professional Education for Laboratory Technicians (Oss, the Netherlands) and a M.Sc. in chemistry from the Institute of Technology (Rotterdam, the Netherlands) and a Ph.D. in molecular immunology from Maastricht University.

Dr. Torsten Dreier has served as our Chief Development Officer since May 2008. Dr. Dreier has been developing antibodies for more than 20 years and led teams that progressed six antibody products from preclinical research into clinical trials. Dr. Dreier holds an M.Sc. and a Ph.D. in biochemistry from the University of Tübingen (Germany).

Dr. Debbie Allen has served as our Senior Vice President of Business Development since November 1, 2010. Dr. Allen has been active in the antibody engineering field since the 1980s. She has more than 30 years of corporate and business development experience with small and large biotech companies focused on biopharmaceuticals. Dr. Allen is an inventor of HUMIRA (adalimumab). Prior to joining us, Dr. Allen acted as an independent consultant to emerging biotech companies, providing strategic management and business development support. Dr. Allen holds an B.Sc. in cellular pathology from the University of Bristol and a Ph.D. in viral oncology from the University of London.

Dirk Beeusaert has served as our General Counsel since April 1, 2017. Mr. Beeusaert has extensive general experience in corporate governance and as general counsel of a listed company. Mr. Beeusaert worked in various roles from February 1996 to July 2016 for Gimv NV, a European private equity company listed on Euronext Brussels, including chief legal officer from January 2001 to 2006, and general counsel from 2006 to July 2016, where he was co-responsible for operations and corporate governance. Mr. Beeusaert currently serves as a member of the boards of directors of Pragma Capital SAS and Cubigo NV. Mr. Beeusaert holds a Bachelor in Law and a Master Law degree from Ghent University and an MBA in Fiscal Studies and Accounting Research, Tax and Accounting from Vlerick School of Management.

General Information About Our Directors and Executive Management

As of the date of this Annual Report, none of the members of our board of directors and executive management has a family relationship with any other member of our board of directors or executive management.

As of the date of this Annual Report and except as set out below, none of the members of our board of directors and executive management for at least the previous five years:

- has been convicted of any fraudulent offenses;
- has been a senior manager or a member of the administrative, management or supervisory bodies of any company at the time of or preceding any bankruptcy, receivership or liquidation;
- has been subject to any official public incrimination and/or sanction by any statutory or regulatory authority (including any designated professional body); or
- has ever been disqualified by a court from acting as a member of the administrative, management or supervisory bodies of any company or from acting in the management or conduct of affairs of any company.

Peter K.M. Verhaeghe—PharmaNeuroBoost NV

Mr. Verhaeghe was chairman of the board of directors of PharmaNeuroBoost NV, which voluntarily filed for bankruptcy in 2013 after its Phase 3 trial failed and no additional funding was found to continue its operations.

Peter K.M. Verhaeghe—KBC Private Equity Fund Biotech NV

Mr. Verhaeghe was a member of the board of directors of KBC Private Equity Fund Biotech NV, a Euronext-listed fund, when it voluntarily liquidated pursuant to a decision of its shareholders. Mr. Verhaeghe was appointed as liquidator in charge and closed the liquidation by the end of 2012 with net proceeds for the shareholders of over €6 per share.

B. COMPENSATION**Compensation of Our Executive Management and Board of Directors**

Our shareholders have adopted a policy governing the remuneration of our board of directors, which is aimed to attract, reward and retain highly qualified executive and non-executive directors and to provide and motivate the members of our board of directors with a balanced and competitive remuneration that is focused on sustainable results and is aligned with the long-term strategy of the company as set out in its business plan.

At the General Meeting on April 28, 2016, the shareholders approved an amended remuneration policy, or the Remuneration Policy, which allows for the granting of compensation packages to our directors in line with a benchmarking analysis performed by an independent consulting firm engaged by our remuneration and nomination committee and an assessment of the duties of the directors, and includes competitive severance arrangements intended to attract and retain highly qualified personnel. At the extraordinary shareholders' meeting of our shareholders held on November 7, 2017, the shareholders approved an amendment to the Remuneration Policy, discussed in more detail below. For a discussion of our employment arrangements with our executive management, see the section of this annual report titled "Item 7.B.—Related Party Transactions—Agreements with Our Executive Management."

Except the arrangements described in the section of this annual report titled "Related-Party Transactions—Agreements with Our Executive Management" there are no arrangements or understanding between us and any of the executive directors providing for benefits upon termination of their employment, other than as required by applicable law.

Compensation of Our Executive Management

The remuneration of our executive management (including our executive directors) consists of the following fixed and variable components:

- a fixed base salary;
- a variable annual cash bonus (short-term annual cash incentive);
- long-term variable incentive awards, in the form of stock options;
- severance arrangements; and
- pension and fringe benefits.

Fixed base salary. The base salary of our executive management was determined on the basis of a benchmarking analysis completed by an independent consulting firm. In accordance with this benchmarking analysis, our board of directors has resolved to aim for a compensation of our executive management in the 75th percentile of the compensation offered by the European peer group for executive management living in Europe and 50th percentile offered by the U.S. peer group for executive management living in the United States, each time as identified by the independent consulting firm used in this analysis. The base salary of the executive directors will be determined at a range around the median salary levels payable within a blend of both European and U.S. peer groups.

Variable annual cash bonus. The objective of this short-term annual cash incentive is to ensure that our executive management is incentivized to achieve performance targets in the shorter term. Our executive

management is eligible for an annual cash incentive up to a maximum percentage of his/her annual base salary. The maximum percentage for this purpose was set at 50% of base salary of the chief executive officer, and at 35% of base salary for other members of the executive management. Performance conditions are established by our board of directors before or at the beginning of the relevant calendar year and shall include criteria concerning our financial performance, qualitative criteria representing our performance and/or individual qualitative performance.

Long-term incentive awards. Our board of directors intends to incentivize our executive management by issuing Options from time to time to be able to attract and retain well-qualified executive management in connection with the argenx Employee Stock Option Plan, as set out below.

Severance arrangements. We have entered into management contracts and employment agreements with our executive management, each of which provides for certain minimum notice periods if their service or employment with us is terminated in certain circumstances as described below in “Related Party Transactions—Agreements with our Executive Management.”

Pension and fringe benefits. Our executive management participates in a defined contribution pension scheme operated by a third party pension insurance organization. Our executive management is entitled to customary fringe benefits, such as a company car and a hospitalization plan.

The following table sets forth information regarding compensation paid by us for Tim Van Hauwermeiren during the year ended December 31, 2018:

Tim Van Hauwermeiren

	Compensation (€)
Base salary	500,000
Option awards(1)	3,559,200
Employer social security contribution stock options	—
Non-equity incentive plan compensation(2)	284,600
Pension contributions	15,102
Social security costs	10,011
Other(3)	33,855
Total	4,402,768

- (1) Amount shown represents the expenses recorded with respect to the option awards granted in 2018 to Mr. Van Hauwermeiren measured using the Black Scholes formula. For a description of the assumptions used in valuing these awards, see note 4.9 to our financial statements included elsewhere in this annual report. These amounts do not reflect the actual economic value realized by Mr. Van Hauwermeiren.
- (2) We have an established practice to increase the variable pay with a certain percentage (for 2018: 13.84%) for those beneficiaries that opt to receive their bonus through over the counter (OTC) options rather than through a payment in cash. As a result, whereas the basis for calculating the cash bonus is a maximum of 50% of base salary, in practice this may be paid in OTC options, representing a higher percentage of the annual base salary (in 2018: 56.92%).
- (3) Consists of €21,292 rent paid by the company, €12,149 attributable to the lease of a company car and €414 in employer-paid medical insurance premiums.

The following table sets forth information regarding aggregate compensation paid by us for the members of our executive management (excluding Tim Van Hauwermeiren) during the year ended December 31, 2018:

	Compensation (€)
Base salary	2,005,379
Option awards(1)	9,803,878
Employer social security contribution stock options(2)	2,792,503
Non-equity incentive plan compensation	793,347
Pension contributions	137,485
Social security costs	518,482
Other(3)	90,192
TOTAL	16,141,266

- (1) Amount shown represents the expenses recorded with respect to the option awards granted in 2018 to Mr. Eric Castaldi, Mr. Woods, Mr. Nicolas Leupin, Prof. Hans de Haard, Dr. Torsten Dreier and Dr. Debbie Allen measured using the Black Scholes formula. For a description of the assumptions used in valuing these awards, see note 4.9 to our financial statements included elsewhere in this annual report. These amounts do not reflect the actual economic value realized by these members of our executive management.
- (2) The Company incurs employer social security costs with respect to the option awards granted to the members of our executive management. The amount of employer social security costs depends on the actual economic value realized and therefore varies based on the price of our ordinary shares. At each reporting date, the Company makes a calculation of the exposure.
- (3) Consists of €48,644 attributable to the leases of company cars, €25,342 in car, housing and other allowances and €16,206 in employer-paid medical insurance premiums.

The following table sets forth information regarding option awards granted to our executive management during the year ended December 31, 2018:

Name	Stock options	Expiration date	Exercise price
Tim Van Hauwermeiren (1)	80,000	12/21/2028	€ 86.32
Eric Castaldi (1)	50,000	12/21/2028	€ 86.32
Hans de Haard (1)	50,000	12/21/2028	€ 86.32
Keith Woods	50,000	12/21/2028	€ 86.32
Debbie Allen	28,200	12/21/2028	€ 86.32
Dirk Beeusaert	28,200	6/28/2023	€ 80.82
Dirk Beeusaert (1)	21,800	12/21/2028	€ 86.32

- (1) On December 21, 2018, the company granted options for which the beneficiary had a 60-day period to choose between a contractual term of five or ten years.

The table below shows the stock options held at the start of the year ended December 31, 2018 and the stock options granted to our executive management which have vested during the year ended December 31, 2018, as well as the stock options to vest in the years ending December 31, 2019, December 31, 2020 and December 31, 2021 (in number of stock options), and the respective exercise price of such stock options:

Name	Total options held on January 1, 2018	Options granted in 2018	Options exercised in 2018	Total options held on December 31, 2018	Options vested until 2017	Exercise price	Options vested in 2018	Exercise price	Options to vest in 2019	Exercise price	Options to vest in 2020	Exercise price	Options to vest in 2021	Exercise price
Tim Van Hauwermeiren	296,200	80,000	(40,000)	336,200	65,000	€ 7.17								
					20,400	€ 9.47	10,200	€ 9.47	6,944	€ 11.47				
					26,389	€ 11.47	16,667	€ 11.47	10,200	€ 14.13				
					10,200	€ 14.13	26,667	€ 21.17	26,666	€ 21.17	26,667	€ 21.17		
									26,667	€ 86.32	26,666	€ 86.32	26,667	€ 86.32
Eric Castaldi	273,807	50,000	(74,039)	249,768	41,007	€ 2.44								
					30,961	€ 7.17								
					18,800	€ 9.47	9,400	€ 9.47	3,917	€ 11.47				
					14,883	€ 11.47	9,400	€ 11.47	9,400	€ 14.13				
					9,400	€ 14.13	14,400	€ 21.17	14,400	€ 21.17	14,400	€ 21.17		
									16,667	€ 86.32	16,666	€ 86.32	16,667	€ 86.32
Nicolas Leupin	127,800	—	—	127,800	18,800	€ 9.47	9,400	€ 9.47	3,917	€ 11.47				
					14,883	€ 11.47	9,400	€ 11.47	9,400	€ 14.13				
					9,400	€ 14.13	14,400	€ 21.17	14,400	€ 21.17	14,400	€ 21.17		
Hans De Haard	395,975	50,000	—	445,975	144,822	€ 2.44								
					109,000	€ 7.17								
					18,800	€ 9.47	9,400	€ 9.47	3,917	€ 11.47				
					14,883	€ 11.47	9,400	€ 11.47	9,400	€ 14.13				
					9,400	€ 14.13	14,400	€ 21.17	14,400	€ 21.17	14,400	€ 21.17		
							7,177	€ 18.41	4,784	€ 18.41	2,392	€ 18.41		
							14,400	€ 21.17	14,400	€ 21.17	14,400	€ 21.17	16,667	€ 86.32
									16,667	€ 86.32	16,666	€ 86.32		
Torsten Dreier	379,948	—	—	379,948	137,580	€ 2.44								
					105,000	€ 7.17								
					18,800	€ 9.47	9,400	€ 9.47	3,917	€ 11.47				
					14,883	€ 11.47	9,400	€ 11.47	9,400	€ 14.13				
					9,400	€ 14.13	14,400	€ 21.17	14,400	€ 21.17	14,400	€ 21.17		
							4,784	€ 18.41	3,189	€ 18.41	1,595	€ 18.41		
							14,400	€ 21.17	14,400	€ 21.17	14,400	€ 21.17		
Debbie Allen	221,111	28,200	—	249,311	39,195	€ 2.44								
					10,616	€ 3.95								
					43,500	€ 7.17								
					18,800	€ 9.47	9,400	€ 9.47	3,917	€ 11.47				
					14,883	€ 11.47	9,400	€ 11.47	9,400	€ 14.13				
					9,400	€ 14.13	14,400	€ 21.17	14,400	€ 21.17	14,400	€ 21.17	9,400	€ 86.32
									9,400	€ 86.32	9,400	€ 86.32		
Dirk Beusaert	54,682	50,000	—	104,682	—	€ 18.41	19,841	€ 18.41	13,227	€ 18.41	6,614	€ 18.41		
					—	€ 21.17	5,000	€ 21.17	5,000	€ 21.17	5,000	€ 21.17	4,700	€ 80.82
									14,100	€ 80.82	9,400	€ 80.82	7,267	€ 86.32
									7,267	€ 86.32	7,266	€ 86.32		
Keith Woods	75,000	50,000	—	125,000	—	€ 21.17	25,000	€ 21.17	25,000	€ 21.17	25,000	€ 21.17	16,667	€ 86.32
									16,667	€ 86.32	16,666	€ 86.32		

The table below shows the remaining term of the stock options held by our executive management during the year ended December 31, 2018.

Name	Number of stock options	Remaining term on December 31, 2018 (rounded up)
Tim Van Hauwermeiren	65,000	6.0 years
	30,600	7.0 years
	50,000	7.5 years
	30,600	8.0 years
	80,000	9.0 years
	80,000	5.0 / 10.0 years (1)
Eric Castaldi	20,970	5.5 years
	50,998	6.0 years
	28,200	7.0 years
	28,200	7.5 years
	28,200	8.0 years
	43,200	9.0 years
	50,000	5.0 / 10.0 years (1)
Nicolas Leupin	28,200	7.0 years
	28,200	7.5 years
	28,200	8.0 years
	43,200	9.0 years
Hans De Haard	69,360	4.5 years
	39,636	5.0 years
	144,826	6.0 years
	28,200	7.0 years
	28,200	7.5 years
	28,200	8.0 years
	14,353	8.5 years
	43,200	9.0 years
	50,000	5.0 / 10.0 years (1)
Torsten Dreier	65,890	4.5 years
	37,654	5.0 years
	139,036	6.0 years
	28,200	7.0 years
	28,200	7.5 years
	28,200	8.0 years
	9,568	8.5 years
	43,200	9.0 years
Debbie Allen	7,180	1.5 years
	810	2.0 years
	18,770	4.5 years
	10,727	5.0 years
	55,824	6.0 years
	28,200	7.0 years
	28,200	7.5 years
	28,200	8.0 years
	43,200	9.0 years
	28,200	10.0 years
Dirk Beetsaert	39,682	8.5 years
	15,000	9.0 years
	28,200	4.5 years
	21,800	5.0 / 10.0 years (1)
Keith Woods	75,000	9.0 years

The table below shows the stock options exercised by our executive management during the year ended December 31, 2018 and the exercise price of those stock options. Per exercised option, one share was issued.

Name	Number of stock options	Exercise price
Tim Van Hauwermeiren	40,000	€ 7.17
Eric Castaldi	40,000	€ 2.44
Eric Castaldi	34,039	€ 7.17
Total	114,039	

Compensation of Our Non-Executive Directors

The remuneration of the individual members of the board of directors is determined by the non-executive directors, at the recommendation of the remuneration and nomination committee, within the limits of the Remuneration Policy adopted by the shareholders at the General Meeting. The description below reflects the status of our Remuneration Policy as updated by our board of directors on September 12, 2017 and giving effect to the update to the Remuneration Policy approved by our shareholders at the extraordinary shareholders' meeting held on November 7, 2017. The board of directors expects to propose minor changes to the Remuneration Policy at the General Meeting to be held in 2019.

Pursuant to the Remuneration Policy, the remuneration of the non-executive directors consists of the following fixed and variable components:

- a fixed fee, which fee will be prorated if the non-executive director does not attend all meetings where his or her presence is required;
- if applicable, a fee for chairing the audit committee, the research and development committee or the remuneration and nomination committee;
- a fixed fee for board committee membership; and
- a long-term variable incentive, in the form of stock options.

Fixed fee. The board of directors has set the annual base remuneration for non-executive directors at €35,000, additional remuneration for the chairperson of the board of directors at €30,000, additional remuneration for the chairperson of the audit committee and the research and development committee of the board of directors at €15,000 and additional remuneration for the chairperson of the remuneration and nomination committee of the board of directors at €10,000. Board committee members, other than the chairman of the relevant committee, receive an annual retainer of €5,000 for the remuneration and nomination committee and a €7,500 retainer for the members of the audit committee and the research and development committee.

Long-term incentive plan. The board of directors intends to incentivize the non-executive directors by issuing options from time to time to be able to attract and retain well-qualified non-executive directors in connection with the argenx Employee Stock Option Plan. The board of directors grants options to the non-executive directors on the recommendation of the remuneration and nomination committee. Such option grants are based on an option allocation scheme established by the board of directors pursuant to the argenx Employee Stock Option Plan. The conditions of our option plan apply to our non-executive directors, as set forth in “—argenx Employee Stock Option Plan.”

Success payment. In exceptional circumstances, the board of directors may decide to reward a non-executive director with a success payment relating to the occurrence of specific events achieved through the exceptional efforts of that person (such as a platform licensing or product licensing deal brokered by that non-executive director).

Pursuant to the Remuneration Policy, in case of a dismissal, non-executive directors will not be entitled to a severance payment.

The following table sets forth the information regarding the compensation earned by our non-executive directors during the year ended December 31, 2018:

Name	Fees earned or paid in cash (€)	Option awards (€)(1)	Total
Peter K.M. Verhaeghe	77,500	444,900	€ 522,400
David L. Lacey	50,000	444,900	494,900
Werner Lanthaler	55,000	444,900	499,900
Pamela Klein	42,500	444,900	487,400
J. Donald deBethizy	52,500	444,900	497,400
A.A. Rosenberg	42,500	444,900	487,400
James M. Daly	35,000	926,750	961,750

- (1) Amount shown represents the expenses recorded with respect to the option awards granted in 2018 to the non-executive directors measured using the Black Scholes formula. For a description of the assumptions used in valuing these awards, see note 4.9 to our financial statements included elsewhere in this annual report. These amounts do not reflect the actual economic value realized by the non-executive director.

The table below shows the stock options held at the start of the year ended December 31, 2018 and the stock options granted to the non-executive directors which have vested during the year ended December 31, 2018,

as well as the stock options to vest in the years ending December 31, 2019, December 31, 2020 and December 31, 2021 (in number of stock options), and the respective exercise price of such stock options:

Name	Total options held on January 1, 2018	Options granted in 2018	Options exercised in 2018	Total options held on December 31, 2018	Options vested until 2017	Exercise price	Options vested in 2018	Exercise price	Options to vest in 2019	Exercise price	Options to vest in 2020	Exercise price	Options to vest in 2021	Exercise price
Peter Verhaeghe	34,585	10,000		44,585	11,626	€ 2.44								
					7,959	€ 3.95								
					5,000	€ 7.17								
					5,000	€ 11.38	3,333	€ 11.38	1,667	€ 11.38				
									3,333	€ 86.32	3,334	€ 86.32	3,333	€ 86.32
David L. Lacey	44,443	10,000		54,443	6,643	€ 2.44								
					12,800	€ 7.17								
					5,000	€ 11.38	3,333	€ 11.38	1,667	€ 11.38				
							5,000	€ 21.17	5,000	€ 21.17	5,000	€ 21.17		
									3,333	€ 86.32	3,334	€ 86.32	3,333	€ 86.32
Werner Lanthaler	29,416	10,000	(24,972)	14,444	—	€ 2.44								
					—	€ 7.17								
					—	€ 11.38	2,777	€ 11.38	1,667	€ 11.38				
									3,333	€ 86.32	3,334	€ 86.32	3,333	€ 86.32
J. Donald deBethizy	25,000	10,000		35,000	12,500	€ 11.44	2,500	€ 11.44						
					5,000	€ 11.38	3,333	€ 11.38	1,667	€ 11.38				
									3,333	€ 86.32	3,334	€ 86.32	3,333	€ 86.32
Pamela Klein	25,000	10,000		35,000	12,500	€ 11.44	2,500	€ 11.44						
					5,000	€ 11.38	3,333	€ 11.38	1,667	€ 11.38				
									3,333	€ 86.32	3,334	€ 86.32	3,333	€ 86.32
A.A. Rosenberg	15,000	10,000		25,000	5,000	€ 14.13	5,000	€ 14.13	5,000	€ 14.13				
									3,333	€ 86.32	3,334	€ 86.32	3,333	€ 86.32
James M. Daly	—	25,000		25,000					7,500	€ 80.82	5,000	€ 80.82	2,500	€ 80.82
									3,333	€ 86.32	3,334	€ 86.32	3,333	€ 86.32

The table below shows the remaining term of the stock options held by the non-executive directors during the year ended December 31, 2018.

Name	Number of stock options	Remaining term on December 31, 2018 (rounded up)
Peter K.M. Verhaeghe	3,650	1.5 years
	2,340	2.0 years
	5,560	4.5 years
	3,181	5.0 years
	9,854	6.0 years
	10,000	7.5 years
	10,000	10.0 years
David L. Lacey	3,180	4.5 years
	1,818	5.0 years
	14,445	6.0 years
	10,000	7.5 years
	15,000	9.0 years
	10,000	10.0 years
Werner Lanthaler	4,444	7.5 years
	10,000	10.0 years
J. Donald deBethizy	15,000	6.5 years
	10,000	7.5 years
	10,000	10.0 years
Pamela Klein	15,000	6.5 years
	10,000	7.5 years
	10,000	10.0 years
A.A. Rosenberg	15,000	8.0 years
	10,000	10.0 years
James M. Daly	15,000	9.5 years
	10,000	10.0 years

The table below shows the stock options exercised by our executive management during the year ended December 31, 2018 and the exercise price of those stock options. Per exercised option, one share was issued.

Name	Number of stock options	Exercise price
Werner Lanthaler	14,416	€ 2.44
Werner Lanthaler	5,000	€ 7.17
Werner Lanthaler	5,556	€ 11.38
Total	24,972	

argenx Employee Stock Option Plan

On December 18, 2014, our board of directors adopted an employee stock option plan, or the Option Plan, which was approved by the shareholders at the General Meeting on May 13, 2015 and amended by the General Meeting on April 28, 2016. The aim of the Option Plan is to encourage our executive management, directors and key outside consultants and advisors to acquire an economic and beneficial ownership interest in the growth and performance of the company, to increase their incentive to contribute to our value and to attract and retain individuals who are key to our company.

In connection with the Option Plan, our board of directors has also established an option allocation scheme. The option allocation scheme contains (i) the date on which options are granted each year, which shall be the same date each year and (ii) the number of options granted to each person or to each group of persons, which shall be based on objective criteria only.

Our board of directors, in each case subject to the approval of the majority of the non-executive directors, may grant options to our executive management, directors or key outside consultants or advisors and in accordance with the option allocation scheme. Our board of directors may also grant options at its discretion outside of the option allocation scheme, but only in a period when no inside information (as specified our insider trading policy) is available. Persons to whom options are granted cannot refuse to accept such options.

The aggregate number of shares that may be available for the issuance of options is equal to 14.5% of our fully-diluted share capital. Shares issued pursuant to the exercise of an option are counted towards the share capital, and options that cease to exist (whether through exercise, termination or otherwise) are restored to the foregoing limit and shall again be available for issuance under the Option Plan. Shares shall be charged against the foregoing limit upon the grant of each option, but if such shares are thereafter forfeited or such option otherwise terminates without the issuance of such shares or of other consideration in lieu of such shares, the shares so forfeited or related to the terminated portion of such option shall be restored to the foregoing limit and shall again be available for options under the Option Plan.

Options granted pursuant to the Option Plan shall vest with respect to one third of the shares upon the first anniversary of the date of grant, with the remaining two thirds vesting in twenty-four equal monthly installments with the option fully vesting upon the third anniversary of the date of grant, subject, in each case, to the optionee's continued status.

Each option shall be granted with an exercise price equal to the fair market value upon the date of grant and shall have a term equal to ten years from the date of grant. In the case of a (i) sale, merger, consolidation, tender offer or similar acquisition of shares or other transaction or series of related transactions as a result of which a change in control occurs, (ii) sale or other disposition of all or substantially all of the company's assets or (iii) dissolution and/or liquidation of the company, then 100% of any unvested options shall vest.

Our board of directors, upon approval of a majority of the non-executive directors may amend or terminate the Option Plan or may amend the terms of any outstanding options, provided that no amendment or termination may affect any existing rights without the consent of the affected optionees.

The board of directors may seek shareholder approval at the 2019 General Meeting for certain amendments to the Option Plan, details of which will be disclosed in the convocation materials for the 2019 General meeting. These relate primarily to amendments in applicable laws and regulations since the date the option plan was last amended, including the Regulation (EU) No 596/2014 of the European Parliament and of the Council of April 16, 2014 on market abuse (market abuse regulation) as well as changes in tax laws and regulations in Belgium

As of March 22, 2019, there were 3,273,583 options outstanding which represent approximately 8.6% of the total number of all our issued and outstanding voting financial instruments.

The table below sets forth the details of all options granted under the argenx Employee Stock Option Plan in force as of December 31, 2018, including the offer date, exercise price, expiry date, number of options exercised, number of options voided and number of options outstanding. Aside from the stock options set forth in the below table, there are currently no other stock options, options to purchase securities, convertible securities or other rights to subscribe for or purchase outstanding securities.

Plan	Offer date	Exercise price (€)	Number of options granted	Options Number of options exercised	Number of options voided	Number of options still outstanding	Exercisable from	Expiry date
SOP A	11/05/2010	3,95	103.370	89.490	—	13.880	11/05/2013	11/05/2020
SOP A	30/11/2010	3,95	62.460	58.140	—	4.320	30/11/2013	30/11/2020
SOP A	1/02/2011	3,95	3.800	3.800	—	—	1/02/2014	1/02/2021
SOP B	23/05/2013	2,44	305.740	119.390	—	186.350	23/05/2016	23/05/2023
SOP B	4/12/2013	2,44	174.747	66.697	—	108.050	4/12/2016	4/12/2023
SOP B	30/06/2014	2,44	109.820	82.850	—	26.970	30/06/2017	30/06/2024
Reshuffling A	30/09/2014	3,95	55.746	48.851	—	6.895	30/09/2017	30/09/2024
Reshuffling B1	30/09/2014	2,44	174.362	62.265	—	112.097	30/09/2017	30/09/2024
Reshuffling B2	30/09/2014	2,44	19.719	14.083	—	5.636	30/09/2017	30/09/2024
SOP 2014.12.18	18/12/2014	7,17	585.250	130.439	47.750	407.061	18/12/2017	18/12/2024
SOP 2015.06.18	18/06/2015	11,44	56.500	—	17.500	39.000	18/06/2018	18/06/2025
SOP 2015.09.03	3/09/2015	10,34	3.000	—	—	3.000	3/09/2018	3/09/2025
SOP 2015.12.15	15/12/2015	9,47	243.400	9.027	8.050	226.323	15/12/2018	15/12/2025
SOP 2016.05.25	25/05/2016	11,47	288.950	23.687	7.647	257.616	25/05/2019	25/05/2026
SOP 2016.06.18	18/06/2016	11,38	60.000	9.585	—	50.415	18/06/2019	18/06/2026
SOP 2016.12.13	13/12/2016	14,13	363.226	34.826	13.298	315.102	13/12/2019	13/12/2026
SOP 2017.06.26	26/06/2017	18,41	120.536	6.250	267	114.019	26/06/2020	26/06/2027
SOP 2017.12.14	14/12/2017	21,17	653.825	1.650	23.883	628.292	14/12/2020	14/12/2027
SOP 2018.06.28	28/06/2018	80,82	97.100	—	2.500	94.600	28/06/2021	28/06/2023
SOP 2018.06.28	28/06/2018	80,82	81.800	—	6.350	75.450	28/06/2021	28/06/2028
SOP 2018.12.21 (1)	21/12/2018	86,32	861.575	—	—	861.575	21/12/2021	21/12/2028
Total			4.424.926	761.030	127.245	3.536.651		

- (1) On December 21, 2018, the company had granted options for which the beneficiary had a 60-day period to choose between a contractual term of five or ten years.

C. BOARD PRACTICES

Director Independence

As a foreign private issuer, under the listing requirements and rules of Nasdaq, we are not required to have independent directors on our board of directors, except that our audit committee is required to consist fully of independent directors, subject to certain phase-in schedules. However, our board of directors has determined that, under current listing requirements and rules of Nasdaq and taking into account any applicable committee independence standards, all of our non-executive directors are “independent directors.” In making such determination, our board of directors considered the relationships that each non-executive director has with us and all other facts and circumstances our board of directors deemed relevant in determining the director’s independence, including the number of ordinary shares beneficially owned by the director and his or her affiliated entities (if any).

The DCGC requires that the composition of the non-executive directors is such that the members are able to operate independently and critically vis-à-vis one another, the executive directors, and any particular interests involved. At the date of this annual report, all of our non-executive directors meet the independence criteria contained in the DCGC. Therefore, the composition of our non-executive directors complies with the independence requirements of the DCGC.

Role of the Board in Risk Oversight

Our board of directors is responsible for the oversight of our risk management activities and has delegated to the audit committee the responsibility to assist our board in this task. While our board oversees our risk management, our management is responsible for day-to-day risk management processes. Our board of directors expects our management to consider risk and risk management in each business decision, to proactively develop and monitor risk management strategies and processes for day-to-day activities and to effectively implement risk management strategies adopted by the board of directors. We believe this division of responsibilities is the most effective approach for addressing the risks we face.

Composition, Appointment and Dismissal

The Articles of Association provide that our board of directors will consist of our executive directors and non-executive directors. The number of executive directors must at all times be less than the number of non-executive directors. The number of directors, as well as the number of executive directors and non-executive directors, is determined by our board of directors, with the proviso that the board of directors must consist of at least three members.

Our directors are appointed by the shareholders at the General Meeting. The board of directors is required to make one or more proposals for each seat on our board of directors to be filled. A resolution to nominate a director by our board of directors (with support from the remuneration and nomination committee) may be adopted by a simple majority of the votes cast. A nomination for appointment of an executive director must state the candidate's age and the positions he or she holds, or has held, insofar as these are relevant for the performance of the duties of an executive director. The nomination must state the reasons for the nomination of the relevant person. A nomination for appointment of a non-executive director must state the candidate's age, his or her profession, the number of shares he or she holds and the employment positions he or she holds, or has held, insofar as these are relevant for the performance of the duties of a non-executive director. Furthermore, the names of the legal entities of which he or she is already a supervisory board member or a non-executive member of the board shall be indicated; if those include legal entities which belong to the same group, a reference to that group will be sufficient. The nomination must state the reasons for the nomination of the relevant person.

Our directors are appointed as either an executive director or as a non-executive director by the shareholders at the General Meeting. Our board of directors designates one executive director as chief executive officer. In addition, the board of directors may grant other titles to executive directors. Our board of directors designates a non-executive director as chairperson of the board of directors and a non-executive director as vice chairperson of the board of directors. The legal relationship between a member of the board of directors and the company will not be considered as an employment agreement. Employment agreements between an executive director and a group company (other than us) are permitted. In the absence of an employment agreement, members of a board of directors generally do not enjoy the same protection as employees under Dutch labor law.

Directors may be suspended or removed by the shareholders at the General Meeting at any time, with or without cause, by means of a resolution passed by a simple majority of the votes cast. Under Dutch law, executive directors may also be suspended by the board of directors. A suspension of an executive director by the board of directors may be discontinued by the shareholders at any time at the General Meeting.

We have entered into management contracts and employment agreements with our Board members and executive management that contain certain severance provisions, see section of this annual report titled "Item 7.B.—Related Party Transactions—Agreements with our Executive Management."

Committees

The committees are advisory bodies only, and the decision-making remains within the collegial responsibility of the non-executive directors. The non-executive directors determine the terms of reference of each committee with respect to the organization, procedures, policies and activities of the committee.

Our non-executive directors have established and appointed an audit committee, a remuneration and nomination committee and a research and development committee. The composition and function of all of our committees will comply with all applicable requirements of the Exchange Act, the exchanges on which the ordinary shares are listed, SEC rules and regulations and the DCGC.

Only non-executive directors qualify for membership of the committees. The audit committee and the remuneration and nomination committee may not be chaired by the chairperson of the board of directors or by a former executive director of the company.

Audit Committee

Our audit committee consists of three members: Werner Lanthaler (chairperson), Peter K.M. Verhaeghe and A.A. Rosenberg.

Our board of directors has determined that all members of our audit committee are independent under Rule 10A-3 of the Exchange Act and the applicable rules of the Nasdaq Stock Market and all members of our audit committee are independent under the applicable rules of the DCGC, and that Werner Lanthaler qualifies as an “audit committee financial expert” as defined under the Exchange Act.

Our audit committee assists our board of directors in overseeing the accuracy and integrity of our accounting and financial reporting processes and audits of our consolidated financial statements, the implementation and effectiveness of an internal control system and our compliance with legal and regulatory requirements, the independent auditors’ qualifications and independence and the performance of the independent auditors.

The audit committee is governed by a charter that complies with Nasdaq listing rules and the DCGC. Our audit committee is responsible for, among other things:

- ensuring the integrity of our financial reporting, including review of period information before it is made public;
- supervising the company’s policies with respect to financing and tax;
- evaluating our system of internal controls set up by our board of directors, including evaluation and approval of the explanatory notes on internal controls in our annual reports;
- reviewing the functions of our internal risk management system and the efficacy of these systems, including the review of ICT-applications with a view to cybersecurity;
- assessing the necessity for setting up an internal audit function; and
- supervising our relationship with our external auditors during the external audit process, including evaluation of our auditors’ independence.

Our audit committee meets as often as is required for its proper functioning, but at least four times a year. Our audit committee must meet at least once a year with our statutory auditor.

Our audit committee reports regularly to our board of directors on the exercise of its functions. It informs our board of directors about all areas in which action or improvement is necessary in its opinion and produces recommendations concerning the necessary steps that need to be taken. The audit review and the reporting on that review cover us and our subsidiaries as a whole. The members of the audit committee are entitled to receive all information which they need for the performance of their function, from our board of directors and employees.

Every member of the audit committee shall exercise this right in consultation with the chairperson of the audit committee.

Remuneration and Nomination Committee

Our remuneration and nomination committee consists of three members: J. Donald deBethizy (chairperson), Peter K.M. Verhaeghe and Werner Lanthaler.

Our board of directors has determined that all members of our remuneration and nomination committee are independent under the applicable rules of the Nasdaq Stock Market and all members of our remuneration and nomination committee are independent under the applicable rules of the DCGC.

Our remuneration and nomination committee is responsible for, among other things:

- reviewing and recommending the remuneration policy for approval by the shareholders at the General Meeting;
- reviewing and recommending the remuneration policy for the directors for approval by the shareholders at the General Meeting; such proposal shall, in any event, deal with: (i) the remuneration structure and (ii) the amount of the fixed remuneration, the shares and/or options to be granted and/or other variable remuneration components, pension rights, redundancy pay and other forms of compensation to be awarded, as well as the performance criteria and their application;
- preparing the remuneration report;
- preparing selection criteria and appointment procedures for directors;
- periodically assessing the size and composition of our board of directors and making a proposal for a composition profile of the non-executive directors;
- periodically assessing the performance of individual directors and reporting on this to the non-executive directors;
- making proposals for appointments and reappointments; and
- supervising the policy of our board of directors on the selection criteria and appointment procedures for senior management.

The remuneration and nomination committee consists of at least three members. The remuneration and nomination committee meets as often as is required for its proper functioning, but at least once per year to evaluate its functioning.

Research and Development Committee

Our research and development committee consists of three members: David L. Lacey (chairperson), J. Donald deBethizy and Pamela Klein.

Our board of directors has determined that all members of our research and development committee are independent under the applicable rules of the Nasdaq Stock Market and all members of our research and development committee are independent under the applicable rules of the DCGC.

The research and development committee is responsible for, among other things:

- monitoring and overseeing the research and development goals, strategies and measures of the company;
- serving as a sounding board to the company's research and development management, general management and the board of directors;
- performing strategic reviews of the company's key research and development programs;
- reporting to the board of directors on the outcome of the strategic reviews;
- reviewing the company's scientific publication and communications plan;
- evaluating and challenging the effectiveness and competitiveness of the research and development endeavors of the company;
- reviewing and discussing emerging scientific trends and activities critical to the success of research and development of the company;
- reviewing the company's clinical and preclinical product pipeline; and
- engaging in attracting, retaining and developing senior research and development personnel of the company.

All members of the research and development committee shall have adequate industrial, academic and/or practical experience with the research and development of biopharmaceuticals.

One purpose of our research and development committee is to engage in discussion with our research and development management, and the committee's responsibilities to carry out this purpose include, among others: monitoring the research and development activities, performing strategic reviews of the key research and development programs; and reviewing the scientific publication plan.

Our research and development committee meets as often as is required for its proper functioning, but at least prior to each meeting of our board of directors, and reports regularly to our board of directors on the outcome of the strategic reviews. Our research and development committee consists of at least three members with adequate industrial experience with the research and development of biopharmaceuticals. The chairperson of our research and development committee shall report formally to our board of directors on the research and development committee's deliberations, findings and proceedings after each meeting on all matters within its duties and responsibilities.

Corporate Governance Practices

Our board of directors has adopted rules, or the Board By-Laws, that describe the procedure for holding meetings of the board of directors, for the decision-making by the board of directors and the board of directors' operating procedures.

In accordance with our Articles of Association, our board of directors will meet at least once every three months to discuss the state of affairs within the company and the expected developments.

Under the Board By-Laws, the members of our board of directors must endeavor, insofar as is possible, to ensure that resolutions are adopted unanimously. Where unanimity cannot be achieved and Dutch law, the Articles of Association or the Board By-Laws do not prescribe a larger majority, all resolutions of our board of directors

must be adopted by a simple majority of the votes cast in a meeting at which at least a majority of the members of our board of directors then in office are present or represented. The Articles of Association and the Board By-Laws provide that in case of a tie of votes, the chairperson does not have a casting vote and as such the proposal will be rejected in case of a tie.

In exceptional cases, if the urgent necessity and the interests of the company require this, resolutions of our board of directors may also be adopted by unanimous written approval of all directors in office.

D. EMPLOYEES

As of December 31, 2018, we had 105 employees. At each date shown below, we had the following number of employees, broken out by department and geography:

	At December 31,		
	2018	2017	2016
Function:			
Research and development	75	58	48
Selling, general and administrative	30	15	10
Total	105	73	58
Geography:			
Zwijnaarde, Belgium	94	73	58
Boston, USA	11	—	—
Breda, the Netherlands	—	—	—
Total	105	73	58

Collective bargaining agreements, or CBAs, can be entered into in Belgium at the national, industry, or company levels. These CBAs are binding on both employers and employees. We have no trade union representation or CBAs at the company level, but we are subject to the national and industry level CBAs that relate to the chemical industry. The CBAs currently applicable to us relate to employment conditions such as wages, working time, job security, innovation and supplementary pensions. We have not had, and do not anticipate having, disputes on any of these subjects. CBAs may, however, change the employment conditions of our employees in the future and hence adversely affect our employment relationships.

E. SHARE OWNERSHIP

For information regarding the share ownership of our directors and members of our executive committee, see “Item 6.B.—Compensation” and “Item 7.A.—Major Shareholders”.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. MAJOR SHAREHOLDERS

The following table sets forth information with respect to the beneficial ownership of our ordinary shares as of March 22, 2019 for:

- each person who is known by us to own beneficially more than 3% of our total outstanding ordinary shares;
- each member of our board of directors and our executive management;
- all members of our board of directors and our executive management as a group.

Beneficial ownership is determined in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment

power with respect to those securities and include ordinary shares that can be acquired within 60 days of March 22, 2019. The percentage ownership information shown in the table is based upon 37,991,779 ordinary shares outstanding as of March 22, 2019.

Except as otherwise indicated, all of the shares reflected in the table are ordinary shares and all persons listed below have sole voting and investment power with respect to the shares beneficially owned by them, subject to applicable community property laws. The information is not necessarily indicative of beneficial ownership for any other purpose.

In computing the number of ordinary shares beneficially owned by a person and the percentage ownership of that person, we deemed outstanding ordinary shares subject to options held by that person that are immediately exercisable or exercisable within 60 days of March 22, 2019. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person. The information in the table below is based on information known to us or ascertained by us from public filings made by the shareholders.

Name of beneficial owner	Shares beneficially owned	
	Number	Percentage
3% or Greater Shareholders:		
FMR LLC(1)(2)	3,789,576	9.97 %
Federated Equity Management Company of Pennsylvania(1)(3)	2,891,897	7.61 %
Johnson & Johnson Innovation - JJDC, Inc(1)(4)	1,766,899	4.65 %
T. Rowe Price Group, Inc. (1)(5)	1,680,077	4.42 %
RTW Investments(1)(6)	1,436,705	3.78 %
Entities affiliated with Baker Bros. Advisors GP LLC(1)(7)	1,190,197	3.13 %
Directors and Executive Management:		
Tim Van Hauwermeiren(8)	173,567	*
Peter Verhaeghe(9)	34,029	*
David Lacey(10)	35,554	*
Werner Lanthaler(11)	29,860	*
Donald deBethizy(12)	24,444	*
Pamela Klein(13)	24,444	*
A.A. Rosenberg(14)	11,667	*
James M. Daly	—	—
Eric Castaldi(15)	119,297	*
Nicolas Leupin(16)	80,750	*
Hans de Haard(17)	445,253	1.16 %
Torsten Dreier(18)	431,087	1.13 %
Debbie Allen(19)	190,061	*
Keith Woods(20)	33,333	*
Dirk Beusaert(21)	30,917	*
All directors and executive management as a group (15 persons)(22)	1,664,263	4.23 %

* Indicates beneficial ownership of less than 1% of the total outstanding ordinary shares.

- (1) Based on the number of shares reported in, and at the time of, the most recent transparency notification.
- (2) Consists of 3,789,576 ordinary shares beneficially held. Members of the Johnson family, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment

Company Act of 1940, to form a controlling group with respect to FMR LLC. Neither FMR LLC nor Abigail P. Johnson has the sole power to vote or direct the voting of the shares owned directly by the various investment companies registered under the Investment Company Act (“Fidelity Funds”) advised by Fidelity Management & Research Company (“FMR Co”), a wholly owned subsidiary of FMR LLC, which power resides with the Fidelity Funds’ Boards of Trustees. Fidelity Management & Research Company carries out the voting of the shares under written guidelines established by the Fidelity Funds’ Boards of Trustees. The address for FMR LLC is 245 Summer Street, Boston, Massachusetts 02210.

- (3) Consists of (i) 2,478,414 ordinary shares held by Federated Kaufmann Fund, a portfolio of Federated Equity Funds, (ii) 351,010 ordinary shares held by Federated Kaufmann Small Cap Fund, a portfolio of Federated Equity Funds and (iii) 62,473 ordinary shares held by Federated Kaufmann Fund II, a portfolio of Federated Insurance Series (collectively, the “Federated Kaufmann Funds”). The address of the Federated Kaufmann Funds is 101 Park Avenue, Suite 4100, New York, NY 10178.
- (4) Consists of 1,766,899 ordinary shares held by Johnson & Johnson Innovation – JJDC, Inc. (“JJDC”), a wholly-owned subsidiary of Johnson & Johnson (“J&J”). JJDC and J&J have shared voting and dispositive power over the shares, and J&J may be deemed to indirectly beneficially own the securities that are directly beneficially owned by JJDC. The address for JJDC is One Johnson & Johnson Plaza, New Brunswick, NJ 08933.
- (5) Consists of 1,680,077 ADSs held by T. Rowe Price Associates, Inc. The address for T. Rowe Price Associates, Inc is 100 East Pratt Street, Baltimore, MD 21202.
- (6) Based on the most recent transparency notification filed by R.W. Wong, Managing Partner of RTW Investments. Consists of 25,260 ADSs and 1,411,445 ordinary shares held by RTW Master Fund, Ltd. and RTW Innovation Master Fund, Ltd. The address for RTW Investments is 412 West 15th Street, Floor 9, New York, NY 10011.
- (7) Based on the most recent transparency notification filed by Baker Bros. Advisors GP LLC. Consists of 950,492 ADSs and 239,705 ordinary shares beneficially owned by Baker Bros. Advisors LP; Baker Brothers Life Sciences, L.P.; and 667, L.P. (collectively, the “Baker Funds”). Baker Bros. Advisors LP is the investment advisor to the Baker Funds and has sole voting and investment power with respect to the shares held by the Baker Funds. Baker Bros. Advisors (GP) LLC is the sole general partner of Baker Bros. Advisors LP. The managing members of Baker Bros. Advisors (GP) LLC are Julian C. Baker and Felix J. Baker. Julian C. Baker and Felix J. Baker disclaim beneficial ownership of all shares except to the extent of their pecuniary interest. The address for each of these entities is 667 Madison Avenue, 21st Floor, New York, NY 10065.
- (8) Consists of 173,567 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 22, 2019. Next to this, 10,000 shares are being held by a Stichting Administratiekantoor for which Tim Van Hauwermeiren is a director.
- (9) Consists of 34,029 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 22, 2019.
- (10) Consists of 35,554 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 22, 2019.
- (11) Consists of (i) 25,972 shares and (ii) 3,888 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 22, 2019.
- (12) Consists of 24,444 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 22, 2019.

- (13) Consists of 24,444 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 22, 2019.
- (14) Consists of 11,667 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 22, 2019.
- (15) Consists of 119,297 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 22, 2019.
- (16) Consists of (i) 38,057 shares and (ii) 42,693 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 22, 2019.
- (17) Consists of (i) 85,910 shares and (ii) 359,343 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 22, 2019.
- (18) Consists of (i) 151,800 shares and (ii) 279,287 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 22, 2019.
- (19) Consists of 190,061 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 22, 2019.
- (20) Consists of 33,333 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 22, 2019.
- (21) Consists of 30,917 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 22, 2019.

Each of our shareholders is entitled to one vote per ordinary share. None of the holders of our shares have different voting rights from other holders of shares. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

As of March 22, 2019, we had one holder of record of our ADSs in the United States, which is Cede & Co., the nominee of The Depository Trust Company. This shareholder held in the aggregate 56.6% of the 37,991,779 ordinary shares outstanding as of March 22, 2019. The number of record holders in the United States is not representative of the number of beneficial holders nor is it representative of where such beneficial holders are resident since many of these ordinary shares were held by brokers or other nominees. As of March 22, 2019, assuming that all of our ordinary shares represented by ADSs are held by residents of the United States, we estimate that approximately 71% of our outstanding ordinary shares were held in the United States by approximately 137 institutional holders of record.

To our knowledge, and other than changes in percentage ownership as a result of the shares issued in connection with our initial and follow-on U.S. public offerings, there has been no significant change in the percentage ownership held by the major shareholders listed above, except as set forth below. On January 31, 2018, we received a transparency notification from Forbion Capital Fund II Coöperatief U.A. indicating that as a result of the sale of its entire position, its shareholding has decreased below the 3% notification threshold of argenx's voting rights. Per its transparency notification dated January 10, 2018, Bank of America reported total shareholdings of over 6% of argenx's voting rights. On March 14, 2018, we received a transparency notification from Bank of America Corporation indicating that as a result of the sale of nearly all of its position, its shareholding has decreased below the 3% notification threshold of argenx's voting rights. On September 21, 2018, we received a transparency notification from Shire plc indicating that as a result of the sale of its shares, its shareholding has decreased below the 3% notification threshold of argenx's voting rights. On January 24, 2019, we received a transparency notification from Perceptive Advisors LLC indicating that as a result of the increased number of argenx's outstanding shares, its shareholding has decreased below the 3% notification threshold of argenx's voting rights. On February 15, 2019, we received a transparency notification from LSP IV Management B.V. indicating

that as a result of the sale of its shares, its shareholding has decreased below the 3% notification threshold of argenx's voting rights.

B. RELATED PARTY TRANSACTIONS

Since January 1, 2014, there has not been, nor is there currently proposed, any material transaction or series of similar material transactions to which we were or are a party in which any of the members of our board of directors or senior management, holders of more than 10% of any class of our voting securities, or any member of the immediate family of any of the foregoing persons, had or will have a direct or indirect material interest, other than the compensation and shareholding arrangements we describe in the sections of this annual report titled "Item 6.B.—Compensation" and "Item 7.A.—Major Shareholders," and the transactions we describe below.

Agreements with Our Executive Management

We have entered into a management agreement with Tim Van Hauwermeiren as our Chief Executive Officer and executive director. The key terms of this agreement, reflecting updates approved by the board of directors on September 12, 2107, are as follows:

	Tim Van Hauwermeiren	
Base salary	€	500,000
Cash bonus		maximum 50% of base salary based on previously determined bonus targets established by the non-executive directors
Pension contributions(1)	€	15,102
Duration		Indefinite

(1) Amounts shown represent pension contributions paid during the year-ended December 31, 2018.

We may terminate Mr. Van Hauwermeiren's services upon 18 months' notice, or payment of 18 months' pro-rated base salary in lieu of notice. Mr. Van Hauwermeiren would be entitled to the same payment in lieu of notice in the event he terminated his services with us in circumstances in which it cannot reasonably be expected for him to continue providing services to us (and after our failure to remedy such conditions after being provided at least 14 days' notice). Mr. Van Hauwermeiren would also be entitled to payment in lieu of notice in the event he terminated his services with us in certain cases of our failure to comply with obligations under applicable law or his agreement (and after our failure to remedy such non-compliance, if non-deliberate, after being provided at least 14 days' notice). In these cases, there will be a full acceleration of the vesting of any outstanding stock options held by Mr. Van Hauwermeiren. There will be no notice period or payment in lieu of notice in certain cases of Mr. Van Hauwermeiren's failure to comply with obligations under applicable law or his agreement.

Eric Castaldi, our Chief Financial Officer, has an employment contract with our subsidiary, argenx BVBA, for an indefinite term. His employment contract may be terminated at any time by us, subject to a notice period and a severance payment of at least 12 months.

Keith Woods, our Chief Operating Officer, has an employment contract with our subsidiary, argenx US Inc., for an indefinite term. His employment contract may be terminated at any time by us, subject to a notice period and a severance payment of at least 12 months.

Nicolas Leupin, our Chief Medical Officer, has an employment contract with our subsidiary, argenx BVBA, for an indefinite term. His employment contract may be terminated at any time by us, subject to a notice period and a severance payment of at least 12 months.

Hans de Haard, our Chief Scientific Officer, has an employment contract with our subsidiary, argenx BVBA, for an indefinite term. His employment contract may be terminated at any time by us, subject to a notice period and a severance payment of at least 12 months.

Torsten Dreier, our Chief Development Officer, has an employment contract with our subsidiary, argenx BVBA, for an indefinite term. His employment contract may be terminated at any time by us, subject to a notice period and a severance payment of at least 12 months.

Debbie Allen, our Senior Vice President of Business Development, has a consultancy agreement with our subsidiary, argenx BVBA, which is effective until January 1, 2018. Her consultancy agreement may be terminated at any time by mutual written consent of both parties and by us, subject to a one month notice period.

Dirk Beeusaert, our General Counsel, has an employment contract with our subsidiary, argenx BVBA, for an indefinite term. His employment contract may be terminated at any time by us, subject to a notice period and a severance payment of at least 12 months.

Indemnification Agreements

In connection with our initial U.S. public offering, we entered into indemnification agreements with each of our non-executive directors and each member of our executive management. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to non-executive directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Transactions with Related Companies

Agreement with FairJourney Biologics LDA

FairJourney Biologics LDA, or FairJourney, is a fee-for-service company focused on antibody discovery and engineering services. FairJourney was founded in 2012 and, as compensation for their support with the formation of FairJourney, our chief executive officer and executive director Tim Van Hauwermeiren acquired shares representing 5% of the equity securities of FairJourney, and our chief scientific officer, Hans de Haard, acquired shares representing 20% of the equity securities of FairJourney. In July 2012, we entered into a license and exclusive option agreement with FairJourney, pursuant to which we granted FairJourney a worldwide, non-exclusive license to our SIMPLE Antibody™ Platform to develop, manufacture and commercialize SIMPLE Antibodies to certain targets selected by FairJourney. Under the terms of the agreement, once FairJourney has advanced a product candidate discovered under the agreement to near proof-of-concept stage, we have the option to acquire patent rights generated by FairJourney specific to such product candidate along with a non-exclusive license to additional FairJourney intellectual property useful for further development, manufacture, or commercialization of the product candidate. Upon exercising this option, we must pay FairJourney an option fee equal to two times the expenses incurred by FairJourney for advancing such product candidate through the option exercise date, and we are required to pay a specified royalty in the mid-single digits on any sub-licensing revenue received by us for such product candidate. Alternatively, if we elect not to exercise the option, FairJourney is required to pay us a specified royalty in the mid-single digits on any sub-licensing revenue received by FairJourney for such product candidate. In connection with the agreement, we acquired shares of FairJourney representing 15% of the fully-diluted equity securities of FairJourney at the time of issuance. In December 2017, the company and executive director Tim Van Hauwermeiren sold their respective shareholding in FairJourney Biologics LDA, and thus FairJourney Biologics LDA is no longer a related company.

Services Provided by VVGB Advocaten-Avocats

In relation to the initial public offering of our shares on Euronext Brussels in July 2014, VVGB Advocaten-Avocats provided legal services to us. Peter K.M. Verhaeghe, one of our non-executive directors, is the managing partner of VVGB Advocaten-Avocats.

Related Party Transactions Policy

In connection with our initial U.S. public offering, we entered into a related party transaction policy.

C. INTERESTS OF EXPERTS AND COUNSEL

Not applicable.

ITEM 8. FINANCIAL INFORMATION

A. CONSOLIDATED STATEMENTS AND OTHER FINANCIAL INFORMATION

Consolidated financial statements

Our consolidated financial statements are appended at the end of this annual report, starting at page F-1, and incorporated herein by reference.

Legal proceedings

From time to time we may become involved in legal, governmental or arbitration proceedings or be subject to claims arising in the ordinary course of our business. We are not presently a party to any legal, governmental or arbitration proceeding. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Dividend Distribution Policy

We have not paid or declared any cash dividends on our ordinary shares, and we do not anticipate paying any cash dividends in the foreseeable future. Even if future operations lead to significant levels of distributable profits, we currently intend that any earnings will be reinvested in our business and that cash dividends will not be paid until we have an established revenue stream to support continuing cash dividends. In addition, payment of any future dividends to shareholders would be subject to shareholder approval at our General Meeting, upon proposal of the board of directors, which proposal would be subject to the approval of the majority of the non-executive directors after taking into account various factors including our business prospects, cash requirements, financial performance and new product development. In addition, payment of future cash dividends may be made only if our shareholders' equity exceeds the sum of our paid-in and called-up share capital plus the reserves required to be maintained by Dutch law or by our Articles of Association.

If we complete our possible redomiciliation, under Belgian corporate law, we may pay dividends only up to an amount equal to the excess of our shareholders' equity over the sum of (i) paid-up or called-up share capital, and (ii) reserves not available for distribution pursuant to law or our Belgian Articles of Association, based on the most recent statutory audited financial statements, prepared in accordance with the generally accepted accounting principles in Belgium, or Belgian GAAP. In addition, under Belgian law, prior to distributing dividends, we must allocate an amount of 5% of our annual net profit on an unconsolidated basis to a legal reserve in our unconsolidated financial statements until such reserve equals 10% of our share capital. If Belgian corporate law is amended, these and/or other provisions may contain similar restrictions.

B. SIGNIFICANT CHANGES

On January 18, 2019, the Company announced the closing of an exclusive global collaboration and license agreement for cusatuzumab with Janssen. The collaboration agreement became effective following expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act and the closing of the private placement of 1,766,899 new argenx shares at a price of €100.02 per share to JJDC, Inc. argenx and Janssen have agreed to a joint global clinical development plan to evaluate cusatuzumab in acute myeloid leukemia, myelodysplastic syndromes and other potential future indications. Under the terms of the agreement, Janssen has

paid argenx \$300 million in an upfront payment. argenx will be eligible to receive potentially up to \$1.3 billion in development, regulatory and sales milestones, in addition to tiered royalties. Janssen will be responsible for commercialization worldwide. argenx retains the option to participate in commercialization efforts in the U.S., where the companies have agreed to share royalties on a 50/50 basis, and outside the U.S., Janssen will pay royalties to argenx, ranging from the low double digits to the high teens.

On February 4, 2019, the Company announced that it entered into a global collaboration and license agreement with Halozyme that enables use by argenx of Halozyme's ENHANZE® drug delivery technology to develop multiple subcutaneous product formulations for current or future argenx product candidates. Under the terms of the agreement, argenx will pay an upfront payment of \$30 million to Halozyme, \$10 million per target for future target nominations and potential future payments of up to \$160 million per selected target, subject to the achievement of specified development, regulatory and sales-based milestones. Halozyme will also receive mid-single digit royalties on sales of commercialized products.

ITEM 9. THE OFFER AND LISTING

A. OFFER AND LISTING DETAILS

Our ADSs have been listed on the Nasdaq Global Select Market under the symbol "ARGX" since May 18, 2017. Prior to that date, there was no public trading market for our ADSs. Our ordinary shares have been trading on Euronext Brussels under the symbol "ARGX" since July 2014. Prior to that date, there was no public trading market for our ADSs or our ordinary shares. Our initial U.S. public offering in May 2017 was priced at \$17.00 per ADS.

B. PLAN OF DISTRIBUTION

Not applicable.

C. MARKETS

The ADSs have been listed on NASDAQ under the symbol "ARGX" since May 18, 2017, and our ordinary shares have been listed on Euronext Brussels under the symbol "ARGX" since July 2014.

D. SELLING SHAREHOLDERS

Not applicable.

E. DILUTION

Not applicable.

F. EXPENSES OF THE ISSUE

Not applicable.

ITEM 10. ADDITIONAL INFORMATION

A. SHARE CAPITAL

Not applicable.

B. MEMORANDUM AND ARTICLES OF ASSOCIATION

The information set forth in our Registration Statement on Form F-3ASR (File No. 333-225370), automatically effective upon filing with the SEC on June 1, 2018, under the heading “Description of Share Capital” as supplemented by the section titled “Description of Share Capital” in the final prospectus supplement on Form 424(b)(5) dated September 18, 2018 filed with the SEC on September 20, 2018 is incorporated herein by reference.

C. MATERIAL CONTRACTS

We entered into underwriting agreements among Cowen and Company, LLC and Piper Jaffray & Co., as representatives of the underwriters on each of May 17, 2017 and December 13, 2017, with respect to the ADSs offered in our initial U.S. and follow-on public offerings, respectively. In addition, we entered into an underwriting agreement with Morgan Stanley & Co., LLC, Cowen and Company, LLC and Evercore Group L.L.C., as representatives of the underwriters on September 18, 2018, with respect to the ADSs offered in our U.S. follow-on public offering. In each underwriting agreement, we agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriters may be required to make in respect of such liabilities. For additional information on our material contracts, please see the sections of this annual report titled “Item 4—Information on the Company,” “Item 7.A.—Major Shareholders,” and “Item 7.B.—Related Party Transactions.”

D. EXCHANGE CONTROLS

Pursuant to Dutch law, there are no exchange controls applicable to the transfer to persons outside of the Netherlands of dividends or other distributions with respect to, or of the proceeds from the sale of, shares of a Dutch company.

Pursuant to Dutch law, there are no exchange controls applicable to our import or export of capital, including the availability of cash and cash equivalents to us as a Dutch company.

E. TAXATION

Certain Material U.S. Federal Income Tax Considerations to U.S. Holders

The following is a summary of certain material U.S. federal income tax considerations relating to the ownership and disposition of ADSs by a U.S. holder (as defined below). This summary addresses only the U.S. federal income tax considerations for U.S. holders that hold ADSs as capital assets for U.S. federal income tax purposes. This summary does not address all U.S. federal income tax matters that may be relevant to a particular U.S. holder. This summary does not address tax considerations applicable to a holder of ADSs that may be subject to special tax rules including, without limitation, the following:

- banks, financial institutions or insurance companies;
- brokers, dealers or traders in securities, currencies, commodities, or notional principal contracts;
- tax-exempt entities or organizations, including an “individual retirement account” or “Roth IRA” as defined in Section 408 or 408A of the Code (as defined below), respectively;
- real estate investment trusts, regulated investment companies or grantor trusts;
- persons that hold the ADSs as part of a “hedging,” “integrated” or “conversion” transaction or as a position in a “straddle” for U.S. federal income tax purposes;

- partnerships (including entities or arrangements classified as partnerships for U.S. federal income tax purposes) or other pass-through entities, or persons that will hold the ADSs through such an entity;
- certain former citizens or long-term residents of the United States;
- holders that own directly, indirectly, or through attribution 10% or more of the voting power or value of our ordinary shares and ADSs; and
- holders that have a “functional currency” for U.S. federal income tax purposes other than the U.S. dollar.

Further, this summary does not address U.S. federal estate, gift, or alternative minimum tax considerations, any election to apply Section 1400Z-2 of the Code to gains recognized with respect to ADSs, or any U.S. state, local, or non-U.S. tax considerations of the ownership and disposition of ADSs.

This description is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code; existing, proposed and temporary U.S. Treasury Regulations promulgated thereunder, administrative and judicial interpretations thereof; and the income tax treaties between the Netherlands and the United States, and Belgium and the United States, in each case as in effect and available on the date hereof. All the foregoing is subject to change, which change could apply retroactively, and to differing interpretations, all of which could affect the tax considerations described below. There can be no assurances that the U.S. Internal Revenue Service, or the IRS, will not take a contrary or different position concerning the tax consequences of the ownership and disposition of our ordinary shares or that such a position would not be sustained. Holders should consult their own tax advisors concerning the U.S. federal, state, local and non-U.S. tax consequences of owning and disposing of ADSs in their particular circumstances.

For the purposes of this summary, a “U.S. holder” is a beneficial owner of ADSs that is (or is treated as), for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation, or other entity that is treated as a corporation for U.S. federal income tax purposes, created or organized in or under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust, if a court within the United States is able to exercise primary supervision over its administration and one or more U.S. persons have the authority to control all of the substantial decisions of such trust or have a valid election in effect under applicable U.S. Treasury Regulations to be treated as a United States person.

If a partnership (or any other entity or arrangement treated as a partnership for U.S. federal income tax purposes) holds ADSs, the U.S. federal income tax consequences relating to an investment in those ADSs will depend in part upon the status of the partner and the activities of the partnership. Such a partner or partnership should consult its tax advisor regarding the U.S. federal income tax considerations of owning and disposing of ADSs in its particular circumstances.

In general, a U.S. holder who owns ADSs will be treated as the beneficial owner of the underlying shares represented by those ADSs for U.S. federal income tax purposes. Accordingly, no gain or loss will generally be recognized if a U.S. holder exchanges ADSs for the underlying shares represented by those ADSs.

As indicated below, this discussion is subject to U.S. federal income tax rules applicable to a “passive foreign investment company,” or a PFIC, discussed under “—Passive Foreign Investment Company Considerations.”

Persons considering an investment in the ADSs should consult their own tax advisors as to the particular tax consequences applicable to them relating to the ownership and disposition of ADSs, including the applicability of U.S. federal, state and local tax laws and non-U.S. tax laws.

Distributions. Although we do not currently plan to pay dividends, and subject to the discussion under “—Passive Foreign Investment Company Considerations” below, the gross amount of any distribution (before reduction for any amounts withheld in respect of Dutch or Belgian withholding tax) actually or constructively received by a U.S. holder with respect to ADSs will be taxable to the U.S. holder as a dividend to the extent of the U.S. holder’s pro rata share of our current and accumulated earnings and profits as determined under U.S. federal income tax principles. Distributions in excess of earnings and profits will be non-taxable to the U.S. holder to the extent of, and will be applied against and reduce, the U.S. holder’s adjusted tax basis in ADSs. Distributions in excess of earnings and profits and such adjusted tax basis will generally be taxable to the U.S. holder as either long-term or short-term capital gain depending upon whether the U.S. holder has held the ADSs for more than one year as of the time such distribution is received. However, since we do not calculate our earnings and profits under U.S. federal income tax principles, it is expected that any distribution will be reported as a dividend, even if that distribution would otherwise be treated as a non-taxable return of capital or as capital gain under the rules described above. Non-corporate U.S. holders may qualify for the preferential rates of taxation with respect to dividends on ADSs applicable to long-term capital gains (i.e., gains from the sale of capital assets held for more than one year) applicable to qualified dividend income (as discussed below) if we are a “qualified foreign corporation” and certain other requirements (discussed below) are met. A non-U.S. corporation (other than a corporation that is a PFIC for the taxable year in which the dividend is paid or the preceding taxable year) generally will be considered to be a qualified foreign corporation with respect to any dividend it pays on shares which are readily tradable on an established securities market in the United States. We have been approved to list our ordinary shares on the Nasdaq Global Select Market, which is an established securities market in the United States, and we expect our ADSs to be readily tradable on the Nasdaq Global Select Market. However, there can be no assurance that the ADSs will be considered readily tradable on an established securities market in the United States in later years. Therefore, subject to the discussion under “—Passive Foreign Investment Company Considerations” below, such dividends will generally be “qualified dividend income” in the hands of non-corporate U.S. holders, provided that a holding period requirement (more than 60 days of ownership, without protection from the risk of loss, during the 121-day period beginning 60 days before the ex-dividend date) and certain other requirements are met. The dividends will not be eligible for the dividends-received deduction generally allowed to corporate U.S. holders.

A U.S. holder generally may claim the amount of any Dutch or Belgian withholding tax as either a deduction from gross income or a credit against U.S. federal income tax liability. However, the foreign tax credit is subject to numerous complex limitations that must be determined and applied on an individual basis. Generally, the credit cannot exceed the proportionate share of a U.S. holder’s U.S. federal income tax liability that such U.S. holder’s taxable income bears to such U.S. holder’s worldwide taxable income. In applying this limitation, a U.S. holder’s various items of income and deduction must be classified, under complex rules, as either “foreign source” or “U.S. source.” In addition, this limitation is calculated separately with respect to specific categories of income. The amount of a distribution with respect to the ADSs that is treated as a “dividend” may be lower for U.S. federal income tax purposes than it is for Dutch or Belgian income tax purposes, potentially resulting in a reduced foreign tax credit for the U.S. holder. Furthermore, Dutch or Belgian income taxes withheld in excess of the rate applicable under the income tax treaty between the Netherlands or Belgium and the United States will not be eligible for credit against U.S. holders’ federal income tax liability. Each U.S. holder should consult its own tax advisors regarding the foreign tax credit rules.

Sale, Exchange or Other Taxable Disposition of ADSs. A U.S. holder will generally recognize gain or loss for U.S. federal income tax purposes upon the sale, exchange or other taxable disposition of ADSs in an amount equal to the difference between the U.S. dollar value of the amount realized from such sale or exchange

and the U.S. holder's tax basis for those ADSs. Subject to the discussion under "—Passive Foreign Investment Company Considerations" below, this gain or loss will generally be a capital gain or loss. The adjusted tax basis in ADSs generally will be equal to the cost of such ADSs. Capital gain from the sale, exchange or other taxable disposition of ADSs of a non-corporate U.S. holder is generally eligible for a preferential rate of taxation applicable to capital gains, if the non-corporate U.S. holder's holding period determined at the time of such sale, exchange or other taxable disposition for such ADSs exceeds one year (i.e., such gain is long-term taxable gain). The deductibility of capital losses for U.S. federal income tax purposes is subject to limitations. Any such gain or loss that a U.S. holder recognizes generally will be treated as U.S. source income or loss for foreign tax credit limitation purposes.

Medicare Tax. Certain U.S. holders that are individuals, estates or trusts are subject to a 3.8% tax on all or a portion of their "net investment income," which may include all or a portion of their dividend income and net gains from the disposition of ADSs. Each U.S. holder that is an individual, estate or trust is urged to consult its tax advisors regarding the applicability of the Medicare tax to its income and gains in respect of its investment in ADSs.

Passive Foreign Investment Company Considerations. If we are classified as a passive foreign investment company, or PFIC, for any taxable year, a U.S. holder would be subject to special rules generally intended to reduce or eliminate any benefits from the deferral of U.S. federal income tax that a U.S. holder could derive from investing in a non-U.S. company that does not distribute all of its earnings on a current basis.

A corporation organized outside the United States generally will be a PFIC for U.S. federal income tax purposes for any taxable year in which, after applying certain look-through rules, either: (i) at least 75% of its gross income is "passive income" or (ii) at least 50% of the average quarterly value of its total gross assets (for which purpose the total value of our assets may be determined in part by reference to the market value of our ordinary shares and ADSs, which is subject to change) is attributable to assets that produce "passive income" or are held for the production of "passive income."

Passive income for this purpose generally includes dividends, interest, royalties, rents, gains from commodities and securities transactions, the excess of gains over losses from the disposition of assets which produce passive income, and includes amounts derived by reason of the temporary investment of cash, including the funds raised in offerings of the ADSs. If a non-U.S. corporation owns directly or indirectly at least 25% by value of the stock of another corporation, the non-U.S. corporation is treated for purposes of the PFIC tests as owning its proportionate share of the assets of the other corporation and as receiving directly its proportionate share of the other corporation's income for purposes of the PFIC tests. If we are a PFIC for any year with respect to which a U.S. holder owns ADSs, we will continue to be treated as a PFIC with respect to such U.S. holder in all succeeding years during which the U.S. holder owns ADSs, regardless of whether we continue to meet the tests described above.

Whether we are a PFIC for any taxable year will depend on the composition of our income and the projected composition and estimated fair market values of our assets in each year, and because this is a factual determination made annually after the end of each taxable year, there can be no assurance that we will not be considered a PFIC for any taxable year. The market value of our assets may be determined in large part by reference to the market price of our ordinary shares and ADSs, which is likely to fluctuate after a public offering. Based on the foregoing, we do not anticipate that we will be a PFIC for the 2018 taxable year based upon the expected value of our assets, including any goodwill, and the expected composition of our income and assets, however, as previously mentioned, we cannot provide any assurances regarding our PFIC status for the current or any prior or future taxable years.

If we are a PFIC, for any taxable year, then unless you make one of the elections described below, a special tax regime will apply to both (a) any "excess distribution" by us to you (generally, your ratable portion of distributions in any year which are greater than 125% of the average annual distribution received by you in the shorter of the three preceding years or your holding period for ADSs) and (b) any gain realized on the sale or other disposition of ADSs. Under this regime, any excess distribution and realized gain will be treated as ordinary

income and will be subject to tax as if (a) the excess distribution or gain had been realized ratably over your holding period, (b) the amount deemed realized in each year had been subject to tax in each year of that holding period at the highest marginal rate for such year (other than income allocated to the current period or any taxable period before we became a PFIC, which would be subject to tax at the U.S. holder's regular ordinary income rate for the current year and would not be subject to the interest charge discussed below), and (c) the interest charge generally applicable to underpayments of tax had been imposed on the taxes deemed to have been payable in those years. In addition, dividend distributions made to you will not qualify for the lower rates of taxation applicable to long-term capital gains discussed above under "—Distributions."

Certain elections exist that would result in an alternative treatment (such as mark-to-market treatment) of ADSs. If a U.S. holder makes the mark-to-market election, the U.S. holder generally will recognize as ordinary income any excess of the fair market value of the ADSs at the end of each taxable year over their adjusted tax basis, and will recognize an ordinary loss in respect of any excess of the adjusted tax basis of the ADSs over their fair market value at the end of the taxable year (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). If a U.S. holder makes the election, the U.S. holder's tax basis in ADSs will be adjusted to reflect these income or loss amounts. Any gain recognized on the sale or other disposition of the ADSs in a year when we are a PFIC will be treated as ordinary income and any loss will be treated as an ordinary loss (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). The mark-to-market election is available only if we are a PFIC and the ADSs are "regularly traded" on a "qualified exchange." ADSs will be treated as "regularly traded" in any calendar year in which more than a *de minimis* quantity of ADSs are traded on a qualified exchange on at least 15 days during each calendar quarter (subject to the rule that trades that have as one of their principal purposes the meeting of the trading requirement as disregarded). Nasdaq is a qualified exchange for this purpose and, consequently, if the ADSs are regularly traded, the mark-to-market election will generally be available to a U.S. holder.

If we are a PFIC for any year during which a U.S. holder holds ADSs, we must generally continue to be treated as a PFIC by that U.S. holder for all succeeding years during which the U.S. holder holds the ADSs, unless we cease to meet the requirements for PFIC status and the U.S. holder makes a "deemed sale" election with respect to the ADSs. If such election is made, the U.S. holder will be deemed to have sold the ADSs it holds at their fair market value on the last day of the last taxable year in which we qualified as a PFIC, and any gain from such deemed sale would be subject to the consequences applicable to sales of PFIC shares described above. After the deemed sale election, the U.S. holder's ADSs with respect to which the deemed sale election was made will not be treated as shares in a PFIC unless we subsequently become a PFIC.

The tax consequences that would apply if we were a PFIC would also be different from those described above if a U.S. holder were able to make a valid "qualified electing fund," or QEF, election. However, we do not currently intend to provide the information necessary for U.S. holders to make a QEF election if we were treated as a PFIC for any taxable year and prospective investors should assume that a QEF election will not be available. U.S. holders should consult their tax advisors to determine whether any of these above elections would be available and if so, what the consequences of the alternative treatments would be in their particular circumstances.

If we are determined to be a PFIC, the general tax treatment for U.S. holders described in this section would apply to indirect distributions and gains deemed to be realized by U.S. holders in respect of any of our subsidiaries that also may be determined to be PFICs.

If a U.S. holder owns ADSs during any taxable year in which we are a PFIC, the U.S. holder generally will be required to file an IRS Form 8621 (Information Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund) with respect to the company, generally with the U.S. holder's federal income tax return for that year. If our company were a PFIC for a given taxable year, then you should consult your tax advisor concerning your annual filing requirements.

The U.S. federal income tax rules relating to PFICs are complex. Prospective U.S. investors are urged to consult their own tax advisors with respect to the ownership and disposition of ADSs, the consequences to them of an investment in a PFIC, any elections available with respect to our ordinary shares and the IRS information reporting obligations with respect to the ownership and disposition of the ADSs.

Backup Withholding and Information Reporting. U.S. holders generally will be subject to information reporting requirements with respect to dividends on ADSs and on the proceeds from the sale, exchange or disposition of the ADSs that are paid within the United States or through U.S.- related financial intermediaries, unless the U.S. holder is an “exempt recipient.” In addition, U.S. holders may be subject to backup withholding on such payments, unless the U.S. holder provides a correct taxpayer identification number and a duly executed IRS Form W-9 or otherwise establishes an exemption. Backup withholding is not an additional tax, and the amount of any backup withholding will be allowed as a credit against a U.S. holder’s U.S. federal income tax liability and may entitle such holder to a refund, provided that the required information is timely furnished to the IRS.

Foreign Asset Reporting. Certain U.S. holders who are individuals and certain entities controlled by individuals may be required to report information relating to an interest in ADSs, subject to certain exceptions (including an exception for shares held in accounts maintained by U.S. financial institutions) by filing IRS Form 8938 (Statement of Specified Foreign Financial Assets) with their federal income tax return. U.S. holders are urged to consult their tax advisors regarding their information reporting obligations, if any, with respect to their ownership and disposition of the ADSs.

THE DISCUSSION ABOVE IS A GENERAL SUMMARY. IT DOES NOT COVER ALL TAX MATTERS THAT MAY BE OF IMPORTANCE TO A PROSPECTIVE INVESTOR. EACH PROSPECTIVE INVESTOR IS URGED TO CONSULT ITS OWN TAX ADVISOR ABOUT THE TAX CONSEQUENCES TO IT OF AN INVESTMENT IN THE ADSs IN LIGHT OF THE INVESTOR’S OWN CIRCUMSTANCES.

Dutch Tax Consequences

The following summary outlines certain Dutch tax consequences in connection with the acquisition, ownership and disposal of the ADSs. All references in this summary to the Netherlands and Dutch law are to the European part of the Kingdom of the Netherlands and its law, respectively, only. The summary does not purport to present any comprehensive or complete picture of all Dutch tax aspects that could be of relevance to the acquisition, ownership and disposal of the ADSs by a (prospective) holder of the ADSs who may be subject to special tax treatment under applicable law. The summary is based on the tax laws and practice of the Netherlands as in effect on the date of this annual report, which are subject to changes that could prospectively or retrospectively affect the Dutch tax consequences.

For purposes of Dutch income and corporate income tax, shares, or certain other assets, which may include depositary receipts in respect of shares, legally owned by a third party such as a trustee, foundation or similar entity or arrangement, or a Third Party, may under certain circumstances have to be allocated to the (deemed) settlor, grantor or similar originator, or the Settlor, or, upon the death of the Settlor, his/her beneficiaries, or the Beneficiaries, in proportion to their entitlement to the estate of the Settlor of such trust or similar arrangement, or the Separated Private Assets.

The summary does not address the tax consequences of a holder of the ADSs who is an individual and who has a substantial interest (*aanmerkelijk belang*) in the company. Generally, a holder of the ADSs will have a substantial interest in the company if such holder of the ADSs, whether alone or together with his spouse or partner and/or certain other close relatives, holds directly or indirectly, or as Settlor or Beneficiary of Separated Private Assets (i) (x) the ownership of, (y) certain other rights, such as usufruct, over, or (z) rights to acquire (whether or not already issued), shares (including the ADSs) representing 5% or more of the total issued and outstanding capital (or the issued and outstanding capital of any class of shares) of the company or (ii) (x) the ownership of, or (y) certain other rights, such as usufruct over, profit participating certificates (*winstbewijzen*) that relate to 5% or more of the annual profit of the company or to 5% or more of the liquidation proceeds of the company.

In addition, a holder of the ADSs has a substantial interest in the company if he, whether alone or together with his spouse or partner and/or certain other close relatives, has the ownership of, or other rights over, shares, or depositary receipts in respect of shares, in, or profit certificates issued by, the company that represent less than 5% of the relevant aggregate that either (a) qualified as part of a substantial interest as set forth above and where shares, or depositary receipts in respect of shares, profit certificates and/or rights there over have been, or are deemed to have been, partially disposed of, or (b) have been acquired as part of a transaction that qualified for non-recognition of gain treatment.

This summary does not address the tax consequences of a holder of our ordinary shares who:

- (a) receives income or realizes capital gains in connection with his or her employment activities or in his/her capacity as (former) board member and/or (former) supervisory board member; or
- (b) is a resident of any non-European part of the Kingdom of the Netherlands.

PROSPECTIVE HOLDERS OF THE ADSs SHOULD CONSULT THEIR OWN PROFESSIONAL ADVISER WITH RESPECT TO THE TAX CONSEQUENCES OF ANY ACQUISITION, OWNERSHIP OR DISPOSAL OF THE ADSs IN THEIR INDIVIDUAL CIRCUMSTANCES.

Dividend Withholding Tax

General

The company is generally required to withhold dividend withholding tax imposed by the Netherlands at a rate of 15% on dividends distributed by the company in respect of our ordinary shares underlying the ADSs. The expression “dividends distributed by the company” as used herein includes, but is not limited to:

- (a) distributions in cash or in kind, deemed and constructive distributions and repayments of paid-in capital (“*gestort kapitaal*”) not recognized for Dutch dividend withholding tax purposes;
- (b) liquidation proceeds, proceeds of redemption of our ordinary shares or, as a rule, consideration for the repurchase of our ordinary shares by the company in excess of the average paid-in capital recognized for Dutch dividend withholding tax purposes;
- (c) the par value of our ordinary shares issued to a holder of our ordinary shares or an increase of the par value of our ordinary shares, to the extent that it does not appear that a contribution, recognized for Dutch dividend withholding tax purposes, has been made or will be made; and
- (d) partial repayment of paid-in capital, recognized for Dutch dividend withholding tax purposes, if and to the extent that there are net profits (*zuivere winst*), unless (i) the shareholders at the General Meeting have resolved in advance to make such repayment and (ii) the par value of our ordinary shares concerned has been reduced by an equal amount by way of an amendment of the articles of association.

Holders of the ADSs Resident in the Netherlands

A holder of the ADSs that is resident or deemed to be resident in the Netherlands is generally entitled, subject to the anti-dividend stripping rules described below, to a full credit against its (corporate) income tax liability, or a full refund, of the Dutch dividend withholding tax. The same generally applies to holders of the ADSs that are neither resident nor deemed to be resident in the Netherlands if the ADSs are attributable to a permanent establishment in the Netherlands of such non-resident holder.

Holders of the ADSs Resident Outside the Netherlands

A holder of the ADSs that is resident in a country with which the Netherlands has a double taxation convention in effect, may, depending on the terms of such double taxation convention and subject to the anti-dividend stripping rules described below, be eligible for a full or partial exemption from, or full or partial refund of, Dutch dividend withholding tax on dividends received.

A holder of the ADSs, that is a legal entity (a) resident in (i) a Member State of the European Union, (ii) Iceland, Norway or Liechtenstein, or (iii) a country with which the Netherlands has concluded a tax treaty that includes an article on dividends and (b) that is in its state of residence under the terms of a double taxation agreement concluded with a third state, not considered to be resident for tax purposes in a country with which the Netherlands has not concluded a tax treaty that includes an article on dividends (not being a Member State of the European Union, Iceland, Norway or Liechtenstein), is generally entitled, subject to the anti-abuse rules and the anti-dividend stripping rules described below, to a full exemption from Dutch dividend withholding tax on dividends received if it holds an interest of at least 5% (in shares or, in certain cases, in voting rights) in the company or if it holds an interest of less than 5%, in either case where, had the holder of the ADSs been a Dutch resident, it would have had the benefit of the participation exemption (this may include a situation where another related party holds an interest of 5% or more in the company).

The full exemption from Dutch dividend withholding tax on dividends received by a holder of our ordinary shares, that is a legal entity (a) resident in (i) a Member State of the European Union, (ii) Iceland, Norway or Liechtenstein, or (iii) a country with which the Netherlands has concluded a tax treaty that includes an article on dividends is not granted if the interest held by such holder (i) is held with the avoidance of Dutch dividend withholding tax of another person as (one of) the main purpose(s) and (ii) forms part of an artificial structure or series of structures (such as structures which are not put into place for valid business reasons reflecting economic reality).

A holder of the ADSs, that is an entity resident in (i) a Member State of the European Union, or (ii) Iceland, Norway or Liechtenstein, or (iii) in a jurisdiction which has an arrangement for the exchange of tax information with the Netherlands (and such holder as described under (iii) holds the ADSs as a portfolio investment, *i.e.*, such holding is not acquired with a view to the establishment or maintenance of lasting and direct economic links between the holder of the ADSs and the company and does not allow the holder of the ADSs to participate effectively in the management or control of the company), which is exempt from tax in its country of residence, and that would have been exempt from Dutch corporate income tax if it had been a resident of the Netherlands, is generally entitled, subject to the anti-dividend stripping rules described below, to a full refund of Dutch dividend withholding tax on dividends received. This full refund will in general benefit certain foreign pension funds, government agencies and certain government controlled commercial entities.

According to the anti-dividend stripping rules, no exemption, reduction, credit or refund of Dutch dividend withholding tax will be granted if the recipient of the dividend paid by the company is not considered the beneficial owner (*uiteindelijk gerechtigde*) of the dividend as defined in these rules. A recipient of a dividend is not considered the beneficial owner of the dividend if, as a consequence of a combination of transactions, (i) a person (other than the holder of the dividend coupon), directly or indirectly, partly or wholly benefits from the dividend, (ii) such person directly or indirectly retains or acquires a comparable interest in the ADSs, and (iii) such person is entitled to a less favorable exemption, refund or credit of dividend withholding tax than the recipient of the dividend distribution. The term “combination of transactions” includes transactions that have been entered into in the anonymity of a regulated stock market, the sole acquisition of one or more dividend coupons and the establishment of short-term rights or enjoyment on the ADSs (*e.g.*, usufruct).

Holders of the ADSs Resident in the United States

Dividends distributed by the company to U.S. resident holders of the ADSs that are eligible for benefits under the Convention between the Kingdom of the Netherlands and the United States of America for the avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes and Income, dated December 18, 1992 as amended by the protocol of March 8, 2004, or the U.S. Tax Treaty, generally will be entitled to a reduced

dividend withholding tax rate of 5% in case of certain U.S. corporate shareholders owning at least 10% of the company's total voting power. Certain U.S. pension funds and tax-exempt organizations may qualify for a complete exemption from Dutch dividend withholding tax.

Under the U.S. Tax Treaty such benefits are generally available to U.S. residents if such resident is the beneficial owner of the dividends, provided that such shareholder does not have an enterprise or an interest in an enterprise that is, in whole or in part, carried on through a permanent establishment or permanent representative in the Netherlands and to which enterprise or part of an enterprise the ADSs are attributable. A person may, however, not claim the benefits of the U.S. Tax

Treaty if such person's entitlement to such benefits is limited by the provisions of Article 26 (the limitation on benefits provision) of the U.S. Tax Treaty. The reduced dividend withholding tax rate can generally be applied at source upon the distribution of the dividends, provided that the proper forms have been filed in advance of the distribution. In the case of certain tax-exempt organizations, as a general rule, the so-called refund method applies; only when certain administrative conditions have been fulfilled may such tax-exempt organization use the exemption method.

Taxes on Income and Capital Gains

Holders of the ADSs Resident in the Netherlands: Individuals

A holder of the ADSs, who is an individual resident or deemed to be resident in the Netherlands will be subject to regular Dutch income tax on the income derived from the ADSs and the gains realized upon the acquisition, redemption and/or disposal of the ADSs by the holder thereof, if:

- (a) such holder of the ADSs has an enterprise or an interest in an enterprise, to which enterprise the ADSs are attributable; and/or
- (b) such income or capital gain forms "a benefit from miscellaneous activities" ("*resultaat uit overige werkzaamheden*") which, for instance, would be the case if the activities with respect to the ADSs exceed "normal active asset management" ("*normaal, actief vermogensbeheer*") or if income and gains are derived from the holding, whether directly or indirectly, of (a combination of) shares, debt claims or other rights (together, a "lucrative interest" ("*lucratief belang*")) that the holder thereof has acquired under such circumstances that such income and gains are intended to be remuneration for work or services performed by such holder (or a related person), whether within or outside an employment relation, where such lucrative interest provides the holder thereof, economically speaking, with certain benefits that have a relation to the relevant work or services.

If either of the abovementioned conditions (a) or (b) applies, income derived from the ADSs and the gains realized upon the acquisition, redemption and/or disposal of the ADSs will in general be subject to Dutch income tax at the progressive rates up to 51.95%.

If the abovementioned conditions (a) and (b) do not apply, a holder of the ADSs who is an individual, resident or deemed to be resident in the Netherlands will not be subject to taxes on income and capital gains in the Netherlands. Instead, such individual is generally taxed at a flat rate of 30% on deemed income from "savings and investments" ("*sparen en beleggen*"), which deemed income is determined on the basis of the amount included in the individual's "yield basis" ("*rendementsgrondslag*") at the beginning of the calendar year (minus a tax-free threshold). For the 2018 tax year, the deemed income derived from savings and investments will amount to 2.02% of the individual's yield basis up to €70,800, 4.33% of the individual's yield basis exceeding €70,800 up to and including €978,000 and 5.38% of the individual's yield basis in excess of €978,000. The tax-free threshold for 2018 is €30,000.

Holders of the ADSs Resident in the Netherlands: Corporate Entities

A holder of the ADSs that is resident or deemed to be resident in the Netherlands for corporate income tax purposes, and that is:

- a corporation;
- another entity with a capital divided into shares;
- a cooperative (association); or
- another legal entity that has an enterprise or an interest in an enterprise to which the ADSs are attributable,

but which is not:

- a qualifying pension fund;
- a qualifying investment fund (*fiscale beleggingsinstelling*) or a qualifying exempt investment institution (*vrijgestelde beleggingsinstelling*); or
- another entity exempt from corporate income tax,

will in general be subject to regular corporate income tax, generally levied at a rate of 25% (20% over profits up to €200,000) over income derived from the ADSs and the gains realized upon the acquisition, redemption and/or disposal of the ADSs, unless, and to the extent that, the participation exemption (*deelnemingsvrijstelling*) applies.

Holders of the ADSs Resident Outside the Netherlands: Individuals

A holder of the ADSs who is an individual, not resident or deemed to be resident in the Netherlands will not be subject to any Dutch taxes on income derived from the ADSs and the gains realized upon the acquisition, redemption and/or disposal of the ADSs (other than the dividend withholding tax described above), unless:

- (a) such holder has an enterprise or an interest in an enterprise that is, in whole or in part, carried on through a permanent establishment (*vaste inrichting*) or a permanent representative (*vaste vertegenwoordiger*) in the Netherlands and to which enterprise or part of an enterprise, as the case may be, the ADSs are attributable; or
- (b) such income or capital gain forms a “benefit from miscellaneous activities in the Netherlands” (*“resultaat uit overige werkzaamheden in Nederland”*) which would for instance be the case if the activities in the Netherlands with respect to the ADSs exceed “normal active asset management” (*“normaal, actief vermogensbeheer”*) or if such income and gains are derived from the holding, whether directly or indirectly, of (a combination of) shares, debt claims or other rights (together, a “lucrative interest” (*“lucratief belang”*)) that the holder thereof has acquired under such circumstances that such income and gains are intended to be remuneration for work or services performed by such holder (or a related person), in whole or in part, in the Netherlands, whether within or outside an employment relation, where such lucrative interest provides the holder thereof, economically speaking, with certain benefits that have a relation to the relevant work or services.

If either of the abovementioned conditions (a) or (b) applies, income or capital gains in respect of dividends distributed by the company or in respect of any gains realized upon the acquisition, redemption and/or disposal of the ADSs will in general be subject to Dutch income tax at the progressive rates up to 51.95%.

Holders of the ADSs Resident Outside the Netherlands: Legal and Other Entities

A holder of the ADSs, that is a legal entity, another entity with a capital divided into shares, an association, a foundation or a fund or trust, not resident or deemed to be resident in the Netherlands for corporate income tax purposes, will not be subject to any Dutch taxes on income derived from the ADSs and the gains realized upon the acquisition, redemption and/or disposal of the ADSs (other than the dividend withholding tax described above), unless:

- (a) such holder has an enterprise or an interest in an enterprise that is, in whole or in part, carried on through a permanent establishment (*vaste inrichting*) or a permanent representative (*vaste vertegenwoordiger*) in the Netherlands and to which enterprise or part of an enterprise, as the case may be, the ADSs are attributable; or
- (b) such holder has a substantial interest (*aanmerkelijk belang*) in the company, that (i) is held with the avoidance of Dutch income tax of another person as (one of) the main purpose(s) and (ii) forms part of an artificial structure or series of structures (such as structures which are not put into place for valid business reasons reflecting economic reality).

If one of the abovementioned conditions applies, income derived from the ADSs and the gains realized upon the acquisition, redemption and/or disposal of the ADSs will, in general, be subject to Dutch regular corporate income tax, levied at a rate of 25% (20% over profits up to €200,000), unless, and to the extent that, with respect to a holder as described under (a), the participation exemption (*deelnemingsvrijstelling*) applies.

Gift, Estate and Inheritance Taxes

Holders of the ADSs Resident in the Netherlands

Gift tax may be due in the Netherlands with respect to an acquisition of the ADSs by way of a gift by a holder of the ADSs who is resident or deemed to be resident of the Netherlands at the time of the gift.

Inheritance tax may be due in the Netherlands with respect to an acquisition or deemed acquisition of the ADSs by way of an inheritance or bequest on the death of a holder of the ADSs who is resident or deemed to be resident of the Netherlands, or by way of a gift within 180 days before his death by an individual who is resident or deemed to be resident in the Netherlands at the time of his death.

For purposes of Dutch gift and inheritance tax, an individual with the Dutch nationality will be deemed to be resident in the Netherlands if he has been resident in the Netherlands at any time during the ten years preceding the date of the gift or his death. For purposes of Dutch gift tax, an individual not holding the Dutch nationality will be deemed to be resident of the Netherlands if he has been resident in the Netherlands at any time during the twelve months preceding the date of the gift.

Holders of the ADSs Resident Outside the Netherlands

No gift, estate or inheritance taxes will arise in the Netherlands with respect to an acquisition of our ordinary shares by way of a gift by, or on the death of, a holder of the ADSs who is neither resident nor deemed to be resident of the Netherlands, unless, in the case of a gift of the ADSs by an individual who at the date of the gift was neither resident nor deemed to be resident in the Netherlands, such individual dies within 180 days after the date of the gift, while being resident or deemed to be resident in the Netherlands.

Certain Special Situations

For purposes of Dutch gift, estate and inheritance tax, (i) a gift by a Third Party will be construed as a gift by the Settlor, and (ii) upon the death of the Settlor, as a rule his/her Beneficiaries will be deemed to have inherited directly from the Settlor. Subsequently, such Beneficiaries will be deemed the settlor, grantor or similar originator

of the Separated Private Assets for purposes of Dutch gift, estate and inheritance tax in case of subsequent gifts or inheritances.

For the purposes of Dutch gift and inheritance tax, a gift that is made under a condition precedent is deemed to have been made at the moment such condition precedent is satisfied. If the condition precedent is fulfilled after the death of the donor, the gift is deemed to be made upon the death of the donor.

Value Added Tax

No Dutch value added tax will arise in respect of or in connection with the subscription, issue, placement, allotment or delivery of the ADSs.

Other Taxes and Duties

No Dutch registration tax, capital tax, custom duty, transfer tax, stamp duty or any other similar documentary tax or duty, other than court fees, will be payable in the Netherlands in respect of or in connection with the subscription, issue, placement, allotment or delivery of the ADSs.

Residency

A holder of the ADSs will not be treated as a resident, or a deemed resident, of the Netherlands by reason only of the acquisition, or the holding, of the ADSs or the performance by the company under the ADSs.

Dutch Tax Consequences Upon Completion of Our Possible Redomiciliation

The following summary outlines certain Dutch tax consequences in connection with the acquisition, ownership and disposal of the ADSs, if and when our possible redomiciliation is completed. All references in this summary to the Netherlands and Dutch law are to the European part of the Kingdom of the Netherlands and its law, respectively, only. The summary does not purport to present any comprehensive or complete picture of all Dutch tax aspects that could be of relevance to the acquisition, ownership and disposal of the ADSs by a (prospective) holder of the ADSs who may be subject to special tax treatment under applicable law. The summary is based on the tax laws and practice of the Netherlands as in effect on the date of this annual report, which are subject to changes that could prospectively or retrospectively affect the Dutch tax consequences.

For purposes of Dutch income and corporate income tax, shares, or certain other assets which may include depositary receipts in respect of shares, legally owned by a third party such as a trustee, foundation or similar entity or arrangement, or a Third Party, may under certain circumstances have to be allocated to the (deemed) settlor, grantor or similar originator, or the Settlor, or, upon the death of the Settlor, his/her beneficiaries, or the Beneficiaries, in proportion to their entitlement to the estate of the Settlor of such trust or similar arrangement, or the Separated Private Assets.

The summary does not address the tax consequences of a holder of the ADSs who is an individual and who has a substantial interest (*aanmerkelijk belang*) in the company. Generally, a holder of the ADSs will have a substantial interest in the company if such holder of the ADSs, whether alone or together with his spouse or partner and/or certain other close relatives, holds directly or indirectly, or as Settlor or Beneficiary of Separated Private Assets (i) (x) the ownership of, (y) certain other rights, such as usufruct, over, or (z) rights to acquire (whether or not already issued), shares (including the ADSs) representing 5% or more of the total issued and outstanding capital (or the issued and outstanding capital of any class of shares) of the company or (ii) (x) the ownership of, or (y) certain other rights, such as usufruct over, profit participating certificates (*winstbewijzen*) that relate to 5% or more of the annual profit of the company or to 5% or more of the liquidation proceeds of the company.

In addition, a holder of our ordinary shares has a substantial interest in the company if he, whether alone or together with his spouse or partner and/or certain other close relatives, has the ownership of, or other rights over, shares, or depositary receipts in respect of shares, in, or profit certificates issued by, the company that represent

less than 5% of the relevant aggregate that either (a) qualified as part of a substantial interest as set forth above and where shares, or depositary receipts in respect of shares, profit certificates and/or rights there over have been, or are deemed to have been, partially disposed of, or (b) have been acquired as part of a transaction that qualified for non-recognition of gain treatment.

This summary does not address the tax consequences of a holder of the ADSs who:

- (a) receives income or realizes capital gains in connection with his or her employment activities or in his/her capacity as (former) board member and/or (former) supervisory board member; or
- (b) is a resident of any non-European part of the Kingdom of the Netherlands.

PROSPECTIVE HOLDERS OF THE ADSs SHOULD CONSULT THEIR OWN PROFESSIONAL ADVISER WITH RESPECT TO THE TAX CONSEQUENCES OF ANY ACQUISITION, OWNERSHIP OR DISPOSAL OF THE ADSs IN THEIR INDIVIDUAL CIRCUMSTANCES.

Dividend Withholding Tax

General

From a Dutch domestic tax perspective, and subject to double tax treaty relief, dividends distributed by the Belgian argenx SE would continue to be subject to Dutch dividend withholding tax as before our possible redomiciliation, on the basis that we are a company incorporated under Dutch law. Pursuant to the Netherlands/Belgium double tax treaty, however, holders of the ADSs will not be subject to Dutch dividend withholding tax on dividends distributed by the company, unless such holder is resident or deemed to be resident in the Netherlands.

Accordingly, the company could be required to withhold dividend withholding tax imposed by the Netherlands at a rate of 15% on dividends distributed by the company in respect of the ordinary shares underlying the ADSs in the situation described below under “Holders of Our Ordinary Shares Resident in the Netherlands.” The expression “dividends distributed by the company” as used herein includes, but is not limited to:

- (a) distributions in cash or in kind, deemed and constructive distributions and repayments of paid-in capital (“*gestort kapitaal*”) not recognized for Dutch dividend withholding tax purposes;
- (b) liquidation proceeds, proceeds of redemption of our ordinary shares or, as a rule, consideration for the repurchase of our ordinary shares by the company in excess of the average paid-in capital recognized for Dutch dividend withholding tax purposes;
- (c) the par value of our ordinary shares issued to a holder of our ordinary shares or an increase of the par value of our ordinary shares, to the extent that it does not appear that a contribution, recognized for Dutch dividend withholding tax purposes, has been made or will be made; and
- (d) partial repayment of paid-in capital, recognized for Dutch dividend withholding tax purposes, if and to the extent that there are net profits (*zuivere winst*), unless (i) the shareholders at the General Meeting have resolved in advance to make such repayment and (ii) the par value of our ordinary shares concerned has been reduced by an equal amount by way of an amendment of the articles of association.

Holders of the ADSs Resident in the Netherlands

Dividends paid by the company to holders of the ADSs that are resident or deemed to be resident in the Netherlands will be subject to Dutch dividend withholding tax.

A holder of the ADSs that is resident or deemed to be resident in the Netherlands is generally entitled, subject to the anti-dividend stripping rules described below, to a full credit against its (corporate) income tax liability, or a full refund, of the Dutch dividend withholding tax. The same generally applies to holders of the ADSs that are neither resident nor deemed to be resident in the Netherlands if the ADSs are attributable to a permanent establishment in the Netherlands of such non-resident holder.

Holders of the ADSs Resident Outside the Netherlands

A holder of the ADSs, who is an individual or that is a legal entity, another entity with a capital divided into shares, an association, a foundation or a fund or trust, not resident or deemed to be resident in the Netherlands for (corporate) income tax purposes, will not be subject to any Dutch dividend withholding tax on distributions made on the ADSs.

Taxes on Income and Capital Gains

Holders of the ADSs Resident in the Netherlands: Individuals

A holder of the ADSs, who is an individual resident or deemed to be resident in the Netherlands will be subject to regular Dutch income tax on the income derived from the ADSs and the gains realized upon the acquisition, redemption and/or disposal of the ADSs by the holder thereof, if:

- (a) such holder of the ADSs has an enterprise or an interest in an enterprise, to which enterprise the ADSs are attributable; and/or
- (b) such income or capital gain forms “a benefit from miscellaneous activities” (“*resultaat uit overige werkzaamheden*”) which, for instance, would be the case if the activities with respect to the ADSs exceed “normal active asset management” (“*normaal, actief vermogensbeheer*”) or if income and gains are derived from the holding, whether directly or indirectly, of (a combination of) shares, debt claims or other rights (together, a “lucrative interest” (“*lucratief belang*”)) that the holder thereof has acquired under such circumstances that such income and gains are intended to be remuneration for work or services performed by such holder (or a related person), whether within or outside an employment relation, where such lucrative interest provides the holder thereof, economically speaking, with certain benefits that have a relation to the relevant work or services.

If either of the abovementioned conditions (a) or (b) applies, income derived from the ADSs and the gains realized upon the acquisition, redemption and/or disposal of the ADSs will in general be subject to Dutch income tax at the progressive rates up to 51.95%.

If the abovementioned conditions (a) and (b) do not apply, a holder of the ADSs who is an individual, resident or deemed to be resident in the Netherlands will not be subject to taxes on income and capital gains in the Netherlands. Instead, such individual is generally taxed at a flat rate of 30% on deemed income from “savings and investments” (“*sparen en beleggen*”), which deemed income is determined on the basis of the amount included in the individual’s “yield basis” (“*rendementsgrondslag*”) at the beginning of the calendar year (minus a tax-free threshold). For the 2018 tax year, the deemed income derived from savings and investments will amount to 2.02% of the individual’s yield basis up to €70,800, 4.33% of the individual’s yield basis exceeding €70,800 up to and including €978,000 and 5.38% of the individual’s yield basis in excess of €978,000. The tax-free threshold for 2018 is €30,000.

Holders of the ADSs Resident in the Netherlands: Corporate Entities

A holder of the ADSs that is resident or deemed to be resident in the Netherlands for corporate income tax purposes, and that is:

- a corporation;

- another entity with a capital divided into shares;
- a cooperative (association); or
- another legal entity that has an enterprise or an interest in an enterprise to which the ADSs are attributable,

but which is not:

- a qualifying pension fund;
- a qualifying investment fund (*fiscale beleggingsinstelling*) or a qualifying exempt investment institution (*vrijgestelde beleggingsinstelling*); or
- another entity exempt from corporate income tax,

will in general be subject to regular corporate income tax, generally levied at a rate of 25% (20% over profits up to €200,000) over income derived from the ADSs and the gains realized upon the acquisition, redemption and/or disposal of the ADSs, unless, and to the extent that, the participation exemption (*deelnemingsvrijstelling*) applies.

Holders of the ADSs Resident Outside the Netherlands: Individuals

A holder of the ADSs who is an individual, not resident or deemed to be resident in the Netherlands will not be subject to any Dutch taxes on income derived from the ADSs and the gains realized upon the acquisition, redemption and/or disposal of the ADSs (other than the dividend withholding tax described above), unless:

- (a) such holder has an enterprise or an interest in an enterprise that is, in whole or in part, carried on through a permanent establishment (*vaste inrichting*) or a permanent representative (*vaste vertegenwoordiger*) in the Netherlands and to which enterprise or part of an enterprise, as the case may be, the ADSs are attributable; or
- (b) such income or capital gain forms a “benefit from miscellaneous activities in the Netherlands” (*“resultaat uit overige werkzaamheden in Nederland”*) which would for instance be the case if the activities in the Netherlands with respect to the ADSs exceed “normal active asset management” (*“normaal, actief vermogensbeheer”*) or if such income and gains are derived from the holding, whether directly or indirectly, of (a combination of) shares, debt claims or other rights (together, a “lucrative interest” (*“lucratief belang”*)) that the holder thereof has acquired under such circumstances that such income and gains are intended to be remuneration for work or services performed by such holder (or a related person), in whole or in part, in the Netherlands, whether within or outside an employment relation, where such lucrative interest provides the holder thereof, economically speaking, with certain benefits that have a relation to the relevant work or services.

If either of the abovementioned conditions (a) or (b) applies, income or capital gains in respect of dividends distributed by the company or in respect of any gains realized upon the acquisition, redemption and/or disposal of the ADSs will in general be subject to Dutch income tax at the progressive rates up to 51.95%.

Holders of the ADSs Resident Outside the Netherlands: Legal and Other Entities

A holder of the ADSs, that is a legal entity, another entity with a capital divided into shares, an association, a foundation or a fund or trust, not resident or deemed to be resident in the Netherlands for corporate income tax purposes, will not be subject to any Dutch taxes on income derived from the ADSs and the gains

realized upon the acquisition, redemption and/or disposal of the ADSs (other than the dividend withholding tax described above), unless:

- (a) such holder has an enterprise or an interest in an enterprise that is, in whole or in part, carried on through a permanent establishment (*vaste inrichting*) or a permanent representative (*vaste vertegenwoordiger*) in the Netherlands and to which enterprise or part of an enterprise, as the case may be, the ADSs are attributable; or
- (b) such holder has a substantial interest (*aanmerkelijk belang*) in the company, that (i) is held with the avoidance of Dutch income tax of another person as (one of) the main purpose(s) and (ii) forms part of an artificial structure or series of structures (such as structures which are not put into place for valid business reasons reflecting economic reality).

If one of the abovementioned conditions applies, income derived from the ADSs and the gains realized upon the acquisition, redemption and/or disposal of the ADSs will, in general, be subject to Dutch regular corporate income tax, levied at a rate of 25% (20% over profits up to €200,000), unless, and to the extent that, with respect to a holder as described under (a), the participation exemption (*deelnemingsvrijstelling*) applies.

Gift, Estate and Inheritance Taxes

Holders of the ADSs Resident in the Netherlands

Gift tax may be due in the Netherlands with respect to an acquisition of the ADSs by way of a gift by a holder of the ADSs who is resident or deemed to be resident of the Netherlands at the time of the gift.

Inheritance tax may be due in the Netherlands with respect to an acquisition or deemed acquisition of the ADSs by way of an inheritance or bequest on the death of a holder of the ADSs who is resident or deemed to be resident of the Netherlands, or by way of a gift within 180 days before his death by an individual who is resident or deemed to be resident in the Netherlands at the time of his death.

For purposes of Dutch gift and inheritance tax, an individual with the Dutch nationality will be deemed to be resident in the Netherlands if he has been resident in the Netherlands at any time during the ten years preceding the date of the gift or his death. For purposes of Dutch gift tax, an individual not holding the Dutch nationality will be deemed to be resident of the Netherlands if he has been resident in the Netherlands at any time during the twelve months preceding the date of the gift.

Holders of the ADSs Resident Outside the Netherlands

No gift, estate or inheritance taxes will arise in the Netherlands with respect to an acquisition of the ADSs by way of a gift by, or on the death of, a holder of the ADSs who is neither resident nor deemed to be resident of the Netherlands, unless, in the case of a gift of the ADSs by an individual who at the date of the gift was neither resident nor deemed to be resident in the Netherlands, such individual dies within 180 days after the date of the gift, while being resident or deemed to be resident in the Netherlands.

Certain Special Situations

For purposes of Dutch gift, estate and inheritance tax, (i) a gift by a Third Party will be construed as a gift by the Settlor, and (ii) upon the death of the Settlor, as a rule his/her Beneficiaries will be deemed to have inherited directly from the Settlor. Subsequently, such Beneficiaries will be deemed the settlor, grantor or similar originator of the Separated Private Assets for purposes of Dutch gift, estate and inheritance tax in case of subsequent gifts or inheritances.

For the purposes of Dutch gift and inheritance tax, a gift that is made under a condition precedent is deemed to have been made at the moment such condition precedent is satisfied. If the condition precedent is fulfilled after the death of the donor, the gift is deemed to be made upon the death of the donor.

Value Added Tax

No Dutch value added tax will arise in respect of or in connection with the subscription, issue, placement, allotment or delivery of the ADSs.

Other Taxes and Duties

No Dutch registration tax, capital tax, custom duty, transfer tax, stamp duty or any other similar documentary tax or duty, other than court fees, will be payable in the Netherlands in respect of or in connection with the subscription, issue, placement, allotment or delivery of the ADSs.

Residency

A holder of our ordinary shares will not be treated as a resident, or a deemed resident, of the Netherlands by reason only of the acquisition, or the holding, of the ADSs or the performance by the company under the ADSs.

Belgian Tax Consequences

The paragraphs below present a summary of certain Belgian federal income tax consequences of the ownership and disposal of ADSs by an investor that purchases such ADSs. The summary is based on laws, treaties and regulatory interpretations in effect in Belgium on the date of this annual report, all of which are subject to change, including changes that could have retroactive effect.

Investors should appreciate that, as a result of evolutions in law or practice, the eventual tax consequences may be different from what is stated below.

This summary does not purport to address all tax consequences of the ownership and disposal of ADSs, and does not take into account the specific circumstances of particular investors, some of which may be subject to special rules, or the tax laws of any country other than Belgium. This summary does not describe the tax treatment of investors that are subject to special rules, such as banks, insurance companies, collective investment undertakings, dealers in securities or currencies, persons that hold, or will hold, ADSs as a position in a straddle, share-repurchase transaction, conversion transactions, synthetic security or other integrated financial transactions. This summary does not address the local taxes that may be due in connection with an investment in shares, other than the additional municipal taxes which generally vary between 0% and 9% of the investor's income tax liability in Belgium.

Investors should consult their own advisors regarding the tax consequences of an investment in the ADSs in light of their particular situation, including the effect of any state, local or other national laws, treaties and regulatory interpretations thereof.

For purposes of this summary, a Belgian resident is an individual subject to Belgian personal income tax (that is, an individual who is domiciled in Belgium or has his seat of wealth in Belgium or a person assimilated to a resident for purposes of Belgian tax law), a company subject to Belgian corporate income tax (that is, a corporate entity that has its official seat, its main establishment, its administrative seat or seat of management in Belgium), an Organization for Financing Pensions subject to Belgian corporate income tax (that is a Belgian pension fund incorporated under the form of an Organization for Financing Pensions), or a legal entity subject to Belgian income tax on legal entities (that is, a legal entity other than a company subject to Belgian corporate income tax, that has its official seat, its main establishment, its administrative seat or seat of management in Belgium). A Belgian non-resident is any person that is not a Belgian resident.

Dividends

For Belgian income tax purposes, the gross amount of all benefits paid on or attributed to the ADSs is generally treated as a dividend distribution. By way of exception, the repayment of capital carried out in accordance with applicable Dutch company law provisions not treated as a dividend distribution to the extent that such repayment is imputed to fiscal capital. This fiscal capital includes, in principle, the actual paid-up statutory share capital and, subject to certain conditions, the paid-up share premiums and the cash amounts subscribed to at the time of the issue of profit sharing certificates. However, it is not possible to fully impute a repayment of capital to fiscal capital if the company also has certain reserves. Indeed, in such case, a reimbursement of capital is proratedly imputed on, on the one hand, fiscal capital and, on the other hand, taxed reserves (whether or not incorporated in capital) and tax-exempt reserves incorporated in capital (according to a specific priority rule). The part imputed on the reserves is treated as a dividend distribution subject to applicable tax rules.

Belgian withholding tax of 30% is normally levied on dividends by any intermediary established in Belgium that is in any way involved in the processing of the payment of non-Belgian sourced dividends (e.g. a Belgian financial institution). This withholding tax rate is subject to such relief as may be available under applicable domestic or tax treaty provisions.

The Belgian withholding tax is calculated on the dividend amount after deduction of any non-Belgian dividend withholding tax.

In the case of a redemption of the ADSs, the redemption distribution (after deduction of the part of the fiscal capital represented by the redeemed ADSs) will be treated as a dividend subject to a Belgian withholding tax of 30%, subject to such relief as may be available under applicable domestic or tax treaty provisions. No withholding tax will be triggered if this redemption is carried out on a stock exchange and meets certain conditions.

In the event of our liquidation, any amounts distributed in excess of the fiscal capital will in principle be subject to the 30% withholding tax, subject to such relief as may be available under applicable domestic or tax treaty provisions.

Under Belgian law, non-Belgian dividend withholding tax is not creditable against Belgian income tax and is not reimbursable to the extent that it exceeds Belgian income tax. Please refer to “Item 10.E.—Taxation—Dutch Tax consequences—Dividend Withholding Tax” for a description of withholding tax that may be imposed on dividends by the Netherlands.

Belgian Resident Individuals

For Belgian resident individuals who acquire and hold ordinary shares as a private investment, the Belgian dividend withholding tax fully discharges their personal income tax liability. They may nevertheless need to report the dividends in their personal income tax return if no intermediary established in Belgium was in any way involved in the processing of the payment of the non-Belgian sourced dividends. Moreover, even if an intermediary established in Belgium was involved, they can opt to report the income in their personal income tax return. If (and only if) the dividends are reported, they will normally be eligible for a tax exemption with respect to ordinary dividends in an amount of up to €800 per year and per taxpayer (Article 21, first subsection, 14°, of the Belgian Income Tax Code (“ITC”). For the avoidance of doubt, all reported dividends (not only dividends distributed on our ordinary shares) are taken into account to assess whether the said maximum amount is reached.

Where the beneficiary needs or, as applicable, opts to report them, dividends will normally be taxable at the lower of the generally applicable 30% Belgian withholding tax rate on dividends or, in case globalization is more advantageous, at the progressive personal income tax rates applicable to the taxpayer’s overall declared income. In addition, if the dividends are reported, the Belgian dividend withholding tax levied at source may be credited against the personal income tax due and is reimbursable to the extent that it exceeds the personal income tax due, provided that the dividend distribution does not result in a reduction in value of or a capital loss on our ordinary shares. The latter condition is not applicable if the individual can demonstrate that it has held ordinary

shares in full legal ownership for an uninterrupted period of 12 months prior to the payment or attribution of the dividends.

For Belgian resident individual investors who acquire and hold the ADSs for professional purposes, the Belgian withholding tax does not fully discharge their Belgian income tax liability. Dividends received must be reported by the investor and will, in such a case, be taxable at the investor's personal income tax rate increased with municipal surcharges. Belgian withholding tax levied may be credited against the personal income tax due and is reimbursable to the extent that it exceeds the income tax due, subject to two conditions: (i) the taxpayer must own the ADSs in full legal ownership on the dividend record date and (ii) the dividend distribution may not result in a reduction in value of or a capital loss on the ADSs. The latter condition is not applicable if the investor can demonstrate that it has held the full legal ownership of the ADSs for an uninterrupted period of 12 months prior to the payment or attribution of the dividends.

Belgian Resident Companies

Dividends received by Belgian resident companies are exempt from Belgian withholding tax provided that the investor satisfies the identification requirements in Article 117, par. 11 of the Royal Decree implementing the Belgian Income Tax Code.

For Belgian resident companies, the dividend income (after deduction of any non-Belgian withholding tax but including any Belgian withholding tax) must be declared in the corporate income tax return and will be subject to a corporate income tax rate of 29.58% (including a 2% crisis surcharge), unless the reduced corporate income tax rate of 20.4% (including a 2% crisis surcharge) on the first €100,000 of taxable profits for certain qualifying companies with limited profits applies. As of assessment year 2021 linked to a tax year starting on or after January 1, 2020, the standard corporate income tax rate is 25%, and the reduced rate is 20%.

Belgian resident companies can generally (although subject to certain limitations) deduct 100% of the gross dividend received from their taxable income, or the Dividend Received Deduction, provided that at the time of a dividend payment or attribution: (i) the Belgian resident company holds ordinary shares representing at least 10% of our share capital or a participation with an acquisition value of at least €2,500,000 (it being understood that only one out of the two tests must be satisfied); (ii) the shares representing our share capital have been or will be held in full ownership for an uninterrupted period of at least one year; and (iii) the conditions described in Article 203 of the ITC (relating to the taxation of the underlying distributed income and the absence of abuse), or the Article 203 of the ITC Taxation Condition, are met, or together, the Conditions for the application of the dividend received deduction regime.

The Conditions for the application of the dividend received deduction regime depend on a factual analysis and for this reason the availability of this regime should be verified upon each dividend distribution.

Any Belgian dividend withholding tax levied at source can be credited against the ordinary Belgian corporate income tax and is reimbursable to the extent it exceeds such corporate income tax, subject to two conditions: (i) the taxpayer must own the ADSs in full legal ownership on the dividend record date and (ii) the dividend distribution does not result in a reduction in value of or a capital loss on the ADSs. The latter condition is not applicable: (i) if the taxpayer can demonstrate that it has held the ADSs in full legal ownership for an uninterrupted period of 12 months immediately prior to the payment or attribution of the dividends or (ii) if, during that period, the ADSs never belonged to a taxpayer other than a Belgian resident company or a non-resident company that has, in an uninterrupted manner, invested the ADSs in a permanent establishment, or PE, in Belgium.

Organizations for Financing Pensions

For organizations for financing pensions, or OFPs, i.e., Belgian pension funds incorporated under the form of an OFP (*organisme de financement de pensions/organisme voor de financiering van pensioenen*) within the meaning of Article 8 of the Belgian Law of October 27, 2006, dividend income generally does not constitute taxable income.

Dividends distributed through the intervention of a Belgian intermediary are generally subject to Belgian dividend withholding tax. If dividends are paid or attributed without the intervention of a Belgian intermediary, the applicable Belgian withholding tax will have to be reported and paid by the OFP to the Belgian tax administration.

The Belgian dividend withholding tax can in principle be credited against the OFPs' corporate income tax and is reimbursable to the extent it exceeds the corporate income tax due. However, such Belgian withholding cannot be credited by an OFP if the shares on which the dividends are paid have not been held uninterruptedly in full ownership for at least 60 days, unless the OFP demonstrates that the dividends are not connected to an arrangement (or a series of arrangements) that is not genuine ("kunstmatig"/"pas authentique") and has been put in place for the main purpose or one of the main purposes of obtaining this withholding tax credit.

Other Taxable Legal Entities

For taxpayers subject to the Belgian income tax on legal entities, the Belgian dividend withholding tax in principle fully discharges their income tax liability.

Belgian Non-Resident Individuals and Companies

Dividend payments on the ADSs through a professional intermediary in Belgium will, in principle, be subject to the 30% withholding tax, unless the shareholder is resident in a country with which Belgium has concluded a double taxation agreement and delivers the requested affidavit. Non-resident investors can also obtain an exemption of Belgian dividend withholding tax if they are the owners or usufructors of the ADSs and they deliver an affidavit confirming that they have not allocated the ADSs to business activities in Belgium and that they are non-residents, provided that the dividend is paid through a Belgian credit institution, stock market company or recognized clearing or settlement institution.

If the ADSs are acquired by a non-resident investor in connection with a business in Belgium, the investor must report any dividends received, which are taxable at the applicable non-resident individual or corporate income tax rate, as appropriate. Any Belgian withholding tax levied at source can be credited against the non-resident individual or corporate income tax and is reimbursable to the extent it exceeds the income tax due, subject to two conditions: (i) the taxpayer must own the ADSs in full legal ownership on the dividend record date and (ii) the dividend distribution does not result in a reduction in value of or a capital loss on the ADSs. The latter condition is not applicable if (i) the non-resident individual or the non-resident company can demonstrate that the ADSs were held in full legal ownership for an uninterrupted period of 12 months immediately prior to the payment or attribution of the dividends or (ii) with regard to non-resident companies only, if, during the said period, the ADSs have not belonged to a taxpayer other than a resident company or a non-resident company which has, in an uninterrupted manner, invested the ADSs in a Belgian PE.

Non-resident companies that have invested the ADSs in a Belgian establishment can deduct 100% of the gross dividends included in their taxable profits if, at the date dividends are paid or attributed, the Conditions for the application of the Dividend Received Deduction regime are satisfied. Application of the Dividend Received Deduction regime depends, however, on a factual analysis to be made upon each distribution and its availability should be verified upon each distribution.

Capital Gains and Losses on ADSs

Belgian Resident Individuals

In principle, Belgian resident individuals acquiring the ADSs as a private investment should not be subject to Belgian capital gains tax on the disposal of the ADSs; capital losses are not tax deductible.

Capital gains realized in a private (*i.e.*, non-professional) context on the transfer for consideration of shares by a private individual, are taxable at 33% (plus local surcharges) if the capital gain is deemed to be realized

outside the scope of the normal management of the individual's private estate. Capital losses are, however, not tax deductible in such event.

Gains realized by Belgian resident individuals upon the redemption of the ADSs or upon our liquidation are generally taxable as a dividend.

Belgian resident individuals who hold the ADSs for professional purposes are taxable at the ordinary progressive personal income tax rates (plus local surcharges) on any capital gains realized upon the disposal of the ADSs, except for ordinary shares held for more than five years, which are taxable at a flat rate of 16.5% (plus local surcharges). Capital losses on the ordinary shares incurred by Belgian resident individuals who hold the ADSs for professional purposes are in principle tax deductible.

Belgian Resident Companies

Belgian resident companies are normally not subject to Belgian capital gains taxation on gains realized upon the disposal of our ADSs provided that (i) the shares represent at least 10% of our share capital or a participation with an acquisition value of at least € 2,500,000 (it being understood that only one out of the two tests must be satisfied), (ii) the Article 203 ITC Taxation Condition is satisfied and (iii) the ADSs have been held in full legal ownership for an uninterrupted period of at least one year immediately preceding the disposal.

If the one-year minimum holding condition would not be satisfied (but the other conditions are) the capital gains realized upon the disposal of our ADSs by a Belgian resident company are taxable at a flat corporate income tax rate of, currently, 25.5% (including the 2% crisis surcharge). As of assessment year 2021 linked to a tax year starting on or after January 1, 2020, the tax rate in this case will be equal to the 25% standard tax rate.

If the Article 203 ITC Taxation Condition is not satisfied or the participation condition is not met, the capital gains are taxable at the standard corporate tax rate (of 29.58% currently and of 25% as of assessment year 2021 linked to a tax year starting on or after January 1, 2020), unless the reduced corporate income tax rate applies.

Capital losses on our ADSs incurred by resident companies are as a general rule not tax deductible.

Our ADSs held in the trading portfolios (*portefeuille commercial/handelsportefeuille*) of qualifying credit institutions, investment enterprises and management companies of collective investment undertakings which are subject to the Royal Decree of 23 September 1992 on the annual accounts of credit institutions, investment firms and management companies of collective investment undertakings (*comptes annuels des établissements de crédit, des entreprises d'investissement et des sociétés de gestion d'organismes de placement collectif/jaarrekening van de kredietinstellingen, de beleggingsondernemingen en de beheervennootschappen van instellingen voor collectieve belegging*) are subject to a different regime. The capital gains on such shares are taxable at the ordinary corporate income tax rate of 29.58% (including the 2% crisis surcharge), which is reduced to 25% as of assessment year 2021 linked to a tax year starting on or after January 1, 2020. Capital losses on such shares are tax deductible. Internal transfers to and from the trading portfolio are assimilated to a realization.

Capital gains realized by Belgian resident companies (both non-SMEs and SMEs and both ordinary Belgian resident companies and qualifying credit institutions, investment enterprises and management companies of collective investment undertakings) upon the redemption of our ADSs or upon our liquidation are, in principle, subject to the same taxation regime as dividends. See "Item 10.E.—Taxation—Dividends."

Organizations for Financing Pensions

OFPs are, in principle, not subject to Belgian capital gains taxation realized upon the disposal of the ADSs, and capital losses are not tax deductible.

Other Taxable Legal Entities

Belgian resident legal entities subject to the legal entities income tax are, in principle, not subject to Belgian capital gains taxation on the disposal of ADSs.

Capital gains realized by Belgian resident legal entities upon the redemption of ADSs or upon our liquidation will in principle be taxed as dividends.

Capital losses on ADSs incurred by Belgian resident legal entities are not tax deductible.

Belgian Non-Resident Individuals and Companies

Non-resident individuals or companies are, in principle, not subject to Belgian income tax on capital gains realized upon disposal of the ADSs, unless such ADSs are held as part of a business conducted in Belgium through a Belgian establishment. In such a case, the same principles apply as described with regard to Belgian individuals (holding the shares for professional purposes) or Belgian companies.

Non-resident individuals who do not use the shares for professional purposes and who have their fiscal residence in a country with which Belgium has not concluded a tax treaty or with which Belgium has concluded a tax treaty that confers the authority to tax capital gains on the ADSs to Belgium, might be subject to tax in Belgium if the capital gains arise from transactions which are to be considered speculative or beyond the normal management of one's private estate. See "Item 10.E.—Taxation—Capital gains and losses on ADSs—Belgian resident individuals." Such non-resident individuals might therefore be obliged to file a tax return and should consult their own tax advisor.

Capital gains realized by non-resident individuals or non-resident companies upon repurchase of the shares or upon our liquidation will, in principle, be subject to the same taxation regime as dividends.

Tax on Stock Exchange Transactions

Upon the issue of the ADSs (primary market), no Tax on Stock Exchange Transactions ("*taks op de beursverrichtingen*" / "*taxe sur les opérations de bourse*") is due.

The purchase and the sale and any other acquisition or transfer for consideration of ADSs (secondary market transactions) is subject to the Tax on Stock Exchange Transactions if (i) it is executed in Belgium through a professional intermediary, or (ii) deemed to be executed in Belgium, which is the case if the order is directly or indirectly made to a professional intermediary established outside of Belgium, either by private individuals with habitual residence in Belgium, or legal entities for the account of their seat or establishment in Belgium (both, a Belgian Investor).

The Tax on Stock Exchange Transactions is levied at a rate of 0.35% of the purchase price, capped at €1,600 per transaction and per party.

A separate tax is due by each party to the transaction, and both taxes are collected by the professional intermediary. However, if the intermediary is established outside of Belgium, the tax will in principle be due by the Belgian Investor, unless that Belgian Investor can demonstrate that the tax has already been paid. Professional intermediaries established outside of Belgium can, subject to certain conditions and formalities, appoint a Belgian Stock Exchange Tax Representative, which will be liable for the Tax on Stock Exchange Transactions in respect of the transactions executed through the professional intermediary. If the Stock Exchange Tax Representative would have paid the Tax on Stock Exchange Transactions due, the Belgian Investor will, as per the above, no longer be the debtor of the Tax on Stock Exchange Transactions.

No tax on stock exchange transactions is due on transactions entered into by the following parties, provided they are acting for their own account: (i) professional intermediaries described in Article 2,9° and 10° of

the Belgian Law of August 2, 2002; (ii) insurance companies described in Article 2, §1 of the Belgian Law of July 9, 1975; (iii) professional retirement institutions referred to in Article 2,1° of the Belgian Law of October 27, 2006 concerning the supervision on institutions for occupational pension; (iv) collective investment institutions; (v) regulated real estate companies; and (vi) Belgian non-residents provided they deliver a certificate to their financial intermediary in Belgium confirming their non-resident status.

The EU Commission adopted on February 14, 2013 the Draft Directive on a Financial Transaction Tax, or FTT. The Draft Directive currently stipulates that once the FTT enters into force, the Participating Member States shall not maintain or introduce taxes on financial transactions other than the FTT (or VAT as provided in the Council Directive 2006/112/EC of November 28, 2006 on the common system of value added tax). For Belgium, the tax on stock exchange transactions should thus be abolished once the FTT enters into force. The Draft Directive regarding the FTT is still subject to negotiation between the Participating Member States and therefore may be changed at any time.

Tax on Securities Accounts

On March 10, 2018, the law on the introduction of a tax on securities accounts entered into force. Pursuant to this law, Belgian resident and non-resident individuals are taxed at a rate of 0.15 percent. on their share in the average value of qualifying financial instruments (such as our ordinary shares and other shares, bonds, certain other type of debt instruments, units of undertakings for collective investment, warrants) held on one or more securities accounts during a reference period of 12 consecutive months starting on October 1 and ending on September 30 of the subsequent year. ("Tax on Securities Accounts").

No Tax on Securities Accounts is due provided the holder's share in the average value of the qualifying financial instruments on those accounts amounts to less than €500,000. If, however, the holder's share in the average value of the qualifying financial instruments on those accounts amounts to €500,000 or more, the Tax on Securities Accounts is due on the entire share of the holder in the average value of the qualifying financial instruments on those accounts (and hence, not only on the part which exceeds the €500,000 threshold).

Qualifying financial instruments held by non-resident individuals only fall within the scope of the Tax on Securities Accounts provided they are held on securities accounts with a financial intermediary established or located in Belgium. Note that pursuant to certain double tax treaties, Belgium has no right to tax capital. Hence, to the extent the Tax on Securities Accounts is viewed as a tax on capital within the meaning of these double tax treaties, incompatibility of the Tax on Securities Accounts with a treaty may, subject to certain conditions, be claimed.

The Tax on Securities Accounts is in principle due by the financial intermediary established or located in Belgium if (i) the holder's share in the average value of the qualifying financial instruments held on one or more securities accounts with said intermediary amounts to €500,000 or more; or (ii) the holder instructed the financial intermediary to levy the Tax on Securities Accounts due (e.g. in case such holder holds qualifying financial instruments on several securities accounts held with multiple intermediaries of which the average value does not amount to €500,000 or more but of which the holder's share in the total average value of these accounts exceeds €500,000). Otherwise, the Tax on Securities Accounts must be declared and is due by the holder itself, unless the holder provides evidence that the Tax on Securities Accounts has already been withheld, declared and paid by an intermediary which is not established or located in Belgium. In that respect, intermediaries located or established outside of Belgium could appoint a Tax on the Securities Accounts representative in Belgium, subject to certain conditions and formalities. Such a Tax on the Securities Accounts Representative is then liable towards the Belgian Treasury for the Tax on the Securities Accounts due and for complying with certain reporting obligations in that respect.

Prospective investors are advised to seek their own professional advice in relation to the Tax on Securities Accounts.

Belgian Taxation Upon Completion of Our Possible Redomiciliation

The summary below presents certain Belgian federal income tax consequences of the ownership and disposal of ADSs by an investor that purchases such ADSs, if and when our possible redomiciliation is completed. The summary is based on laws, treaties and regulatory interpretations in effect in Belgium on the date of this annual report, all of which are subject to change, including changes that could have retroactive effect.

Investors should appreciate that, as a result of evolutions in law or practice, the eventual tax consequences may be different from what is stated below.

This summary does not purport to address all tax consequences of the ownership and disposal of ADSs, and does not take into account the specific circumstances of particular investors, some of which may be subject to special rules, or the tax laws of any country other than Belgium. This summary does not describe the tax treatment of investors that are subject to special rules, such as banks, insurance companies, collective investment undertakings, dealers in securities or currencies, persons that hold, or will hold, ADSs as a position in a straddle, share-repurchase transaction, conversion transactions, synthetic security or other integrated financial transactions. This summary does not address the local taxes that may be due in connection with an investment in shares, other than the additional municipal taxes which generally vary between 0% and 9% of the investor's income tax liability in Belgium.

Investors should consult their own advisors regarding the tax consequences of an investment in the ADSs in light of their particular situation, including the effect of any state, local or other national laws, treaties and regulatory interpretations thereof.

For purposes of this summary, a Belgian resident is an individual subject to Belgian personal income tax (that is, an individual who is domiciled in Belgium or has his seat of wealth in Belgium or a person assimilated to a resident for purposes of Belgian tax law), a company subject to Belgian corporate income tax (that is, a corporate entity that has its official seat, its main establishment, its administrative seat or seat of management in Belgium), an Organization for Financing Pensions subject to Belgian corporate income tax (that is a Belgian pension fund incorporated under the form of an Organization for Financing Pensions), or a legal entity subject to Belgian income tax on legal entities (that is, a legal entity other than a company subject to Belgian corporate income tax, that has its official seat, its main establishment, its administrative seat or seat of management in Belgium). A Belgian non-resident is any person that is not a Belgian resident.

Dividends

For Belgian income tax purposes, the gross amount of all benefits paid on or attributed to ADSs is generally treated as a dividend distribution. By way of exception, the repayment of capital carried out in accordance with the Belgian Companies Code is not treated as a dividend distribution to the extent such repayment is imputed to fiscal capital. This fiscal capital includes, in principle, the actual paid-up statutory share capital and, subject to certain conditions, the paid-up share premiums and the cash amounts subscribed to at the time of the issue of profit sharing certificates. However, it is not possible to fully impute a repayment of capital to fiscal capital if the company also has certain reserves. Indeed, in such case, a reimbursement of capital is proratedly imputed on, on the one hand, fiscal capital and, on the other hand, on taxed reserves (whether or not incorporated in capital) and tax-exempt reserves incorporated in capital (in accordance with a certain priority rule). The part imputed on reserves would be treated as a dividend distribution subject to applicable tax rules.

Belgian dividend withholding tax of 30% is levied on dividends, subject to such relief as may be available under applicable domestic or tax treaty provisions.

In the case of a redemption of the ADSs, the redemption distribution (after deduction of the part of the fiscal capital represented by the redeemed ADSs) will be treated as a dividend subject to Belgian withholding tax of 30%, subject to such relief as may be available under applicable domestic or tax treaty provisions. No withholding tax will be triggered if this redemption is carried out on a stock exchange and meets certain conditions.

In the event of our liquidation, any amounts distributed in excess of the fiscal capital will in principle be subject to the 30% withholding tax, subject to such relief as may be available under applicable domestic or tax treaty provisions.

Belgian Resident Individuals

For Belgian resident individuals who acquire and hold ADSs as a private investment, the Belgian dividend withholding tax fully discharges their personal income tax liability. They may nevertheless elect to report the dividends in their personal income tax return. If (and only if) the dividends are reported, they will normally be eligible for a tax exemption with respect to ordinary dividends in an amount of up to €800 per year and per taxpayer (Article 21, first subsection, 14°, ITC). For the avoidance of doubt, all reported dividends (not only dividends distributed on our ordinary shares) are taken into account to assess whether the said maximum amount is reached.

Where the beneficiary opts to report them, dividends will normally be taxable at the lower of the generally applicable 30% Belgian withholding tax rate on dividends, or in case globalization is more advantageous, at the progressive personal income tax rates applicable to the taxpayer's overall declared income. In addition, if the dividends are reported, the Belgian dividend withholding tax levied at source may be credited against the personal income tax due and is reimbursable to the extent that it exceeds the personal income tax due, provided that the dividend distribution does not result in a reduction in value of or a capital loss on the ADSs. The latter condition is not applicable if the individual can demonstrate that it has held the ADSs in full legal ownership for an uninterrupted period of 12 months prior to the payment or attribution of the dividends.

For Belgian resident individual investors who acquire and hold the ADSs for professional purposes, the Belgian withholding tax does not fully discharge their Belgian income tax liability. Dividends received must be reported by the investor and will, in such a case, be taxable at the investor's personal income tax rate increased with municipal surcharges. Belgian withholding tax levied may be credited against the personal income tax due and is reimbursable to the extent that it exceeds the income tax due, subject to two conditions: (i) the taxpayer must own the ADSs in full legal ownership on the dividend record date, and (ii) the dividend distribution may not result in a reduction in value of or a capital loss on the ADSs. The latter condition is not applicable if the investor can demonstrate that it has held the full legal ownership of the ADSs for an uninterrupted period of 12 months prior to the payment or attribution of the dividends.

Belgian Resident Companies

Corporate Income Tax

For Belgian resident companies, the dividend withholding tax does not fully discharge corporate income tax liability. The gross dividend income (including any Belgian withholding tax) must be declared in the corporate income tax return and will be subject to a corporate income tax rate of 29.58% (including a 2% crisis surcharge), unless the reduced corporate income tax rate of 20.4% (including a 2% crisis surcharge) on the first €100,000 of taxable profits for certain qualifying companies with limited profits applies. As of assessment year 2021 linked to a tax year starting on or after January 1, 2020, the standard corporate income tax rate is 25% and the reduced rate is 20%.

Belgian resident companies can generally (although subject to certain limitations) deduct 100% of the gross dividend received from their taxable income, or the Dividend Received Deduction, provided that at the time of a dividend payment or attribution: (i) the Belgian resident company holds shares representing at least 10% of our share capital or a participation in our shares with an acquisition value of at least € 2,500,000 (it being understood

that only one out of the two tests must be satisfied); (ii) the shares representing our share capital have been or will be held in full ownership for an uninterrupted period of at least one year immediately prior to the payment or attribution of the dividend; and (iii) the conditions described in Article 203 of the ITC (relating to the taxation of the underlying distributed income and the absence of abuse), or the Article 203 ITC Taxation Condition, are met, or together, the Conditions for the application of the dividend received deduction regime). Under certain circumstances the conditions referred to under (i) and (ii) do not need to be fulfilled in order for the Dividend Received Deduction to apply.

The Conditions for the application of the dividend received deduction regime depend on a factual analysis and for this reason the availability of this regime should thus be verified upon each dividend distribution.

Any Belgian dividend withholding tax levied at source can be credited against the ordinary Belgian corporate income tax and is reimbursable to the extent it exceeds such corporate income tax, subject to two conditions: (i) the taxpayer must own the ADSs in full legal ownership on the dividend record date and (ii) the dividend distribution does not result in a reduction in value of or a capital loss on the ADSs. The latter condition is not applicable if: (i) the taxpayer can demonstrate that it has held the ADSs in full legal ownership for an uninterrupted period of 12 months immediately prior to the payment or attribution of the dividends or (ii) during that period, the ADSs never belonged to a taxpayer other than a Belgian resident company or a non-resident company that has, in an uninterrupted manner, invested the ADSs in a permanent establishment, or PE, in Belgium.

Withholding Tax

Dividends distributed to a Belgian resident company will be exempt from Belgian withholding tax provided that the Belgian resident company holds, upon payment or attribution of the dividends, at least 10% of our share capital and such minimum participation is or will be held for an uninterrupted period of at least one year.

In order to benefit from this exemption, the investor must provide us or our paying agent with a certificate confirming its qualifying status and the fact that it satisfies the two conditions set out above. If the investor holds a qualifying participation for less than one uninterrupted year, at the time the dividends are paid or attributed, we will levy the withholding tax but not transfer it to the Belgian Treasury provided the investor certifies its qualifying status, the date from which it has held such minimum participation, and its commitment to hold the qualifying participation for an uninterrupted period of at least one year. The investor must also inform us or our paying agent when the one-year period expires or if its shareholding will drop below 10% of our share capital before the end of the one-year holding period. Upon satisfying the one-year shareholding requirement, the levied dividend withholding tax will be refunded to the investor.

The above withholding tax exemption will not be applicable to dividends which are connected to an arrangement or a series of arrangements (*“rechtshandeling of geheel van rechtshandelingen”/ “acte juridique ou un ensemble d’actes juridiques”*) for which the Belgian tax administration, taking into account all relevant facts and circumstances, has proven, unless evidence to the contrary, that this arrangement or this series of arrangements is not genuine (*“kunstmatig”/ “non authentique”*) and has been put in place for the main purpose or one of the main purposes of obtaining the dividend received deduction, the above dividend withholding tax exemption or one of the advantages of the EU Parent-Subsidiary Directive of November 30, 2011 (2011/96/EU), or the Parent-Subsidiary Directive, in another Member State of the European Union. An arrangement or a series of arrangements is regarded as not genuine to the extent that they are not put into place for valid commercial reasons which reflect economic reality.

Organizations for Financing Pensions

For OFPs, the dividend income is generally tax-exempt. Dividends distributed on our shares to OFPs are in principle subject to 30% Belgian withholding tax. This Belgian dividend withholding tax can be credited against an OFP's corporate income tax and is reimbursable to the extent it exceeds the corporate income tax due, provided that the shares on which the dividends are paid have been held uninterruptedly in full ownership for at least 60 days. The latter condition does not apply if the OFP demonstrates that the dividends are not connected to an

arrangement (or a series of arrangements) that is not genuine (“*kunstmatig*”/“*pas authentique*”) and has been put in place for the main purpose or one of the main purposes of obtaining this withholding tax credit.

Other Taxable Legal Entities

For taxpayers subject to the Belgian income tax on legal entities, the Belgian dividend withholding tax in principle fully discharges their income tax liability.

Belgian Non-Resident Individuals and Companies

Non-resident Income Tax

For non-resident individuals and companies, dividend withholding tax will be the only tax on dividends in Belgium, unless the non-resident holds ADSs in connection with a business conducted in Belgium through a fixed base in Belgium or a Belgian PE.

If the ADSs are acquired by a non-resident investor in connection with a business in Belgium, the investor must report any dividends received, which are taxable at the applicable non-resident individual or corporate income tax rate, as appropriate. Any Belgian withholding tax levied at source can be credited against the non-resident individual or corporate income tax and is reimbursable to the extent it exceeds the income tax due, subject to two conditions: (i) the taxpayer must own the ADSs in full legal ownership on the dividend record date and (ii) the dividend distribution does not result in a reduction in value of or a capital loss on the ADSs. The latter condition is not applicable if (i) the non-resident individual or the non-resident company can demonstrate that the ADSs were held in full legal ownership for an uninterrupted period of 12 months immediately prior to the payment or attribution of the dividends or (ii) with regard to non-resident companies only, if, during the said period, the ADSs have not belonged to a taxpayer other than a resident company or a non-resident company which has, in an uninterrupted manner, invested the ADSs in a Belgian PE.

Non-resident companies that have invested the ADSs in a Belgian establishment can deduct 100% of the gross dividends included in their taxable profits if, at the date dividends are paid or attributed, the Conditions for the application of the Dividend Received Deduction regime are satisfied. See “Belgian resident companies.” Application of the Dividend Received Deduction regime depends, however, on a factual analysis to be made upon each distribution and its availability should be verified upon each distribution.

Belgian Dividend Withholding Tax Relief for Non-residents

Dividends distributed to non-resident individuals who do not use the Shares in the exercise of a professional activity, may be eligible for a tax exemption with respect to ordinary dividends in an amount of up to €800 per year and per taxpayer (Article 21, first subsection, 14°, of the ITC). For the avoidance of doubt, all dividends (not only dividends distributed on our ordinary shares) are taken into account to assess whether the said maximum amount is reached. Consequently, if Belgian withholding tax has been withheld on dividends eligible for the exemption and up to the maximum amount, such non-resident individual may claim reimbursement of such withholding tax from the competent tax service or, if the non-resident is required to file a tax return, may request in such tax return that such withholding tax be credited and, as the case may be, reimbursed.

Under Belgian tax law, Belgian withholding tax is not due on dividends paid to a foreign pension fund which satisfies the following conditions: (i) it is a non-resident saver in the meaning of Article 227, 3° ITC which implies that it has separate legal personality and fiscal residence outside of Belgium; (ii) whose corporate purpose consists solely in managing and investing funds collected in order to pay legal or complementary pensions; (iii) whose activity is limited to the investment of funds collected in the exercise of its corporate purpose, without any profit making aim; (iv) which is exempt from income tax in its country of residence; and (v) except in specific circumstances provided that it is not contractually obligated to redistribute the dividends to any ultimate beneficiary of such dividends for whom it would manage the ADS, nor obligated to pay a manufactured dividend with respect to the shares under a securities borrowing transaction. This withholding tax exemption, however, does

not apply if the pension fund has not held the shares on which dividends are distributed uninterruptedly in full ownership for at least 60 days, unless the pension fund demonstrates that the arrangement (or series of arrangements) with which the dividend is connected is genuine (“*niet kunstmatig*”/“*authentique*”). The exemption will only apply if the foreign pension fund provides a certificate confirming that it is the full legal owner or usufruct holder of the ADS and that the above conditions are satisfied. The foreign pension fund must then provide us or our paying agent with that certificate.

Dividends distributed to non-resident qualifying parent companies established in a Member State of the European Union or in a country with which Belgium has concluded a double tax treaty that includes a qualifying exchange of information clause, will, under certain conditions, be exempt from Belgian withholding tax provided that the ADS held by the non-resident company, upon payment or attribution of the dividends, amount to at least 10% of our share capital and such minimum participation is held or will be held during an uninterrupted period of at least one year. A company qualifies as a parent company provided that (i) for companies established in a Member State of the European Union, it has a legal form as listed in the annex to the Parent-Subsidiary Directive, or, for companies established in a country with which Belgium has concluded a qualifying double tax treaty, it has a legal form similar to the ones listed in such annex; (ii) it is considered to be a tax resident of the country where it is established according to the tax laws of such country and the double tax treaties concluded between such country and third countries; and (iii) it is in such country subject to corporate income tax or a similar tax without benefiting from a tax regime that derogates from the ordinary tax regime.

In order to benefit from this exemption, the non-resident company must provide us or our paying agent with a certificate confirming its qualifying status and the fact that it meets the required conditions.

If the non-resident company holds a minimum participation for less than one year at the time the dividends are paid or attributed to the ADS, we will levy the Belgian withholding tax but not transfer it to the Belgian Treasury provided that the non-resident company provides us or our paying agent at the latest upon the attribution of the dividends with a certificate confirming, in addition to its qualifying status, the date as of which it has held the minimum participation, and its commitment to hold the minimum participation for an uninterrupted period of at least one year. The non-resident company must also inform us or our paying agent if the one-year period has expired or if its shareholding drops below 10% of our share capital before the end of the one-year holding period. Upon satisfying the one-year holding requirement, the dividend withholding tax which was temporarily withheld, will be refunded to the non-resident company.

The above withholding tax exemptions will not be applicable to dividends which are connected to an arrangement or a series of arrangements (“*rechtshandeling of geheel van rechtshandelingen*”/ “*acte juridique ou un ensemble d’actes juridiques*”) for which the Belgian tax administration, taking into account all relevant facts and circumstances, has proven, unless evidence to the contrary, that this arrangement or this series of arrangements is not genuine (“*kunstmatig*”/“*non authentique*”) and has been put in place for the main purpose or one of the main purposes of obtaining the dividend received deduction, the above dividend withholding tax exemptions or one of the advantages of the Parent-Subsidiary Directive in another Member State of the European Union. An arrangement or a series of arrangements is regarded as not genuine to the extent that they are not put into place for valid commercial reasons which reflect economic reality.

Dividends distributed to non-resident companies are exempt from Belgian withholding tax, in case (i) the non-resident company is established in the European Economic Area or in a country with which Belgium has concluded a tax treaty that includes a qualifying exchange of information clause, (ii) the non-resident company and the dividend distributing company are subject to corporate income tax or a similar tax without benefiting from a tax regime that derogates from the ordinary tax regime, (iii) the non-resident company has a participation in our share capital with an acquisition value of at least €2,500,000 but representing less than 10% of our share capital on the date the dividend is paid on or attributed, (iv) the dividends relate to shares which are or will be held in full ownership for at least one year without interruption and (v) the non-resident company has a legal form as listed in the annex to the Parent-Subsidiary Directive, as amended by Directive 2014/86/EU of July 8, 2014, or, has a legal form similar to the ones listed in such annex that is governed by the laws of another Member State of the EEA, or, has a legal form similar to the ones listed in such annex in a country with which Belgium has concluded a

qualifying double tax treaty. This exemption only applies to the extent that the ordinary Belgian withholding tax is, in principle, neither creditable nor reimbursable in the hands of the non-resident company.

In order to benefit from this exemption, the investor must provide us or our paying agent with a certificate confirming (i) it is established in another EEA Member State or in a State with which Belgium has concluded a tax treaty, provided that the tax treaty or any other treaty provides for the exchange of information which is necessary to give effect to the provisions of the domestic laws of the Contracting States, (ii) it has a legal form as listed in the Annex I, part A of the Parent-Subsidiary Directive, as amended by Directive 2014/86/EU of July 8, 2014, or a legal form similar to the ones listed in said Annex and governed by the laws of the EEA Member State, or a legal form similar to the ones listed in said Annex in a country with which Belgium has concluded a tax treaty, (iii) it is subject to corporate income tax or a similar tax without benefiting from a tax regime that deviates from the ordinary domestic tax regime, (iv) it holds a participation of less than 10% in our share capital but with an acquisition value of at least €2,500,000 on the date the dividend is paid on or attributed, (v) the dividends relate to shares which it has held or will hold in full legal ownership for an uninterrupted period of at least one year, (vi) it cannot in principle credit the Belgian withholding tax paid on the dividends or obtain a refund thereof according to the legal provisions in force on December 31 of the year preceding the year of the payment or attribution of the dividends. We or our paying agent may also request confirmation from the investor that the investor commits to keep the shares until the completion of the minimum holding period of one year and that the investor immediately notifies us or our paying agent of the completion of said one year holding period. The investor must furthermore provide on the certificate its full name, legal form, address and tax identification number, if applicable.

Belgium has concluded tax treaties with more than 90 countries, reducing the Belgian dividend withholding tax rate to 20%, 15%, 10%, 5% or 0% for residents of those countries, depending on conditions, among others, related to the size of the shareholding and certain identification formalities. Such reduction may be obtained either directly at source or through a refund of taxes withheld in excess of the applicable tax treaty rate.

Prospective holders should consult their own tax advisers to determine whether they qualify for a reduction of Belgian withholding tax and, if so, to understand the procedural requirements for obtaining a reduced rate of Belgian withholding tax upon the payment of dividends or for making claims for reimbursement.

Capital Gains and Losses on ADSs

Belgian Resident Individuals

In principle, Belgian resident individuals acquiring the ADSs as a private investment should not be subject to Belgian capital gains tax on the disposal of the ADSs; capital losses are not tax deductible.

Capital gains realized in a private (*i.e.*, non-professional) context on the transfer for consideration of shares by a private individual, are taxable at 33% (plus local surcharges) if the capital gain is deemed to be realized outside the scope of the normal management of the individual's private estate. Capital losses are, however, not tax deductible in such event.

Capital gains realized by Belgian resident individuals on the disposal of the shares to a non-resident company (or body constituted in a similar legal form), to a foreign state (or one of its political subdivisions or local authorities) or to a non-resident legal entity, each time established outside the European Economic Area, are taxable at a rate of 16.5% (plus local surcharges) if, at any time during the five years preceding the sale, the Belgian resident individual has owned, directly or indirectly, alone or with his/her spouse or with certain relatives, a substantial shareholding in us (*i.e.*, a shareholding of more than 25% in our shares). Capital losses are, however, not tax deductible in such event.

Gains realized by Belgian resident individuals upon the redemption of ADSs or upon our liquidation are generally taxable as a dividend. See "Dividends—Belgian resident individuals."

Belgian resident individuals who hold the ADSs for professional purposes are taxable at the ordinary progressive personal income tax rates (plus local surcharges) on any capital gains realized upon the disposal of the ADSs, except for ADSs held for more than five years, which are taxable at a flat rate of 16.5% (plus local surcharges). Capital losses on the ADSs incurred by Belgian resident individuals who hold the ADSs for professional purposes are in principle tax deductible.

Belgian Resident Companies

Belgian resident companies are normally not subject to Belgian capital gains taxation on gains realized upon the disposal of our ADSs provided that (i) the shares represent at least 10% of our share capital or a participation with an acquisition value of at least € 2,500,000 (it being understood that only one out of the two tests must be satisfied), (ii) the Article 203 ITC Taxation Condition is satisfied and (iii) the ADSs have been held in full legal ownership for an uninterrupted period of at least one year immediately preceding the disposal.

If the one-year minimum holding condition would not be satisfied (but the other conditions are) the capital gains realized upon the disposal of our ADSs by a Belgian resident company are taxable at a flat corporate income tax rate of 25.5% (including the 2% crisis surcharge). As of assessment year 2021 linked to a tax year starting on or after January 1, 2020, the tax rate in this case will be equal to the standard tax rate of 25%.

If the Article 203 ITC Taxation Condition is not satisfied or the participation condition is not met, the capital gains are taxable at the standard corporate tax rate (of 29.58% currently and of 25% as of assessment year 2021 linked to a tax year starting on or after January 1, 2020), unless the reduced corporate income tax rate applies.

Capital losses on our ADSs incurred by resident companies are as a general rule not tax deductible.

Our ADSs held in the trading portfolios (*portefeuille commercial / handelsportefeuille*) of qualifying credit institutions, investment enterprises and management companies of collective investment undertakings which are subject to the Royal Decree of September 23, 1992 on the annual accounts of credit institutions, investment firms and management companies of collective investment undertakings (*comptes annuels des établissements de crédit, des entreprises d'investissement et des sociétés de gestion d'organismes de placement / jaarrekening van de kredietinstellingen, de beleggingsondernemingen en de beheervennootschappen van instellingen voor collectieve belegging*) are subject to a different regime. The capital gains on such shares are taxable at the ordinary corporate income tax rate of 29.58% (including the 2% crisis surcharge), which is reduced to 25% as of assessment year 2021 linked to a tax year starting on or after January 1, 2020. Capital losses on such shares are tax deductible. Internal transfers to and from the trading portfolio are assimilated to a realization.

Capital gains realized by Belgian resident companies (both non-SMEs and SMEs and both ordinary Belgian resident companies and qualifying credit institutions, investment enterprises and management companies of collective investment undertakings) upon the redemption of our ADSs or upon our liquidation are, in principle, subject to the same taxation regime as dividends. See “Dividends” above.

Organizations for Financing Pensions

OFPs within the meaning of article 8 of the Belgian Act of 27 October 2006 are, in principle, not subject to Belgian capital gains taxation realized upon the disposal of the ADSs, and capital losses are not tax deductible.

However, in general, capital gains realized by Belgian resident OFPs upon redemption of the ADS or upon our liquidation will, in principle, be subject to the same taxation regime as dividends. See “Dividends” above.

Other Taxable Legal Entities

Belgian resident legal entities subject to the legal entities income tax are, in principle, not subject to Belgian capital gains taxation on the disposal of ADSs.

Capital gains realized by Belgian resident legal entities upon the redemption of the ADSs or upon our liquidation will in principle be taxed as dividends. See “Dividends” above.

Capital losses on ADSs incurred by Belgian resident legal entities are not tax deductible.

Belgian Non-Resident Individuals And Companies

Non-resident individuals or companies are, in principle, not subject to Belgian income tax on capital gains realized upon disposal of the ADSs, unless such ADSs are held as part of a business conducted in Belgium through a Belgian PE. In such a case, the same principles apply as described with regard to Belgian individuals (holding the shares for professional purposes) or Belgian companies.

Non-resident individuals who do not use the shares for professional purposes and who have their fiscal residence in a country with which Belgium has not concluded a tax treaty or with which Belgium has concluded a tax treaty that confers the authority to tax capital gains on the ADSs to Belgium, might be subject to tax in Belgium if the capital gains arise from transactions which are to be considered speculative or beyond the normal management of one's private estate or if the transfer concerns a substantial shareholding. See “Capital gains and losses on shares—Belgian resident individuals”. Such non-resident individuals might therefore be obliged to file a tax return and should consult their own tax advisor. Capital losses in such cases are, however, not tax deductible.

Capital gains realized by non-resident individuals or non-resident companies upon repurchase of our shares or upon our liquidation will, in principle, be subject to the same taxation regime as dividends.

Tax on Stock Exchange Transactions

Upon the issue of the ADSs (primary market), no Tax on Stock Exchange Transactions (“*taks op de beursverrichtingen*” / “*taxe sur les opérations de bourse*”) is due.

The purchase and the sale and any other acquisition or transfer for consideration of ADS (secondary market transactions) is subject to the Tax on Stock Exchange Transactions if (i) it is executed in Belgium through a professional intermediary, or (ii) deemed to be executed in Belgium, which is the case if the order is directly or indirectly made to a professional intermediary established outside of Belgium, either by private individuals with habitual residence in Belgium, or legal entities for the account of their seat or establishment in Belgium (both, a Belgian Investor).

The Tax on Stock Exchange Transactions is levied at a rate of 0.35% of the purchase price, capped at €1,600 per transaction and per party.

A separate tax is due by each party to the transaction, and both taxes are collected by the professional intermediary. However, if the intermediary is established outside of Belgium, the tax will in principle be due by the Belgian Investor, unless that Belgian Investor can demonstrate that the tax has already been paid. Professional intermediaries established outside of Belgium can, subject to certain conditions and formalities, appoint a Belgian Stock Exchange Tax Representative, which will be liable for the Tax on Stock Exchange Transactions in respect of the transactions executed through the professional intermediary. If the Stock Exchange Tax Representative would have paid the Tax on Stock Exchange Transactions due, the Belgian Investor will, as per the above, no longer be the debtor of the Tax on Stock Exchange Transactions.

No tax on stock exchange transactions is due on transactions entered into by the following parties, provided they are acting for their own account: (i) professional intermediaries described in Article 2,9° and 10° of the Belgian Law of August 2, 2002; (ii) insurance companies described in Article 2, §1 of the Belgian Law of July 9, 1975; (iii) professional retirement institutions referred to in Article 2,1° of the Belgian Law of October 27, 2006 concerning the supervision on institutions for occupational pension; (iv) collective investment institutions; (v) regulated real estate companies; and (vi) Belgian non-residents provided they deliver a certificate to their financial intermediary in Belgium confirming their non-resident status.

The EU Commission adopted on February 14, 2013 the Draft Directive on a Financial Transaction Tax, or FTT. The Draft Directive currently stipulates that once the FTT enters into force, the Participating Member States shall not maintain or introduce taxes on financial transactions other than the FTT (or VAT as provided in the Council Directive 2006/112/EC of November 28, 2006 on the common system of value added tax). For Belgium, the tax on stock exchange transactions should thus be abolished once the FTT enters into force. The Draft Directive regarding the FTT is still subject to negotiation between the Participating Member States and therefore may be changed at any time.

Tax on Securities Accounts

On March 10, 2018, the law on the introduction of a tax on securities accounts entered into force. Pursuant to this law, Belgian resident and non-resident individuals are taxed at a rate of 0.15 percent. on their share in the average value of qualifying financial instruments (such as our ordinary shares and other shares, bonds, certain other type of debt instruments, units of undertakings for collective investment, warrants) held on one or more securities accounts during a reference period of 12 consecutive months starting on October 1 and ending on September 30 of the subsequent year ("Tax on Securities Accounts").

No Tax on Securities Accounts is due provided the holder's share in the average value of the qualifying financial instruments on those accounts amounts to less than €500,000. If, however, the holder's share in the average value of the qualifying financial instruments on those accounts amounts to €500,000 or more, the Tax on Securities Accounts is due on the entire share of the holder in the average value of the qualifying financial instruments on those accounts (and hence, not only on the part which exceeds the €500,000 threshold).

Qualifying financial instruments held by non-resident individuals only fall within the scope of the Tax on Securities Accounts provided they are held on securities accounts with a financial intermediary established or located in Belgium. Note that pursuant to certain double tax treaties, Belgium has no right to tax capital. Hence, to the extent the Tax on Securities Accounts is viewed as a tax on capital within the meaning of these double tax treaties, incompatibility of the Tax on Securities Accounts with a treaty may, subject to certain conditions, be claimed.

The Tax on Securities Accounts is in principle due by the financial intermediary established or located in Belgium if (i) the holder's share in the average value of the qualifying financial instruments held on one or more securities accounts with said intermediary amounts to €500,000 or more; or (ii) the holder instructed the financial intermediary to levy the Tax on Securities Accounts due (e.g. in case such holder holds qualifying financial instruments on several securities accounts held with multiple intermediaries of which the average value does not amount to €500,000 or more but of which the holder's share in the total average value of these accounts exceeds €500,000). Otherwise, the Tax on Securities Accounts must be declared and is due by the holder itself, unless the holder provides evidence that the Tax on Securities Accounts has already been withheld, declared and paid by an intermediary which is not established or located in Belgium. In that respect, intermediaries located or established outside of Belgium could appoint a Tax on the Securities Accounts representative in Belgium, subject to certain conditions and formalities. Such a Tax on the Securities Accounts Representative is then liable towards the Belgian Treasury for the Tax on the Securities Accounts due and for complying with certain reporting obligations in that respect.

Prospective investors are advised to seek their own professional advice in relation to the Tax on Securities Accounts.

Enforcement of Civil Liabilities

We are a European public company with limited liability (*Societas Europaea* or *SE*) incorporated under the laws of the Netherlands. Upon completion of our redomiciliation, we will be a European public company with limited liability (*Societas Europaea* or *SE*) incorporated under the laws of Belgium. Substantially all of our assets are located outside the United States. The majority of our directors reside outside the United States. As a result, it may not be possible for investors to effect service of process within the United States upon such persons or to

enforce against them or us in U.S. courts, including judgments predicated upon the civil liability provisions of the federal securities laws of the United States.

The United States and the Netherlands currently do not have a treaty providing for the reciprocal recognition and enforcement of judgments, other than arbitration awards, in civil and commercial matters. Consequently, a final judgment for payment given by a court in the United States, whether or not predicated solely upon U.S. securities laws, would not automatically be recognized or enforceable in the Netherlands. In order to obtain a judgment which is enforceable in the Netherlands, the party in whose favor a final and conclusive judgment of the U.S. court has been rendered will be required to file its claim with a court of competent jurisdiction in the Netherlands. Such party may submit to the Dutch court the final judgment rendered by the U.S. court. This court will have discretion to attach such weight to the judgment rendered by the relevant U.S. court as it deems appropriate. The Dutch courts can be expected to give conclusive effect to a final and enforceable judgment of such court in respect of the contractual obligations thereunder without re-examination or re-litigation of the substantive matters adjudicated upon, provided that: (i) the U.S. court involved accepted jurisdiction on the basis of internationally recognized grounds to accept jurisdiction, (ii) the proceedings before such court being in compliance with principles of proper procedure (*behoorlijke rechtspleging*), (iii) such judgment not being contrary to the public policy of the Netherlands and (iv) such judgment not being incompatible with a judgment given between the same parties by a Netherlands court or with a prior judgment given between the same parties by a foreign court in a dispute concerning the same subject matter and based on the same cause of action, provided such prior judgment fulfills the conditions necessary for it to be given binding effect in the Netherlands. Dutch courts may deny the recognition and enforcement of punitive damages or other awards. Moreover, a Dutch court may reduce the amount of damages granted by a U.S. court and recognize damages only to the extent that they are necessary to compensate actual losses or damages. Enforcement and recognition of judgments of U.S. courts in the Netherlands are solely governed by the provisions of the Dutch Civil Procedure Code.

Original actions or actions for the enforcement of judgments of U.S. courts relating to the civil liability provisions of the federal or state securities laws of the United States are not directly enforceable in Belgium. The United States and Belgium currently do not have a treaty providing for reciprocal recognition and enforcement of judgments, other than arbitral awards, in civil and commercial matters. Consequently, a final judgment for payment given by a court in the United States, whether or not predicated solely upon U.S. securities laws, would not automatically be recognized or enforceable in Belgium. In order for a final judgment for the payment of money rendered by U.S. courts based on civil liability to produce any effect on Belgian soil, it is accordingly required that this judgment be recognized and be declared enforceable by a Belgian court pursuant to the relevant provisions of the PIL Code. Recognition or enforcement does not imply a review of the merits of the case and is irrespective of any reciprocity requirement. A U.S. judgment will, however, not be recognized or declared enforceable in Belgium if it infringes upon one or more of the grounds for refusal which are exhaustively listed in article 25 of the PIL Code. In addition to recognition or enforcement, a judgment by a federal or state court in the United States against us may also serve as evidence in a similar action in a Belgian court if it meets the conditions required for the authenticity of judgments according to the law of the state where it was rendered. In addition, with regard to enforcements by legal proceedings in Belgium (including the recognition of foreign court decisions in Belgium), a registration tax at the rate of 3% of the amount of the judgment is payable by the debtor, if the sum of money which the debtor is ordered to pay by a Belgian court, or by a foreign court judgment that is either (i) automatically enforceable and registered in Belgium, or (ii) rendered enforceable by a Belgian court, exceeds €12,500. The registration tax is payable by the debtor. The creditor is jointly liable up to a maximum of one-half of the amount the creditor recovers from the debtor. A stamp duty is payable for each original copy of an enforcement judgment rendered by a Belgian court, with a maximum of €1,450.

Dutch and Belgian civil procedure differs substantially from U.S. civil procedure in a number of respects. Insofar as the production of evidence is concerned, U.S. law and the laws of several other jurisdictions based on common law provide for pre-trial discovery, a process by which parties to the proceedings may prior to trial compel the production of documents by adverse or third parties and the deposition of witnesses. Evidence obtained in this manner may be decisive in the outcome of any proceeding. No such pre-trial discovery process exists under Dutch or Belgian law.

Subject to the foregoing and service of process in accordance with applicable treaties, investors may be able to enforce in the Netherlands or Belgium judgments in civil and commercial matters obtained from U.S. federal or state courts. However, no assurance can be given that those judgments will be enforceable. In addition, it is doubtful whether a Dutch or Belgian court would accept jurisdiction and impose civil liability in an original action commenced in the Netherlands or Belgium and predicated solely upon U.S. federal securities laws.

F. DIVIDENDS AND PAYING AGENTS

Not applicable.

G. STATEMENT BY EXPERTS

Not applicable.

H. DOCUMENTS ON DISPLAY

We are subject to the information reporting requirements of the Exchange Act applicable to foreign private issuers and under those requirements will file reports with the SEC. Those reports may be inspected without charge at the locations described below. As a foreign private issuer, we are exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as United States companies whose securities are registered under the Exchange Act. Nevertheless, we will file with the SEC an annual report containing financial statements that have been examined and reported on, with and opinion expressed by an independent registered public accounting firm.

We maintain a corporate website at www.argenx.com. We intend to post a link to our annual report on Form 20-F as filed with the SEC on our website promptly following it being filed with the SEC. Information contained on, or that can be accessed through, our website does not constitute a part of this annual report. We have included our website address in this annual report solely as an inactive textual reference.

You may also review a copy of this annual report, including exhibits and any schedule filed herewith, and obtain copies of such materials at prescribed rates, at the SEC's Public Reference Room in Room 1580, 100 F Street, NE, Washington, D.C. 20549-0102. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains a website (www.sec.gov) that contains reports, proxy and information statements and other information regarding registrants, such as argenx SE, that file electronically with the SEC.

With respect to references made in this annual report to any contract or other document of argenx SE, such references are not necessarily complete and you should refer to the exhibits attached or incorporated by reference to this annual report for copies of the actual contract or document.

I. SUBSIDIARY INFORMATION

Not applicable.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to a variety of financial risks, including interest rate risk and foreign exchange risk. We do not buy or trade financial instruments for speculative purposes.

Interest Rate Risk

We are currently not exposed to significant interest rate risk. Our only interest-bearing financial assets are cash at banks on deposit and term accounts. Given the short-term nature of these investments, the sensitivity towards interest rate fluctuations is deemed not to be significant. Therefore, the effect of an increase or decrease in interest rates would only have an immaterial effect on our financial results.

Foreign Exchange Risk

We undertake transactions denominated in foreign currencies; consequently, exposures to exchange rate fluctuations arise. Our functional currency is the euro and the majority of our operating expenses are paid in euros, but we also receive payments from our main business partners, Janssen, AbbVie and Shire, in U.S. dollars and we regularly acquire services, consumables and materials in U.S. dollars, Swiss Francs and British Pounds.

In order to finance the growth of our activities in the United States, we invested a significant portion of the proceeds from our initial U.S. public offering completed in May 2017 in U.S. dollar denominated cash deposit accounts and in current financial assets. Depending on the exchange rate fluctuations of the U.S. dollar, this may result in unrealized exchange rate losses which may impact negatively the reporting of our cash and cash equivalents and current financial assets at reporting dates when translating to euros these U.S. denominated cash deposits accounts and current financial assets.

For more information about our exposure to market risk and how we manage this risk, please see “Note 6—Financial instruments and financial risk management” in our consolidated financial statements appended to this annual report.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. DEBT SECURITIES

Not applicable.

B. WARRANTS AND RIGHTS

Not applicable.

C. OTHER SECURITIES

Not applicable.

D. AMERICAN DEPOSITARY SHARES

The Bank of New York Mellon, as depositary, will register and deliver American Depositary Shares, also referred to as ADSs. Each ADS will represent one share (or a right to receive one share) deposited with ING Bank N.V., as custodian for the depositary in The Netherlands. Each ADS will also represent any other securities, cash or other property which may be held by the depositary. The deposited shares together with our other securities, cash and other property held by the depositary, are referred to as the deposited securities. The depositary’s office at which the ADSs are administered is located at 101 Barclay Street, New York, New York 10286. The Bank of New York Mellon’s principal executive office is located at 225 Liberty Street, New York, New York 10286.

A deposit agreement among us, the depositary, ADS holders and all other persons indirectly or beneficially holding ADSs sets out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs. A copy of the deposit agreement is incorporated by reference as an exhibit to this annual report.

Fees and Charges

Persons depositing or withdrawing shares or ADS holders must pay:

\$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)

For:

Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property

Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates

\$.05 (or less) per ADS

Any cash distribution to ADS holders

A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of ADSs

Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders

\$.05 (or less) per ADS per calendar year

Depositary services

Registration or transfer fees

Transfer and registration of shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw shares

Expenses of the depositary

Cable, telex and facsimile transmissions (when expressly provided in the deposit agreement)

Converting foreign currency to U.S. dollars

Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes

As necessary

Any charges incurred by the depositary or its agents for servicing the deposited securities

As necessary

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse us for costs and expenses generally arising out of establishment and maintenance of the ADS program, waive fees and expenses for services

provided to us by the depositary or share revenue from the fees collected from ADS holders. In performing its duties under the deposit agreement, the depositary may use brokers, dealers, foreign currency dealers or other service providers that are owned by or affiliated with the depositary and that may earn or share fees, spreads or commissions.

The depositary may convert currency itself or through any of its affiliates and, in those cases, acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the depositary or its affiliate receives when buying or selling foreign currency for its own account. The depositary makes no representation that the exchange rate used or obtained in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to ADS holders, subject to the depositary's obligations under the deposit agreement. The methodology used to determine exchange rates used in currency conversions is available upon request.

PART II

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

Not applicable.

ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

In May 2017, we sold 6,744,750 ADSs, each representing one ordinary share, with a nominal value of €0.10 per share, in our U.S. initial public offering at a price of \$17.00 per ADS, including the exercise in full by the underwriters of their option to purchase additional ADSs. The offering closed on May 23, 2017 and was made pursuant to a registration statement on Form S-1 (File No. 333-217417) filed on April 21, 2017, as amended, in the form in which it was declared effective by the SEC on May 17, 2017 and a registration statement on Form S-1MEF (File No. 333-218067), which was automatically effective upon filing with the SEC on May 17, 2017. Cowen and Company, LLC and Piper Jaffray & Co. acted as managing joint book-running managers, and JMP Securities LLC and Wedbush PacGrow Inc. acted as co-managers of the initial U.S. public offering. Kempen & Co. N.V. acted as our advisor in connection with the offering.

We received aggregate gross proceeds of approximately \$114.6 million, or aggregate net offering proceeds to us, after deducting underwriting discounts and commissions and offering expenses, of approximately \$103.4 million. None of the underwriting discounts and commissions or offering expenses were paid to directors, officers or general partners of ours or their associates or to persons owning 10% or more of any class of our equity securities, or to any of our affiliates.

We have not used any of the net proceeds from the offering to make payments, directly or indirectly, to any director, officer or general partner of ours or to their associates, persons owning 10% or more of any class of our equity securities, or to any of our affiliates. We have invested the net proceeds from the offering in cash and cash equivalents and current financial assets. There has been no material change in our planned use of the net proceeds from the offering as described in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on May 19, 2017.

ITEM 15. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-15(b) as of December 31, 2018. While there are inherent limitations to the effectiveness of any system of disclosure controls and procedures, including the possibility of human error and the circumvention or overriding of the controls and procedures, our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives.

Based upon our evaluation, as of December 31, 2018, our Chief Executive Officer and Chief Financial Officer have concluded that the disclosure controls and procedures, in accordance with Exchange Act Rule 13a-15(e), are not effective as a result of the material weaknesses in the company's internal control over financial reporting described below.

Notwithstanding these material weaknesses, management has concluded that the company's audited consolidated financial statements for the fiscal years ended December 31, 2018, 2017 and 2016, filed as part of this annual report, fairly present in all material respects the company's financial position, results of operations, cash flows and changes in equity for the period presented, in accordance with the International Financial Reporting Standard (IFRS) as issued by the International Accounting Standards Board (IASB).

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as such term is defined in Rule 13a-15(f) and Rule 15d-15(f) under the Exchange Act) and has designed such internal controls over financial reporting to provide reasonable assurance regarding the reliability of financial reporting and preparation of financial statements for external purposes in accordance with IFRS.

Our management, under the supervision and with the participation of the CEO and CFO, conducted an evaluation of the effectiveness of the internal control over financial reporting as of December 31, 2018, using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control – Integrated Framework (2013). Based on the evaluation performed, management concluded that material weaknesses existed as of December 31, 2018, as described below.

Material Weaknesses Identified Relating to Effectiveness of Risk Assessment, Design and Operating Effectiveness of Control Activities, Information & Communication and Monitoring Activities as of December 31, 2018

The company commenced the risk assessment process and the design and implementation of updated internal control frameworks for revenues and accounts receivable, other income, expenditure and payables, the financial closing and reporting process and general information technology controls ("GITC"). GITC deficiencies were identified related to the financial reporting system and the scope and conclusion of the service auditors' reports for the service organizations relied upon by argenx's accounting software. The risk assessment process and the design and implementation of these control frameworks were not completed as of December 31, 2018 primarily as a result of the GITC deficiencies and therefore effective risk assessment and monitoring activities were not implemented as of December 31, 2018.

Management has concluded that its risk assessment process for the areas described above, did not adequately assess risk at an appropriate level of detail contemplating the GITC deficiencies to allow for (i) the design of controls with the appropriate precision and responsiveness to address those risks, (ii) the design of controls to validate the completeness and accuracy of data and financial reports generated by the affected financial reporting system and used in the performance of controls over the determination of significant estimates, accounting transactions and disclosures, (iii) the timely and effective implementation of controls, including evidence of operating effectiveness, and (iv) effective monitoring of the controls.

Accordingly, a reasonable possibility exists that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis by the company's internal control. Management, including our CEO and CFO, concluded that internal controls over financial reporting was not effective as of December 31, 2018.

Deloitte Accountants B.V., the independent registered public accounting firm that audited our Annual Financial Statements included in this annual report, has issued an attestation report on the effectiveness of our internal control over financial reporting as of December 31, 2018. Their attestation report, which expresses an adverse opinion on the company's internal control over financial reporting, is included in this annual report.

There were no material adjustments to our Annual Financial Statement for the year ended December 31, 2018. However, we identified control deficiencies in the aggregate that constitute material weaknesses in four components of internal control as defined by COSO 2013 (i.e. Risk Assessment, Control Activities, Information and Communication, and Monitoring). As the company has experienced significant expansion of operations, we have increased the number of personnel in our organization and specifically in our financial reporting team. Despite this progress, management determined that it did not design and maintain effective controls over financial reporting.

Plan for Remediation of the Material Weaknesses

While considerable progress has been made, there are still more controls that need to be implemented or existing controls to be remediated, and the related documentation needs to be completed. We expect to finalize the risk assessment and control design and implementation during 2019 and commence monitoring activities to test operating effectiveness commencing in the first quarter of 2019. Remediation will require that changed or new controls operate for a sufficient period of time such that the effectiveness of those changes is demonstrated with an appropriate level of consistency. As the company implements these plans, management may determine that additional steps may be necessary to remediate the material weaknesses.

We are implementing measures designed to improve our internal control over financial reporting to remediate this material weakness, including the following:

- hiring a full-time Internal Controls Manager to lead the monitoring and testing of internal controls over financial reporting;
- developing enhanced controls related to database administrator access with a specific focus on systems supporting our financial reporting processes;
- increasing the frequency of user access review controls on privileged users;
- implementing an improvement plan together with our external information technology service provider; and
- improving quarterly reporting on the remediation measures to the Audit Committee.

Senior management has discussed the material weaknesses described above with the Audit Committee, which will continue to review the progress of these remediation activities.

As the company continues to evaluate and work to improve its internal control over financial reporting, management may take additional measures to address control deficiencies. The material weaknesses cannot be considered remediated until the applicable relevant controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively. No assurance can be provided at this time that the actions and remediation efforts will effectively remediate the material weaknesses described above or prevent the incidence of other material weaknesses in the company's internal control over financial reporting in the future. We do not know the specific time frame needed to fully remediate the material weaknesses identified above. See "Item 3.D.—Risk Factors." Management, including the CEO and CFO, does not expect that disclosure controls and procedures or internal control over financial reporting will prevent all misstatements, even as the remediation measures are implemented and further improved to address the material weaknesses. The design of any system of internal controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving the stated goals under all potential future conditions.

Changes in Internal Control Over Financial Reporting

During the period covered by this annual report, we have not made any change to our internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 16. RESERVED

Not applicable.

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

Our board of directors has determined that Werner Lanthaler qualifies as an audit committee financial expert as defined by SEC rules and has the requisite financial sophistication under the applicable rules and regulations of the NASDAQ Stock Market. Dr. Lanthaler is independent under Rule 10A-3 of the Exchange Act.

ITEM 16B. CODE OF ETHICS

We adopted a Code of Business Conduct and Ethics, or the Code of Conduct, that is applicable to all of our employees and directors. The Code of Conduct is available on our website at www.argenx.com. The audit committee of our board of directors is responsible for overseeing the Code of Conduct and is required to approve any waivers of the Code of Conduct for employees and directors. We expect that any amendments to the Code of Conduct, and any waivers of its requirements, will be disclosed on our website.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Deloitte Accountants B.V. has served as our independent registered public accounting firm for 2017 and 2018. Our accountants billed the following fees to us for professional services in each of those fiscal years:

Fees	Year Ended December 31,	
	2018	2017
	in thousands of €	
Audit Fees	€ 648	€ 179
Audit-Related Fees	143	724
Tax Fees	—	—
All Other Fees	—	—
Total	€ 791	€ 903

“Audit Fees” are the aggregate fees billed for the audit of our annual financial statements. This category also includes services that generally the independent accountants provide, such as consents and assistance with and review of documents filed with the SEC.

“Audit-Related Fees” are the aggregate fees billed for assurance and related services that are reasonably related to the performance of the audit and are not reported under Audit Fees. In 2017 and 2018, “Audit-Related Fees” also include fees billed for assurance and audit-related services regarding our public offerings on Nasdaq.

“Tax Fees” are the aggregate fees billed for professional services rendered by the principal accountant for tax compliance, tax advice and tax planning related services.

“All Other Fees” are any additional amounts billed for products and services provided by the principal accountant. No other fees were paid to Deloitte Accountants B.V. for the fiscal years ended December 31, 2018 and 2017.

Audit Committee’s Pre-Approval Policies and Procedures

The audit committee has responsibility for, among other things, appointing, setting compensation of and overseeing the work of our independent registered public accounting firm, or external auditor. In recognition of these responsibilities, the audit committee has adopted a policy governing the pre-approval of all audit and permitted non-audit services performed by our external auditor to ensure that the provision of such services does not impair the external auditor’s independence from us and our management. Unless a type of service to be provided by our external auditor has received general pre-approval from the audit committee, it requires specific pre-approval by the audit committee. The payment for any proposed services in excess of pre-approved cost levels requires specific pre-approval by the audit committee.

Pursuant to its pre-approval policy, the audit committee may delegate its authority to pre-approve services to the chairperson of the Audit Committee. The decisions of the chairperson to grant pre-approvals must be presented to the full audit committee at its next scheduled meeting. The audit committee may not delegate its responsibilities to pre-approve services to the management.

The audit committee has considered the non-audit services provided by Deloitte Accountants B.V. as described above and believes that they are compatible with maintaining Deloitte Accountants B.V.'s independence as our external auditor. In accordance with Regulation S-X, Rule 2-01, paragraph (c)(7)(i), no fees for services were approved pursuant to any waivers of the pre-approval requirement.

ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

Not applicable.

ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

Not applicable.

ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

Not applicable.

ITEM 16G. CORPORATE GOVERNANCE

We qualify as a foreign private issuer. The Listing Rules of the Nasdaq Stock Market include certain accommodations in the corporate governance requirements that allow foreign private issuers to follow "home country" corporate governance practices in lieu of the otherwise applicable corporate governance standards of the Nasdaq Stock Market. We intend to rely on the certain exemptions for foreign private issuers and to follow Dutch corporate governance practices in lieu of the Nasdaq corporate governance rules.

The following is a summary of the significant ways in which our corporate governance practices differ from those required by the Nasdaq Listing Rules with which we are not required to comply:

- **Quorum at Shareholder Meetings.** In accordance with Dutch law and generally accepted business practices in the Netherlands, our Articles of Association do not provide quorum requirements generally applicable to general meetings of shareholders. To that extent, our practice varies from the requirement of Nasdaq Listing Rule 5620(c), which requires an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting stock.
- **Compensation and Nomination Committees.** We have opted out of Nasdaq Listing Rules 5605(d)(2) and 5605(e)(1), which require separate nomination and compensation committees; however, for practical purposes, our remuneration and nomination committee performs similar tasks pursuant to Dutch law. We have also opted out of the requirements of Nasdaq Listing Rule 5605(d), which requires an issuer to have a compensation committee that consists entirely of independent directors, and Nasdaq Listing Rule 5605(e), which requires an issuer to have independent director oversight of director nominations. Although we have chosen not to comply with Nasdaq Listing Rule 5605(d) regarding the independence of our compensation committee, all of the current members of our remuneration and nomination committee meet the heightened independence requirements under these rules.
- **Executive Sessions.** Nasdaq Listing Rule 5605(b)(2) requires companies to have regularly scheduled meetings at which only independent directors of the company are present. There is no corresponding requirement under Dutch law. Our corporate governance charter requires our non-executive directors to meet without the presence of any executive directors; however, these meetings do not exclude our other non-independent directors and, therefore, we do not believe that we satisfy the requirements of Rule 5605(b)(2).
- **Solicitation of Proxies.** Although we must provide shareholders with an agenda and other relevant documents for the General Meeting, Dutch law does not have a regulatory regime for the solicitation of proxies, and the solicitation of proxies is not a generally accepted business practice in the Netherlands. Thus, our practice will vary from the requirement of Nasdaq Listing Rule 5620(b).
- **Shareholder Approval.** We have opted out of certain Dutch shareholder approval requirements for the issuance of securities in connection with certain events, such as the acquisition of stock or assets of another company, the establishment of or amendments to equity-based compensation plans for employees, changes of control and certain private placements. To that extent, our practice varies from the requirements of Nasdaq Rule 5635, which generally requires an issuer to obtain shareholder approval for the issuance of securities in connection with such events.

ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable.

PART III

ITEM 17. FINANCIAL STATEMENTS

Not applicable.

ITEM 18. FINANCIAL STATEMENTS

See pages F-1 through F-50 of this annual report.

ITEM 19. EXHIBITS

The Exhibits listed in the Exhibit Index at the end of this annual report are filed as Exhibits to this annual report.

EXHIBIT INDEX

Exhibit	Description	Schedule/ Form	Incorporated by Reference		File Date (mm/dd/yyyy)
			File Number	Exhibit	
1.1	Articles of Association (English translation), as amended	Form F-1/A	333-217417	3.1	05/04/2017
1.2	Rules for the Board of Directors	Form F-1	333-217417	3.2	04/21/2017
2.1	Form of Deposit Agreement	Form F-1/A	333-217417	4.1	05/16/2017
2.2	Form of American Depositary Receipt (included in Exhibit 2.1)				
4.1	Leases dated April 1, 2016 between argenx BVBA and Bio-Incubator Gent 2 NV	Form F-1	333-217417	10.1	04/21/2017
4.2**	Patent License Agreement, dated February 15, 2012, between the registrant and The Board of Regents of the University of Texas System, as amended	Form F-1	333-217417	10.2	04/21/2017
4.3†	Form of Indemnification Agreement between the registrant and each of its executive officers and directors	Form F-1	333-217417	10.3	04/21/2017
4.4	argenx option plan and form of option agreement and notice of option grant thereunder	Form F-1	333-221984	10.4	12/11/2017
4.5#**	Collaboration License Agreement, dated December 2, 2018, between the registrant, argenx BVBA and Cilag GmbH International				
4.6#	Investment Agreement, dated December 2, 2018, between the registrant and Johnson & Johnson Innovation – JJDC, Inc.				
8.1	List of subsidiaries of the registrant	Form F-1	333-221984	21.1	12/11/2017

12.1#	Certification by the Principal Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
12.2#	Certification by the Principal Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
13.1*	Certification by the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
13.2*	Certification by the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
15.1#	Consent of Deloitte Accountants B.V.
101.INS#	XBRL Instance Document
101.SCH#	XBRL Taxonomy Extension Schema Document
101.CAL#	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF#	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB#	XBRL Taxonomy Extension Label Linkbase Document
101.PRE#	XBRL Taxonomy Extension Presentation Linkbase Document

Filed herewith.

* Furnished herewith.

† Indicates a management contract or any compensatory plan, contract or arrangement.

** Confidential treatment status has been granted as to certain portions thereto, which portions are omitted and filed separately with the U.S. Securities and Exchange Commission.

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

Date: March 26, 2019

ARGENX SE

By: /s/ Tim Van Hauwermeiren

Name: Tim Van Hauwermeiren

Title: *Chief Executive Officer*

INDEX TO FINANCIAL STATEMENTS

Audited consolidated Financial Statements as of and for the years ended December 31, 2018, 2017 and 2016

Reports of Independent Registered Public Accounting Firm	F-2
Consolidated Statements of Financial Position	F-5
Consolidated Statements of Profit and Loss and Other Comprehensive Income	F-6
Consolidated Statements of Cash Flows	F-7
Consolidated Statements of Changes in Equity	F-8
Notes to the Consolidated Financial Statements	F-9

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of argenx SE

Opinion on the Financial Statements

We have audited the accompanying consolidated statements of financial position of argenx SE and subsidiaries (the "Company") as of December 31, 2018, 2017 and 2016, the related consolidated statements of profit and loss and other comprehensive income, consolidated statement of cash flows and consolidated statement of changes in equity, for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the "financial statements").

In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018, 2017 and 2016, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 26, 2019 expressed an adverse opinion on the Company's internal control over financial reporting because of material weaknesses.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Deloitte Accountants B.V.

Rotterdam, the Netherlands

March 26, 2019

We have served as the Company's auditor since 2015.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the Board of Directors of argenx SE

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of argenx SE and subsidiaries (the “Company”) as of December 31, 2018, based on criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, because of the effect of the material weaknesses identified below on the achievement of the objectives of the control criteria, the Company has not maintained effective internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control — Integrated Framework (2013) issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2018, of the Company and our report dated March 26, 2019, expressed an unqualified opinion on those financial statements.

Basis for Opinion

The Company’s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management’s Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company’s internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company’s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company’s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company’s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Material Weaknesses

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company’s annual or interim

financial statements will not be prevented or detected on a timely basis. The following material weaknesses have been identified and included in management's assessment: Management identified material weaknesses in the Company's control environment due to multiple deficiencies in internal controls, which affected four components of internal control as defined by COSO, specifically risk assessment, control activities, information and communication, and monitoring. In addition, management did not design and maintain effective controls over the following, each of which is a material weakness: (a) general information technology controls over the financial reporting systems, including those related to its inability to rely on a third party service auditor's report that are relevant to data and financial reports produced by the financial information system, which can adversely affect information used in controls and result in deficiencies in the following business process controls (b) the financial closing and reporting process controls (c) revenue and accounts receivable controls, (d) other income controls and (e) the expenditure and payable process controls. These material weaknesses were considered in determining the nature, timing, and extent of audit tests applied in our audit of the consolidated financial statements as of and for the year ended December 31, 2018, of the Company, and this report does not affect our report on such financial statements.

/s/ Deloitte Accountants B.V.

Rotterdam, the Netherlands

March 26, 2019

ARGENX SE

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

(in thousands of €)			As of December 31,		
	Note	2018	2017 (restated)	2016(restated)	
ASSETS					
Current assets					
Cash and cash equivalents	4.7	€ 281,040	€ 190,867	€ 89,897	
Restricted cash — current	4.4	1,692	1,692	786	
Research and development incentive receivables — current	4.3	301	158	163	
Financial assets — current	4.6	283,529	168,907	6,831	
Prepaid expenses		2,995	2,338	2,146	
Trade and other receivables	4.5	2,886	2,842	1,970	
Total current assets		572,443	366,804	101,793	
Non-current assets					
Restricted cash — non-current	4.4	251	256	1,149	
Research and development incentive receivables — non-current	4.3	4,883	3,033	2,046	
Other non-current assets		—	125	—	
Financial assets — non-current		1	1	1	
Property, plant and equipment	4.2	824	676	766	
Intangible assets	4.1	56	13	17	
Total non-current assets		6,015	4,104	3,979	
TOTAL ASSETS		€ 578,458	€ 370,908	€ 105,772	

(in thousands of €)			As of December 31,		
	Note	2018	2017 (restated)	2016(restated)	
EQUITY AND LIABILITIES					
Equity					
	4.8				
Equity attributable to owners of the parent					
Share capital		€ 3,597	€ 3,217	€ 2,012	
Share premium		673,454	430,518	126,358	
Accumulated losses		(169,603)	(100,568)	(72,492)	
Other reserves		30,947	11,764	7,496	
Total equity		€ 538,395	€ 344,931	€ 63,374	
Non-current liabilities					
		7	1,460	10,071	
Provisions for employee benefits	4.10	7	25	1	
Deferred revenue — non-current		—	1,435	10,070	
Current liabilities		40,056	24,517	32,327	
Trade and other payables	4.11	37,072	15,285	12,191	
Tax liabilities	4.12	823	597	—	
Deferred revenue — current	4.13	2,161	8,635	20,136	
Total liabilities		€ 40,063	€ 25,977	€ 42,398	
TOTAL EQUITY AND LIABILITIES		€ 578,458	€ 370,908	€ 105,772	

The notes are an integral part of these consolidated financial statements.

ARGENX SE

CONSOLIDATED STATEMENT OF PROFIT AND LOSS AND OTHER COMPREHENSIVE INCOME

(in thousands of € except for shares and EPS)	Note	Year Ended December 31,		
		2018	2017	2016
Revenue	5.1	€ 21,482	€ 36,415	€ 14,713
Other operating income	5.2	7,749	4,841	2,439
Total operating income		29,231	41,256	17,152
Research and development expenses	5.4	(83,609)	(51,740)	(31,557)
Selling, general and administrative expenses	5.5	(27,471)	(12,448)	(7,011)
Operating loss		€ (81,849)	€ (22,932)	€ (21,416)
Financial income	5.8	3,694	1,250	73
Exchange gains/(losses)	5.8	12,308	(5,797)	(31)
Loss before taxes		€ (65,847)	€ (27,479)	€ (21,374)
Income tax expense	5.9	€ (794)	€ (597)	€ —
Loss for the year and total comprehensive loss		€ (66,641)	€ (28,076)	€ (21,374)
Weighted average number of shares outstanding		33,419,356	24,609,536	18,820,612
Basic and diluted loss per share (in €)	5.10	(1.99)	(1.14)	(1.14)

The notes are an integral part of these consolidated financial statements.

ARGENX SE

CONSOLIDATED STATEMENT OF CASH FLOWS

(in thousands of €)	Note	Year Ended December 31,		
		2018	2017(restated)	2016(restated)
CASH FLOWS (USED IN) / FROM OPERATING ACTIVITIES				
Operating result		€ (81,849)	€ (22,932)	€ (21,416)
Adjustments for non-cash items				
Amortization of intangible assets		19	10	11
Depreciation of property, plant and equipment		474	425	323
Loss on disposal of fixed assets		—	11	—
Provisions for employee benefits		(18)	24	1
Expense recognized in respect of share-based payments		19,183	4,268	2,849
		€ (62,191)	€ (18,195)	€ (18,232)
Movements in current assets/liabilities				
(Increase)/decrease in trade and other receivables	4.5	(44)	(122)	(614)
(Increase)/decrease in other current assets		(800)	(1,093)	(2,641)
Increase/(decrease) in trade and other payables	4.11	21,784	3,094	7,648
Increase/(decrease) in current deferred revenue	4.13	(8,868)	(11,501)	7,545
Movements in non-current assets/liabilities				
(Increase)/decrease in other non-current assets		(1,720)	(94)	(1,627)
(Increase)/decrease in non-current deferred revenue	4.13	(1,435)	(8,635)	18,520
Cash flows (used in)/from operating activities		(53,274)	(36,546)	10,599
Income taxes paid		(565)	—	—
NET CASH FLOWS (USED IN) / FROM OPERATING ACTIVITIES		€ (53,839)	€ (36,546)	€ 10,599
CASH FLOWS (USED IN) / FROM INVESTING ACTIVITIES				
Purchase of intangible assets	4.1	(62)	(6)	(21)
Purchase of property, plant and equipment	4.2	(622)	(345)	(840)
(Increase)/decrease in current financial assets	4.6	(108,229)	(162,076)	(18)
Interest received		1,371	375	73
NET CASH FLOWS (USED IN) / FROM INVESTING ACTIVITIES		€ (107,542)	€ (162,052)	€ (806)
CASH FLOWS (USED IN) / FROM FINANCING ACTIVITIES				
Proceeds from issue of new shares, gross amount	4.8	255,721	327,700	45,977
Issue costs paid	4.8	(14,655)	(23,015)	(1,849)
Exchange gain from currency conversion on proceeds from issue of new shares		1,354	—	—
Proceeds from exercise of stock options	4.8	2,251	679	493
NET CASH FLOWS (USED IN) / FROM FINANCING ACTIVITIES		€ 244,671	€ 305,365	€ 44,621
NET INCREASE (DECREASE) IN CASH & CASH EQUIVALENTS		€ 83,290	€ 106,767	€ 54,414
Cash and cash equivalents at the beginning of the period		€ 190,867	€ 89,897	€ 35,514
Exchange gains/(losses) on cash & cash equivalents	5.8	6,883	€ (5,797)	€ (31)
Cash and cash equivalents at the end of the period		€ 281,040	€ 190,867	€ 89,897

The notes are an integral part of these consolidated financial statements.

ARGENX SE

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

	Attributable to owners of the parent				Total equity attributable to owners of the parent	Total equity
(in thousands of €)	Share capital	Share premium	Accumulated losses	Other reserves		
Balance at January 1, 2016	€ 1,580	€ 82,169	€ (51,118)	€ 4,647	€ 37,278	€ 37,278
Total comprehensive loss of the period	€	€	€ (21,374)	€	€ (21,374)	€ (21,374)
Share-based payment				2,849	2,849	2,849
Issue of share capital (restated)	418	45,559			45,977	45,977
Transaction costs for equity issue (restated)		(1,849)			(1,849)	(1,849)
Exercise of stock options (restated)	14	479			493	493
Balance year ended December 31, 2016	€ 2,012	€ 126,358	€ (72,492)	€ 7,496	€ 63,374	€ 63,374
Total comprehensive loss of the period	€	€	€ (28,076)	€	€ (28,076)	€ (28,076)
Share-based payment				4,268	4,268	4,268
Issue of share capital (restated)	1,185	326,515			327,700	327,700
Transaction costs for equity issue (restated)		(23,015)			(23,015)	(23,015)
Exercise of stock options (restated)	19	660			679	679
Balance year ended December 31, 2017	€ 3,216	€ 430,518	€ (100,568)	€ 11,764	€ 344,931	€ 344,931
Adoption of IFRS 15 (modified retrospective approach)	€	€	€ (2,395)	€	€ (2,395)	€ (2,395)
Total comprehensive loss of the period			(66,641)		(66,641)	(66,641)
Share-based payment				19,183	19,183	19,183
Issue of new shares	347	255,374			255,721	255,721
Transaction costs for equity issue		(14,655)			(14,655)	(14,655)
Exercise of stock options	34	2,217			2,251	2,251
Balance year ended December 31, 2018	€ 3,597	€ 673,454	€ (169,603)	€ 30,947	€ 538,395	€ 538,395

Please refer to note 4.8 for more information on the share capital and movement in number of shares. See also note 4.9 for more information on the share-based payments.

The notes are an integral part of these consolidated financial statements.

ARGENX SE**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS****1. General information about the company**

argenx SE is a Dutch European public company with limited liability incorporated under the laws of the Netherlands. The company (COC 24435214) has its official seat in Rotterdam, the Netherlands, and its registered office is at Willemstraat 5, 4811 AH, Breda, the Netherlands. An overview of the company and its subsidiaries (the Company) are described in note 7.5.

argenx SE is a publicly traded company with ordinary shares listed on Euronext Brussels under the symbol “ARGX” since July 2014 and with American Depositary Shares listed on Nasdaq under the symbol “ARGX” since May 2017.

2. Significant accounting policies

The significant Company’s accounting policies are summarized below.

2.1 Statement of compliance and basis of preparation

The consolidated financial statements are prepared in accordance with the International Financial Reporting Standards (IFRS), issued by the International Accounting Standards Board (IASB) and the interpretations issued by the IASB’s International Financial Reporting Interpretation Committee. The consolidated financial statements provide a general overview of the Company’s activities and the results achieved. They present fairly the entity’s financial position, its financial performance and cash flows, on a going concern basis. The accounting policies described in Note 2 to our consolidated financial statements have been applied in preparing the consolidated financial statements as of and for the year ended December 31, 2018 and for the comparative information as of and for the years ended December 31, 2017 and 2016.

The preparation of consolidated financial statements in conformity with IFRS, issued by the IASB, requires the use of certain critical accounting estimates. It also requires management to exercise its judgment in the process of applying the Company’s accounting policies. The areas involving a higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements are disclosed in Note 3.

The significant accounting policies applied in the preparation of the above consolidated financial statements are set out below. All amounts are presented in thousands of euro, unless otherwise indicated, rounded to the nearest € ‘000.

The consolidated financial statements have been approved for issue by the Company’s Board of Directors (the Board) on March 26, 2019.

Correction of an immaterial error

Subsequent to the issuance of the Company’s consolidated financial statements for the year ended December 31, 2017 on Form 20-F, the Company determined that the current versus non-current classification of deferred revenue as of December 31, 2017 and December 31, 2016, respectively, was not made correctly, impacting the Company’s consolidated statement of financial position and the consolidated statement of cash flows.

Management evaluated the materiality of the errors from a quantitative and qualitative perspective and concluded that this adjustment was not material to the Company’s previously issued consolidated financial statements. The Company has elected to revise the historical consolidated financial information presented herein in the consolidated statement of financial position and the consolidated statement of cash flows to reflect the correction of this error for the prior periods presented and to confirm to current year presentation. Since the revisions were not material, no amendments to previously filed reports were required. The revision had the effect of decreasing the current deferred revenue balance and increasing the non-current deferred revenue with €1.4 million as of December

31, 2017 and €10.1 million as of December 31, 2016, respectively. Each affected individual line item within the consolidated statement of cash flows relating to the change in these balances have likewise been revised.

Reclassifications

Certain amounts from previous periods have been reclassified to conform to the 2018 presentation. Specifically, for the years ended December 31, 2017 and December 31, 2016, issue costs paid and proceeds from exercise of stock options are now disclosed on as a separate line item on the consolidated statement of cash flows and on the consolidated statement of changes in equity.

2.2 Basis of consolidation

The consolidated financial statements include the financial statements of the Company and entities controlled by the Company (its subsidiaries). Control is achieved when the Company:

- has power over the investee;
- is exposed, or has rights, to variable returns from its involvement with the investee; and
- has the ability to use its power to affect its returns.

The Company reassesses whether or not it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control listed above.

Consolidation of a subsidiary begins when the Company obtains control over the subsidiary and ceases when the Company loses control of the subsidiary. Income and expenses of subsidiaries acquired or disposed of during the year are included in the consolidated statement of profit and loss and other comprehensive income from the effective date of acquisition and up to the effective date of disposal, as appropriate. Total comprehensive income of subsidiaries is attributed to the owners of the Company and to the non-controlling interests even if this results in the non-controlling interests having a deficit balance.

When necessary, adjustments are made to the financial statements of subsidiaries to bring their accounting policies into line with those used by other members of the Group.

All intra-group transactions, balances, income and expenses are eliminated in full on consolidation.

2.3 Foreign currency transactions

Functional and presentation currency

The consolidated financial statements are presented in euro (€), which is the Company's presentation currency and the Company's functional currency.

Transactions and balances

Transactions in foreign currencies are translated at the exchange rate ruling at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies are translated at the exchange rate ruling at the reporting date. Foreign exchange differences arising on translation are recognized in the statement of profit and loss and other comprehensive income. Non-monetary assets and liabilities denominated in foreign currencies are translated at the foreign exchange rate ruling at the date of the transaction.

Financial statements of foreign entities

For foreign entities using a different functional currency than the euro:

- Non-monetary assets and liabilities are converted to the euro at the historical exchange rate at the date of the transaction.

- Monetary assets and liabilities are converted to the euro using the exchange rate on the reporting date.
- Income statements are converted to the euro at the annual average exchange rate.
- Equity items are converted to the euro at the historical exchange rate for the date of the transaction.

Translation differences resulting from the conversion of equity into euro using the rate at the end of the reporting period are recognized as translation differences under equity. Translation differences remain in equity up to the disposal of the company. In case of disposal, the deferred cumulative amount included in equity is included in the results for the foreign activity in question.

2.4 Intangible assets

Intangible assets with finite useful lives that are acquired separately are carried at cost less accumulated amortization and accumulated impairment losses. Amortization is recognized on a straight-line basis over their estimated useful lives. The estimated useful life and amortization method are reviewed at the end of each reporting period, with the effect of any changes in estimate being accounted for on a prospective basis. Intangible assets with indefinite useful lives that are acquired separately are carried at cost less accumulated impairment losses.

Intangible assets related to software are amortized over 3 years.

Expenditure on research activities is recognized as an expense in the period in which it is incurred.

An internally-generated intangible asset arising from development (or from the development phase of an internal project) is recognized if, and only if, all of the following have been demonstrated:

- the technical feasibility of completing the intangible asset so that it will be available for use or sale;
- the intention to complete the intangible asset and use or sell it;
- the ability to use or sell the intangible asset;
- how the intangible asset will generate probable future economic benefits;
- the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and
- the ability to measure reliably the expenditure attributable to the intangible asset during its development.

The amount initially recognized for internally-generated intangible assets is the sum of the expenditure incurred from the date when the intangible asset first meets the recognition criteria listed above. Where no internally-generated intangible asset can be recognized, development expenditures are recognized in the statement of profit and loss and other comprehensive income in the period in which they are incurred.

Due to uncertainties inherent to the development and registration with the relevant healthcare authorities of its products, the Company estimates that the conditions for capitalization are not met until the regulatory procedures required by such healthcare authorities have been finalized. The Company currently does not own products that have been approved by the relevant healthcare authorities. As such, research expenditures not satisfying the above criteria and expenditures in the research phase of internal projects are recognized in the statement of profit and loss and other comprehensive income as they are incurred.

Subsequent to initial recognition, internally-generated intangible assets are reported at cost less accumulated amortization and accumulated impairment losses, on the same basis as intangible assets that are acquired separately.

An intangible asset is derecognized either on disposal or when no future economic benefits are expected from its use. Gains or losses arising from derecognition of an intangible asset, measured as the difference between the net disposal proceeds and the carrying amount of the asset, are recognized in profit or loss when the asset is derecognized.

2.5 Property, plant and equipment

Items of property, plant and equipment held for use in the production or supply of goods or services, or for administrative purposes, are stated in the statement of financial position at their cost, less accumulated depreciation and accumulated impairment losses.

The cost comprises the initial purchase price plus other direct purchase costs (such as non-refundable tax and transport).

Depreciation is recognized as from acquisition date onwards (unless asset is not ready for use) so as to write off the cost or valuation of assets (other than freehold land and properties under construction) less their residual values over their useful lives, using the straight-line method. The estimated useful lives, residual values and depreciation method are reviewed at the end of each reporting period, with the effect of any changes in estimate accounted for on a prospective basis.

Unless revised due to specific changes in the estimated useful life, annual depreciation rates are as follows:

- Office and lab equipment: 3–5 years
- IT equipment: 3 years

An item of property, plant and equipment is derecognized upon disposal or when no future economic benefits are expected to arise from the continued use of the asset. Any gain or loss arising on the disposal or retirement of an item of property, plant and equipment is determined as the difference between the sales proceeds and the carrying amount of the asset and is recognized in profit or loss.

2.6 Leases

Leases of property, plant and equipment where the Company, as lessee, has substantially all the risks and rewards of ownership are classified as finance leases. Finance leases are capitalised at the lease's inception at the fair value of the leased property or, if lower, the present value of the minimum lease payments. The corresponding rental obligations, net of finance charges, are included in other short-term and long-term payables. Each lease payment is allocated between the liability and finance cost. The finance cost is charged to the profit or loss over the lease period so as to produce a constant periodic rate of interest on the remaining balance of the liability for each period. The property, plant and equipment acquired under finance leases is depreciated over the asset's useful life or over the shorter of the asset's useful life and the lease term if there is no reasonable certainty that the Company will obtain ownership at the end of the lease term.

Operating lease payments are recognized as an expense on a straight-line basis over the lease term, except where another systematic basis is more representative of the time pattern in which economic benefits from the leased asset are consumed. Contingent rentals arising under operating leases are recognized as an expense in the period in which they are incurred.

In the event that lease incentives are received to enter into operating leases, such incentives are recognized as a liability. The aggregate benefit of incentives is recognized as a reduction of rental expense on a straight-line basis, except where another systematic basis is more representative of the time pattern in which economic benefits from the leased asset are consumed.

2.7 Impairment of assets

At the end of each reporting period, the Company reviews the carrying amounts of its tangible and intangible assets to determine whether there is any indication that those assets have suffered an impairment loss. If any such indication exists, the recoverable amount of the asset is estimated in order to determine the extent of the

impairment loss (if any). Where it is not possible to estimate the recoverable amount of an individual asset, the Company estimates the recoverable amount of the cash-generating unit to which the asset belongs.

Intangible assets with indefinite useful lives and intangible assets not yet available for use are tested for impairment at least annually, and whenever there is an indication that the asset may be impaired.

Recoverable amount is the higher of fair value less costs to sell and value in use. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset for which the estimates of future cash flows have not been adjusted.

If the recoverable amount of an asset (or cash-generating unit) is estimated to be less than its carrying amount, the carrying amount of the asset (or cash-generating unit) is reduced to its recoverable amount. An impairment loss is recognized immediately in profit or loss.

Where an impairment loss subsequently reverses, the carrying amount of the asset (or a cash-generating unit) is increased to the revised estimate of its recoverable amount, but so that the increased carrying amount does not exceed the carrying amount that would have been determined had no impairment loss been recognized for the asset (or cash-generating unit) in prior years. A reversal of an impairment loss is recognized immediately in profit or loss.

2.8 Financial instruments

Financial assets and financial liabilities are recognised in the Company's statement of financial position when the Company becomes a party to the contractual provisions of the instrument.

Financial assets and financial liabilities are initially measured at fair value. Transaction costs that are directly attributable to the acquisition or issue of financial assets and financial liabilities (other than financial assets and financial liabilities at fair value through profit or loss) are added to or deducted from the fair value of the financial assets or financial liabilities, as appropriate, on initial recognition. Transaction costs directly attributable to the acquisition of financial assets or financial liabilities at fair value through profit or loss are recognised immediately in profit or loss.

The Company has adopted IFRS 9 on January 1, 2018. In accordance with the transitional provisions in IFRS 9, comparative figures have not been restated. The adoption of IFRS 9 had no material impact on the consolidated financial statements (see also note 6.1).

2.8.1 Investment securities

(i) Classification

From January 1, 2018, the Company classifies its financial assets at fair value through profit and loss (FVTPL).

For assets measured at fair value, gains and losses will either be recorded in profit or loss. For investments in equity instruments that are not held for trading, this will depend on whether the Company has made an irrevocable election at the time of initial recognition to account for the equity investment at fair value through other comprehensive income (FVOCI).

(ii) Recognition and derecognition

Purchases and sales of financial assets are recognised on trade-date, the date on which the Company commits to purchase or sell the asset. Financial assets are derecognised when the rights to receive cash flows from the financial assets have expired or have been transferred and the Company has transferred substantially all the risks and rewards of ownership.

(iii) Measurement

At initial recognition, the Company measures a financial asset at its fair value. Transaction costs of financial assets carried at FVTPL are expensed in profit or loss.

(iv) Impairment

From January 1, 2018, the Company assesses on a forward-looking basis the expected credit losses associated with its debt instruments carried at amortised cost and FVOCI. The impairment methodology applied depends on whether there has been a significant increase in credit risk.

(v) Accounting policies applied until December 31, 2017

Financial assets were classified into the following specified categories: financial assets 'at fair value through profit or loss' (FVTPL), 'held-to-maturity' investments, 'available-for-sale' (AFS) financial assets and 'loans and receivables.' The classification depended on the nature and purpose of the financial assets and was determined at the time of initial recognition. Management determined the classification at the time of the purchase and reevaluated such designation at each subsequent balance sheet date.

Purchase and sale of financial assets were recognized on the settlement date, which was the date an asset is delivered to or by the Group. The cost of financial assets included transaction costs.

The carrying amounts of all financial assets were reviewed for impairment whenever events or changes in circumstances indicated that the carrying amount is impaired. If objective evidence existed that a financial asset or group of financial assets was impaired, the amount of the impairment loss was calculated as the difference between the carrying amount of the financial asset and the present value of estimated future cash flows, discounted at the original effective interest rate (i.e., the effective interest rate computed at initial recognition of these financial assets). The resulting impairment loss was immediately recognized in net finance costs.

An impairment loss on financial assets was reversed if, in a subsequent period, the amount of the impairment loss decreased and this decrease could be related objectively to an event occurring after the impairment loss was recognized. Such reversal was immediately recognized in net finance costs.

2.9 Trade and other receivables

Trade receivables are recognised initially at the amount of consideration that is unconditional. The Company holds the trade receivables with the objective to collect the contractual cash flows and therefore measures them subsequently at amortised cost using the effective interest method. Unless the impact of discounting is material, the nominal value is recognized.

The Company measures the loss allowance for trade receivables at an amount equal to lifetime expected credit loss. The expected credit losses are established when there is objective evidence that the Company will not be able to collect all amounts due according to the original terms of the receivables.

2.10 Research and development incentive receivables

Since the Company carries out extensive research and development activities, it benefits from a research and development incentive tax scheme in Belgium under which the research and development incentives can be refunded after five years if not offset against future income tax expense.

Non-current research and development incentives receivables are discounted over the period until maturity date according to the appropriate discount rates.

2.11 Cash and cash equivalents

Cash and cash equivalents includes cash in hand, deposits held at call with banks and other short term highly liquid investments with original maturities of three months or less and with an insignificant risk of changes in

value. Bank overdrafts, if any, are shown within borrowings in current liabilities on the statement of financial position.

Cash balances that are not available for use by the Company are presented as “restricted cash” in the statement of financial position.

For the purpose of the statements of cash flows, cash and cash equivalents includes cash on hand and deposits held at call or short term maturity with banks (three months or less with insignificant risk of changes in value).

2.12 Shareholder’s equity

An equity instrument is any contract that evidences a residual interest in the assets of an entity after deducting all of its liabilities. Equity instruments issued by the Company are recognized at the proceeds received, net of direct issue costs.

The Company has never distributed any dividends to its shareholders. As of 31 December 2018, no profits were available for distribution.

2.13 Trade and other payables

Payables after and within one year are measured at amortized cost, i.e., at the net present value of the payable amount. Unless the impact of discounting is material, the nominal value is recognized.

2.14 Provisions

Provisions are recognized when the Company has a present obligation (legal or constructive) as a result of a past event, it is probable that the Company will be required to settle the obligation, and a reliable estimate can be made of the amount of the obligation.

The amount recognized as a provision is the best estimate of the consideration required to settle the present obligation at the end of the reporting period, taking into account the risks and uncertainties surrounding the obligation. When a provision is measured using the cash flows estimated to settle the present obligation, its carrying amount is the present value of those cash flows (where the effect of the time value of money is material).

When some or all of the economic benefits required to settle a provision are expected to be recovered from a third party, a receivable is recognized as an asset if it is reasonably certain that reimbursement will be received and the amount of the receivable can be measured reliably.

2.15 Retirement benefits

The Company offers a post-employment, death, disability and healthcare benefit scheme. All employees have access to these schemes. The death, disability and healthcare benefits granted to employees of the Company are covered by an external insurance company, where premiums are paid annually and charged to the income statement as they were incurred.

The post-employment pension plan granted to employees of the Company is a defined contribution plan under Belgian Law.

Under defined contribution plans, the Company pays contributions based on salaries to organizations responsible for paying out pensions and social security benefits, in accordance with the laws and agreements applicable in each country.

The Belgian defined contribution pension plans are by law subject to minimum guaranteed rates of return, historically 3.25% on employer contributions and 3.75% on employee contributions. These rates have been modified by the law of December 18, 2015 and effective for contribution paid as from 2016 to a new variable minimum return based on the OLO (‘Obligation Lineaire Obligaties’—Belgian Government Bond) rates, with a minimum of 1.75% and a maximum of 3.75%.

Hence, those plans classify as defined benefit plans. Until year-end 2015, the net liability recognized in the statement of financial position was based on the sum of the positive differences, determined by individual plan participant, between the minimum guaranteed reserves and the accumulated contributions based on the actual rates of return at the closing date. From 2016 onwards, these plans are accounted for as defined benefit plans (see note 4.13).

The liability recognized in the balance sheet is the present value of the defined benefit obligation less the fair value of plan assets. An independent actuary calculates the defined benefit obligation based on factors such as age, years of service and compensation (projected unit credit method). The present value of the defined benefit obligation is determined by discounting the estimated future cash outflows using interest rates of high-quality corporate bonds denominated in the currency in which the benefits will be paid and with terms to maturity that approximate the term when the related liability is due. Current service costs are recognized in personnel expenses, which are included in Research and development expenses and in Selling, general and administrative expenses, and reflect the increase in the defined benefit obligation resulting from employee service in the current year. Past service costs are recognized immediately in personnel expenses. The net interest expense on the defined benefit liability is determined by applying the discount rate used to measure the defined benefit obligation at the beginning of the year to the then net defined benefit liability. Net interest expense is recognized in personnel expenses. Remeasurement gains and losses of the defined benefit obligation arising from experience adjustments and changes in actuarial assumptions are recognized immediately in other comprehensive income.

2.16 Short-term employee benefits

Short-term employee benefits include payables and accruals for salaries and bonuses to be paid to the employees of the Company. They are recognized as expenses for the period in which employees perform the corresponding services.

2.17 Share-based payments

Equity-settled share-based payments to employees and others providing similar services are measured at the fair value of the equity instruments at the grant date. Details regarding the determination of the fair value of equity-settled share-based transactions are set out in note 4.9.

The fair value determined at the grant date of the equity-settled share-based payments is expensed on a straight-line basis over the vesting period, based on the Company's estimate of equity instruments that will eventually vest, with a corresponding increase in equity. At the end of each reporting period, the Company revises its estimate of the number of equity instruments expected to vest. The impact of the revision of the original estimates, if any, is recognized in profit or loss such that the cumulative expense reflects the revised estimate, with a corresponding adjustment to the equity-settled share-based payment reserve.

Where the terms of equity-settled share-based payments are modified, the minimum expense recognized is the expense that would have been recognized if the terms had not been modified. An additional expense is recognized for any modification that increases the total fair value of the share-based payments, or is otherwise beneficial to the employee as measured at the date of modification.

2.18 Deferred revenue

Current and non-current deferred revenue relates to cash received from commercial partnerships prior to completion of the earnings process. These payments are recognized as revenue over the estimated duration of the Company's involvement in the research and development programs provided for under the terms of the agreements.

IFRS 15 uses the term 'contract liability' to describe what might more commonly be known as 'deferred revenue', however IFRS 15 does not prohibit an entity from using alternative descriptions in the statement of financial position. The Company will continue to report its contract liabilities under the term 'deferred revenue'.

2.19 Income taxes

Income tax expense represents the sum of the tax currently payable and deferred tax.

The tax currently payable is based on taxable profit for the year. Taxable profit differs from profit as reported in the statement of profit and loss and other comprehensive income because of items of income or expense that are taxable or deductible in other years and items that are never taxable or deductible. The Company's liability for current tax is calculated using tax rates that have been enacted or substantively enacted by the end of the reporting period.

Deferred tax is recognized on temporary differences between the carrying amounts of assets and liabilities in the consolidated financial statements and the corresponding tax basis used in the computation of taxable profit (e.g. differences between carrying amounts under IFRS and the statutory tax basis). Deferred tax liabilities are generally recognized for all taxable temporary differences. Deferred tax assets are generally recognized for all deductible temporary differences to the extent that it is probable that taxable profits will be available against which those deductible temporary differences can be utilized. Such deferred tax assets and liabilities are not recognized if the temporary difference arises from goodwill or from the initial recognition (other than in a business combination) of other assets and liabilities in a transaction that affects neither the taxable profit nor the accounting profit.

The carrying amount of deferred tax assets is reviewed at the end of each reporting period and reduced to the extent that it is no longer probable that sufficient taxable profits will be available to allow all or part of the asset to be recovered.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply in the period in which the liability is settled or the asset realized, based on tax rates (and tax laws) that have been enacted or substantially enacted by the end of the reporting period. The measurement of deferred tax liabilities and assets reflects the tax consequences that would follow from the manner in which the Company expects, at the end of the reporting period, to recover or settle the carrying amount of its assets and liabilities.

Deferred tax assets and deferred tax liabilities are offset if there is a legally enforceable right to offset current tax assets and liabilities and if they relate to income taxes imposed by the same authority on the same taxable entity or in different tax entities that intend to settle current tax assets and liabilities on a net basis or their tax assets and liabilities will be realized simultaneously.

2.20 Revenue and other operating income recognition

Collaborations

The Company generates revenue from collaborations and strategic alliances. The Company applies a five-step model to determine when, how and at what amount revenue is to be recognized depending on whether certain criteria are met.

1. Identify the contracts

In our current arrangements, the Company is licensing its Intellectual Property, providing research and development services and in the future, selling its products to collaborative partner entities. Revenue is generated through these arrangements via upfront payments, milestone payments based on development criteria, research and development service fees on an agreed full-time equivalent (FTE) basis and future sales based milestones and sales based royalties.

2. Identify performance obligations

The Company has assessed that there is one single performance obligation for certain arrangements in our material ongoing license and collaboration arrangements, being the transfer of a license combined with performance of research and development services.

This is because we consider that the license has no stand-alone value without the Company being further involved in the research and development collaboration and that there is interdependence between the license and the research and development services to be provided. We estimate that the Company's activities during the collaboration are going to significantly add to Intellectual Property and thereby the value of the programs.

3. Determine the transaction price

We have analyzed the transaction prices of our material ongoing license and collaboration arrangements currently composed of upfront payments, milestone payments and research and development service fees being delivered. Sales based milestones and sales based royalties are part of certain of our arrangements but are not yet included in our revenues as our most advanced license and collaboration arrangement is still in the development phase.

4. Allocate the transaction price

In principle, an entity shall allocate the transaction price to each performance obligation identified in the contract on a relative stand-alone selling price. However, the transaction price of certain of our arrangements is allocated to a single performance obligation since the transfer of a license is considered to be combined with performance of research and development services.

Therefore, research and development milestone payments are variable considerations that are entirely allocated to the single performance obligation.

5. Recognize revenue

Revenue from certain arrangements is recognized over time as the Company satisfies a single performance obligation. Our collaborative partner entities simultaneously receive the benefits provided by the Company's performance as the Company performs.

The Company recognizes upfront payments and milestone payments, allocated to a single performance obligation over the estimated service period based on a pattern that reflects the transfer of the services. The revenues recognized reflect the level of service each period. In this case, the Company would use an input model that considers estimates of the percentage of total research and development service costs that are completed each period compared to the total estimated services costs (percentage of completion method).

Research and development service fees are recognized as revenue when costs are incurred and agreed by the parties as the Company is acting as a principal in the scope of its stake of the research and development activities of its ongoing license and collaboration agreements.

Grants, research and development incentives and payroll tax rebates

Because it carries out extensive research and development activities, the Company benefits from various grants, research and development incentives and payroll tax rebates from certain governmental agencies. These grants, research and development incentives and payroll tax rebates generally aim to partly reimburse approved expenditures incurred in research and development efforts of the Company and are credited to the statement of profit and loss and other comprehensive income, under other operating income, when the relevant expenditure has been incurred and there is reasonable assurance that the grants or research and development incentives are receivable.

2.21 Earnings per share

Basic net profit / (loss) per share is computed based on the weighted average number of ordinary shares outstanding during the period, excluding treasury shares.

Diluted net profit / (loss) per share is computed based on the weighted-average number of ordinary shares outstanding including the dilutive effect of options. Options should be treated as dilutive, when and only when their conversion to ordinary shares would decrease net profit per share from continuing operations.

2.22 Adoption of new and revised standards

New accounting policies and disclosures for 2018

The following new standards and amendments to standards are mandatory for the first time for the financial year beginning on or after January 1, 2018:

- IFRS 9, 'Financial instruments' (effective for fiscal years beginning on or after January 1, 2018). This standard, which covers financial instruments on both the asset as well as the liability side, describes the criteria for recognition, classification and derecognition of such instruments, in addition to the allowed measurement methods. The adoption of IFRS 9 had no material impact on our consolidated financial statements.
- IFRS 15 and amendments to IFRS 15, 'Revenue from contracts with customers' (effective for fiscal years beginning on or after January 1, 2018). The IASB and FASB have jointly published a standard regarding revenue from contracts with customers. The standard will result in better financial reporting and will improve the comparability of the top line in financial statements globally.

The Company has adopted IFRS 15 on January 1, 2018. The Company elected the modified retrospective approach for the transition, which foresees that prior period figures remain as reported under the previous standard IAS 18, and the cumulative effect of applying IFRS 15 is recognized as an adjustment to the opening balance of equity as at the date of initial application (i.e., the beginning of the year 2018). In previous reporting periods, milestone payments were recognized under IAS 18 based upon the achievement of the milestone event, whereas under IFRS 15, the milestone payment is linked to a single performance obligation over the estimated service period. The revenue recognition of the upfront payments was not impacted by the transition from IAS 18 to IFRS 15.

The cumulative effect of adopting IFRS 15 to the consolidated statement of financial position as of January 1, 2018 is as follows:

(in thousands of €)	Balance at December 31, 2017	Adjustments due to adoption IFRS 15	Balance at January 1, 2018
Assets			
Prepaid expenses	€ 2,338	€ (255)	€ 2,083
Liabilities			
Deferred revenue — non-current	€ 1,435	€ 378	€ 1,813
Deferred revenue — current	8,635	2,272	10,907
Equity			
Accumulated losses	€ (100,568)	€ (2,395)	€ (102,962)

In accordance with the new revenue guidance, the disclosure of the impact of adoption on the consolidated statement of financial position and the consolidated statement of profit and loss and other comprehensive income is as follows:

Consolidated statement of financial position (in thousands of €)	For the Year Ended December 31, 2018		
	As reported	Adjustments	Balances without adoption of IFRS 15
Assets			
Prepaid expenses	€ 2,995	€ 68	€ 3,063
Liabilities			
Deferred revenue — current	€ 2,161	€ (726)	€ 1,435
Equity			
Accumulated losses	€ (169,603)	€ 658	€ (168,945)
Consolidated statement of profit and loss and other comprehensive income (in thousands of €)	For the Year Ended December 31, 2018		
	As reported	Adjustments	Balances without adoption of IFRS 15
Revenue	€ 21,482	€ (1,924)	€ 19,558
Research and development expenses	€ (83,609)	€ 188	€ (83,421)
Loss for the year and total comprehensive loss	€ (66,641)	€ (1,736)	€ (68,377)

There is no material impact on the basic and diluted earnings per share.

Consolidated statement of cash flows (in thousands of €)	For the Year Ended December 31, 2018		
	As reported	Adjustments	Balances without adoption of IFRS 15
Operating result	€ (81,849)	€ (1,736)	€ (83,585)
Movements in current assets/liabilities:			
(Increase)/decrease in other current assets	€ (800)	€ 68	€ (732)
Increase/(decrease) in current deferred revenue	(8,868)	1,668	(7,200)
Cash flows (used in)/from operating activities	€ (53,274)	€ (0)	€ (53,274)

- Other new standards and amendments to standards that are mandatory for the first time for the financial year beginning on or after January 1, 2018 had no material impact on our consolidated financial statements.

New accounting policies and disclosures effective in 2019 or later

The following new standards and amendments to standards have been issued, but are not mandatory for the first time for the financial year beginning January 1, 2018 and have been endorsed by the European Union.

- IFRS 16, 'Leases' (effective for fiscal years beginning on or after January 1, 2019). This standard replaces the current guidance in IAS 17 and is a far reaching change in accounting by lessees in particular. Under IAS 17, lessees were required to make a distinction between a finance lease (on balance sheet) and an operating lease (off balance sheet). IFRS 16 requires lessees to recognise a lease liability reflecting future lease payments and a 'right-of-use asset' for virtually all lease contracts. For lessors, the accounting stays almost the same. However, as the IASB has updated the guidance on the definition of a lease (as well as the guidance on the combination and separation of contracts), lessors will also be affected by the new

standard. Under IFRS 16, a contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

We performed a preliminary assessment evaluating the guidance to determine the potential impact on the consolidated financial statements. The standard will affect primarily the accounting for the Company's operating leases.

As of the reporting date, the Company has non-cancellable operating lease commitments of €3.0 million, see note 5.7. Of these commitments, approximately €0.1 million related to short-term leases or low value leases which will be recognized on a straight-line basis as expense in profit and loss.

For the remaining lease commitments, the Company expects to recognize on January 1, 2019 right-of-use assets of approximately €2.8 million and lease liabilities of approximately €2.8 million. Operating cash flows will increase and financing cash flows will decrease by approximately €1.1 million as repayment of the principal portion of the lease liabilities will be classified as cash flows from financing activities. The Company does not use EBITDA to measure its performance.

We plan to adopt IFRS 16 on the effective date using the modified retrospective approach.

- Amendments to IFRS 9, 'Prepayment features with negative compensation' (effective for fiscal years beginning on or after January 1, 2019 with the EU). The amendments to allow companies to measure particular prepayable financial assets with so-called negative compensation at amortised cost or at fair value through other comprehensive income if a specified condition is met—instead of at fair value through profit or loss, because they would otherwise fail the SPPI-test. In addition, this amendment clarifies an aspect of the accounting for financial liabilities following a modification.

These amendments will not have any material impact on our consolidated financial statements.

- IFRIC 23, 'Uncertainty over income tax treatments' (effective for fiscal years beginning on or after January 1, 2019). This interpretation clarifies the accounting for uncertainties in income taxes. The interpretation is to be applied to the determination of taxable profit (tax loss), tax bases, unused tax losses, unused tax credits and tax rates, when there is uncertainty over income tax treatments under IAS 12.

Except for the matters already disclosed in note 4.12 of the consolidated financial statements, the Company does not anticipate that the application of this interpretation will have a material impact on the Company's consolidated financial statements. We plan to adopt IFRIC 23 on the effective date.

- Other new standards and amendments to standards that have been issued, but are not mandatory for the first time for the financial year beginning January 1, 2018 will have no material impact on our consolidated financial statements.

The following new standards and amendments to standards have been issued, but are not mandatory for the first time for the financial year beginning January 1, 2018 and have not been endorsed by the European Union.

- Amendments to IAS 19, 'Plan Amendment, Curtailment or Settlement' (effective for fiscal years beginning on or after January 1, 2019). The amendments require an entity to use updated assumptions to determine current service cost and net interest for the remainder of the period after a plan amendment, curtailment or settlement. In addition, an entity will have to recognise in profit or loss as part of past service cost, or a gain or loss on settlement, any reduction in a surplus, even if that surplus was not previously recognised because of the impact of the asset ceiling. The amendments will affect any entity that changes the terms or the membership of a defined benefit plan such that there is past service cost or a gain or loss on settlement.

These amendments are not expected to have any material impact on our consolidated financial statements.

- Amendments to References to the Conceptual Framework in IFRS Standards (effective for fiscal years beginning on or after January 1, 2020). The revised Conceptual Framework includes a new chapter on measurement; guidance on reporting financial performance; improved definitions and guidance—in

particular the definition of a liability; and clarifications in important areas, such as the roles of stewardship, prudence and measurement uncertainty in financial reporting.

These amendments are not expected to have any material impact on our consolidated financial statements.

- Amendments to the definition of material in IAS 1 and IAS 8 (effective for fiscal years beginning on or after January 1, 2020). The amendments clarify the definition of material and make IFRSs more consistent. The amendment clarifies that the reference to obscuring information addresses situations in which the effect is similar to omitting or misstating that information. It also states that an entity assesses materiality in the context of the financial statements as a whole. The amendment also clarifies the meaning of 'primary users of general purpose financial statements' to whom those financial statements are directed, by defining them as 'existing and potential investors, lenders and other creditors' that must rely on general purpose financial statements for much of the financial information they need.

These amendments will not have any material impact on our consolidated financial statements.

- Annual improvements to IFRS Standards 2015-2017 cycle, applicable as of January 1, 2019 and containing the following amendments to IFRSs:
 - IFRS 3 Business Combinations and IFRS 11 Joint Arrangements, the amendments to IFRS 3 clarify that when an entity obtains control of a business that is a joint operation, it remeasures previously held interests in that business. The amendments to IFRS 11 clarify that when an entity obtains joint control of a business that is a joint operation, the entity does not remeasure previously held interests in that business.
 - IAS 12 Income Taxes, the amendments clarify that all income tax consequences of dividends (i.e. distribution of profits) should be recognised in profit or loss, regardless of how the tax arises.
 - IAS 23 Borrowing Costs, the amendments clarify that if any specific borrowing remains outstanding after the related asset is ready for its intended use or sale, that borrowing becomes part of the funds that an entity borrows generally when calculating the capitalisation rate on general borrowings.

These improvements will not have any material impact on our consolidated financial statements.

2.23 Segment reporting

Segment results include revenue and expenses directly attributable to a segment and the relevant portion of revenue and expenses that can be allocated on a reasonable basis to a segment. Segment assets and liabilities comprise those operating assets and liabilities that are directly attributable to the segment or can be allocated to the segment on a reasonable basis. Segment assets and liabilities do not include income tax items. The Company manages its activities and operates as one business unit which is reflected in its organizational structure and internal reporting. The Company does not distinguish in its internal reporting different segments, neither business nor geographical segments. The chief operating decision-maker is the Board of Directors.

3. Critical accounting judgements and key sources of estimation uncertainty

In the application of the Company's accounting policies, which are described above, the Company is required to make judgments, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period or in the period of the revision and future periods if the revision affects both current and future periods.

The following areas are areas where key assumptions concerning the future, and other key sources of estimation uncertainty at the end of the reporting period, have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year.

Critical judgements in applying accounting policies

Revenue recognition

Revenue from certain arrangements is recognized as the Company satisfies a single performance obligation. The Company recognizes upfront payments and milestone payments, allocated to a single performance obligation over the estimated service period based on a pattern that reflects the transfer of the services. The revenue recognized would reflect the level of service during each period. In this case, the Company would use an input model that considers estimates of the percentage of total research and development service costs that are completed each period compared to the total estimated service costs (percentage of completion method). Research and development service fees are recognized as revenue when costs are incurred and agreed by the parties as the Company is acting as a principal in the scope of its stake in the research and development activities of its ongoing license and collaboration agreements.

Research and development cost accruals

Research and development costs are charged to expense as incurred and are typically made up of payroll costs, clinical and preclinical activities, drug development and manufacturing costs, including costs for clinical research organizations and investigative sites. Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as information provided by vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid expenses.

Critical accounting estimates

Going concern

The Company has incurred net losses since its inception and for the year ended December 31, 2018, its consolidated statement of profit and loss and other comprehensive income reflects a net loss, and its consolidated statement of financial position includes a loss carried forward. On March 26, 2019, the Board has reviewed and approved the consolidated financial statements and accounting policies. Taking into account the cash and cash equivalents and current financial asset position of €564.6 million on December 31, 2018, the Board is of the opinion that the Company can submit its consolidated financial statements on a going concern basis.

Whilst the current cash position is sufficient for the Company's immediate and mid-term needs, the Board pointed out that if the research and development activities continue to deliver added value, the Company may seek additional funding to support the continuing development of its portfolio of products or to be able to execute other business opportunities.

Measurement of share-based payments

In accordance with IFRS 2—*Share-based Payment*, the fair value of the options at grant date is recognized as an expense in the statement of profit and loss and other comprehensive income over the vesting period. Subsequently, the fair value recognized in equity is not re-measured.

The fair value of each stock option granted during the year is calculated using the Black-Scholes pricing model. This pricing model requires the input of subjective assumptions, which are detailed in note 4.9.

Recognition of deferred tax assets

Deferred tax assets are recognized only if management assesses that these tax assets can be offset against positive taxable income within a foreseeable future.

This judgment is made by management on an ongoing basis and is based on budgets and business plans for the coming years, including planned commercial initiatives. These budgets and business plans are reviewed and approved by the Board of Directors.

Since inception, the Company has reported losses, and consequently, the Company has unused tax losses. The deferred tax assets are currently not deemed to meet the criteria for recognition as management is not able to provide any convincing positive evidence that deferred tax assets should be recognized. Therefore, management has concluded that deferred tax assets should not be recognized on December 31, 2018.

4. Notes relating to the consolidated statement of financial position

4.1 Intangible assets

(in thousands of €)

Opening balance as on January 1, 2016	
Cost	€ 72
Accumulated amortization	(65)
Book value at the beginning of the year	7
Movements	
Additions	21
Amortization	(11)
Balance as on December 31, 2016	
Cost	93
Accumulated amortization	(76)
Book value at year end	17
Movements	
Additions	6
Amortization	(10)
Balance as on December 31, 2017	
Cost	99
Accumulated amortization	(86)
Book value at year end	13
Movements	
Additions	62
Cost of disposals	(2)
Amortization	(19)
Accumulated depreciation on disposals	2
Balance as on December 31, 2018	
Cost	159
Accumulated amortization	(103)
Book value at year end	€ 56

The intangible assets correspond to software. As of December 31, 2018, there are no commitments to acquire additional intangible assets.

No intangible assets are pledged as security for liabilities nor are there any intangible assets whose title is restricted.

4.2 Property, plant and equipment

(in thousands of €)	IT equipment	Office and lab equipment	Lease equipment	Total
Opening balance as on January 1, 2016				
Cost	€ 93	€ 1,179	€	€ 1,272
Accumulated depreciation	(66)	(957)		(1,023)
Book value at the beginning of the year	27	222		249
Movements				
Additions	115	725		840
Depreciation	(38)	(285)		(323)
Closing balance as on December 31, 2016				
Cost	208	1,904		2,112
Accumulated depreciation	(104)	(1,242)		(1,346)
Book value at year end	104	662		766
Movements				
Additions	25	321		346
Cost of disposals	—	(69)		(69)
Depreciation	(53)	(372)		(425)
Accumulated depreciation on disposals	—	58		58
Closing balance as on December 31, 2017				
Cost	233	2,156	—	2,389
Accumulated depreciation	(157)	(1,556)	—	(1,713)
Book value at year end	76	600	—	676
Movements				
Additions	111	259	253	623
Cost of disposals	(12)	(34)		(46)
Depreciation	(64)	(399)	(11)	(474)
Accumulated depreciation on disposals	12	34		46
Closing balance as on December 31, 2018				
Cost	331	2,381	253	2,965
Accumulated depreciation	(209)	(1,921)	(11)	(2,141)
Book value at year end	€ 122	€ 460	€ 242	€ 824

There are no commitments to acquire property, plant and equipment. Furthermore, no items of property, plant and equipment are pledged.

4.3 Research and development incentive receivables

(in thousands of €)	Year Ended December 31,		
	2018	2017	2016
Research and development incentive receivables—current	€ 301	€ 158	€ 163
Research and development incentive receivables—non-current	4,883	3,033	2,046
	€ 5,184	€ 3,191	€ 2,209

On December 31, 2018, the Company has recorded a tax receivable of €5.2 million, compared to €3.2 million on December 31, 2017, in relation to a research and development incentive tax scheme in Belgium under which the research and development incentives can be refunded after five years if not offset against future income tax expense. The research and development incentives are recorded in other operating income (see note 5.2) in the consolidated statement of profit and loss and other comprehensive income. These amounts are expected to be gradually reimbursed in cash as from 2019 onwards.

4.4 Restricted cash

(in thousands of €)	Year Ended December 31,		
	2018	2017	2016
Non-current restricted cash			
Rental guarantees	€ 251	€ 256	€ 244
Escrow account > 1 year	—	—	905
Total non-current	€ 251	€ 256	€ 1,149
Current restricted cash			
Escrow account < 1 year	1,692	1,692	786
Total restricted cash	€ 1,943	€ 1,948	€ 1,935

On December 31, 2018, the Company had a total amount of €1.9 million of restricted cash. This amount is split as follows:

- A non-current part for an amount of €0.3 million mainly relating to a deposit guarantee paid under the lease agreement for the laboratory and offices of the Company.
- A current part for an amount of €1.7 million relating to an escrow account opened under an agreement with a third party involved in the collaboration with AbbVie. This escrow account will be released to the Company or to the third party under certain conditions after the completion of the work plan of the related collaboration agreement with AbbVie.

4.5 Trade and other receivables

The trade and other receivables are composed of receivables which are detailed below:

(in thousands of €)	Year Ended December 31,		
	2018	2017	2016
VAT receivable	€ 496	€ 317	€ 278
Trade receivables	214	845	1,118
Other receivables	455	750	—
Interest receivable	556	—	6
VLAIO grant receivable	1,165	930	568
	€ 2,886	€ 2,842	€ 1,970

The nominal amounts of all trade and other receivables approximate their respective fair values. The VAT receivable relates to VAT amounts to be recovered in the first quarter of 2019.

Trade receivables correspond to amounts invoiced to the collaborators or strategic allies of the Company. No bad debt allowance was recorded nor were any trade receivables impaired on December 31, 2018 and December 31, 2017. The Flanders Innovation and Entrepreneurship Agency grant to receive consists of earned income from government grants for which no payments have been received but for which the relating expenditures have been incurred.

For more information on the Flanders Innovation and Entrepreneurship Agency grants to receive, see note 5.2.

4.6 Current financial assets

On December 31, 2018, the current financial assets amounted to €283.5 million compared to €168.9 million on December 31, 2017. These current financial assets relate to financial instruments in the form of money market funds with a recommended investment horizon of 6 months. These funds are highly liquid investments and can be readily converted into a known amount of cash, but because of their historical volatility these funds cannot be classified as cash and cash equivalents. Values recognized on the balance sheet are the fair values, with changes in fair value going through profit and loss.

Please also refer to note 6.1 for more information on the financial instruments.

4.7 Cash and cash equivalents

(in thousands of €)	Year Ended December 31,		
	2018	2017	2016
Cash equivalents	€ 217,626	€ 25,000	€ 54,500
Cash and bank balances	63,414	165,867	35,397
	<u>€ 281,040</u>	<u>€ 190,867</u>	<u>€ 89,897</u>

On December 31, 2018, cash and cash equivalents amounted to €281.0 million compared to €190.9 million on December 31, 2017 and included cash equivalents and cash and bank balances held in different banks. Cash positions are invested with preferred financial partners, which are mostly considered to be high quality financial institutions with sound credit ratings.

Policies are in place that limit the amount of credit exposure to any one financial institution (see also note 6.4).

4.8 Shareholders' capital

Roll forward of number of shares outstanding:

Number of shares outstanding on January 1, 2016	15,802,767
Private placement (Federated Investment) on January 20, 2016	1,480,420
Exercise of options in February 2016	2,200
Exercise of options in March 2016	10,000
Exercise of options in April 2016	10,000
Exercise of options in May 2016	33,092
Private placement (Sunflower) on June 1, 2016	2,703,000
Exercise of options in September 2016	70,000
Exercise of options in October 2016	15,000
Number of shares outstanding on December 31, 2016	20,126,479
U.S. initial public offering on Nasdaq on May 17, 2017	5,865,000
Over-allotment option exercised by underwriters on May 19, 2017	879,750
Exercise of options in August 2017	5,000
Exercise of options in September 2017	15,000
Exercise of options in October 2017	1,400
Exercise of options in November 2017	106,782
U.S. second public offering on Nasdaq on December 13, 2017	4,440,000
Over-allotment option exercised by underwriters on December 14, 2017	666,000
Exercise of options in December 2017	75,230
Number of shares outstanding on December 31, 2017	32,180,641
Exercise of options in January 2018	111,727
Exercise of options in March 2018	113,075
Exercise of options in April 2018	34,039
Exercise of options in May 2018	5,900
Exercise of options in June 2018	5,393
Exercise of options in July 2018	469
Exercise of options in August 2018	2,300
Exercise of options in September 2018	5,913
U.S. third public offering on Nasdaq on September 18, 2018	3,475,000
Exercise of options in October 2018	556
Exercise of options in November 2018	9,768
Exercise of options in December 2018	30,531
Number of shares outstanding on December 31, 2018	35,975,312

New shares issued during 2016

In January 2016, U.S. funds advised by subsidiaries of Federated Investors, Inc. purchased 1,480,420 new shares issued by the Company, and subsequently in June 2016, following a private placement, 2,703,000 additional new shares were issued to institutional investors. 140,292 new shares were also issued in 2016 as a result of the exercise of stock options under the argenx Employee Stock Option Plan.

This resulted in a total of 20,126,479 ordinary shares with a nominal value of €0.1 per share on December 31, 2016. At the same date, the authorized unissued share capital of the Company amounted to €4.5 million divided into 45 million ordinary shares.

New shares issued during 2017

On May 17, 2017, argenx SE offered 5,865,000 of its ordinary shares through an initial public offering in the United States in the form of ADSs at a price to the public of \$17.00 per ADS, before underwriting discounts and commissions and offering expenses. On May 19, 2017, the underwriters of the offering exercised their over-allotment option to purchase 879,750 additional ADSs in full. As a result, argenx SE received €102.1 million of total gross proceeds from the offering, decreased by €9.6 million of underwriter discounts and commissions, and offering expenses, of which €8.9 million has been deducted from equity. The total net cash proceeds from this offering amounted to €92.5 million.

On December 14, 2017, argenx SE offered 4,440,000 of its ordinary shares through a public offering in the United States in the form of ADSs at a price to the public of \$52.00 per ADS, before underwriting discounts and commissions and offering expenses. On December 15, 2017, the underwriters of the offering exercised their over-allotment option to purchase 666,000 additional ADSs in full. As a result, argenx SE received €225.6 million of gross proceeds from this offering, decreased by €14.3 million of underwriter discounts and commissions, and offering expenses, of which €14.1 million has been deducted from equity. The total net cash proceeds from the Offering amounted to €211.3 million.

For both offerings completed in 2017, the ADSs are evidenced by American Depositary Receipts (ADRs), and each ADS represents the right to receive one ordinary share. These ADSs are listed on the NASDAQ Global Select Market under the symbol “ARGX”.

203,412 new shares were also issued in 2017 as a result of the exercise of stock options under the argenx Employee Stock Option Plan.

This resulted in a total of 32,180,641 ordinary shares with a nominal value of €0.1 per share on December 31, 2017. The extraordinary general meeting of the Company of November 7, 2017 had authorized the board of directors to issue up to a maximum of 20% of the then outstanding share capital for a period of 18 months, or up to a capital increase of €537,852.60 represented by 5,378,526 shares. The board of directors has issued 5,106,000 shares on the occasion of the U.S. public offering in December 2017 and as of December 31, 2017, the existing authorization covered the issuance of up to 272,526 shares.

New shares issued during 2018

On September 18, 2018, argenx SE offered 3,475,000 of its ordinary shares through a public offering in the United States in the form of ADSs at a price to the public of \$86.50 per ADS, before underwriting discounts and commissions and offering expenses. As a result, argenx SE received €255.7 million of gross proceeds from this offering, decreased by €14.8 million of underwriter discounts and commissions, and offering expenses, of which €14.7 million has been deducted from equity. The total net cash proceeds from the offering amounted to €240.9 million.

As a result of the exercise of options under the argenx Employee Stock Option Plan, 319,671 new shares were created in 2018.

This resulted in a total of 35,975,312 ordinary shares, with a nominal value of €0.1 per share, on December 31, 2018. The annual general meeting of the Company on May 8, 2018 had authorized the board of directors to issue up to a maximum of 20% of the then outstanding share capital for a period of 18 months, or up to a capital increase

of €648,790 represented by 6,487,896 shares. The board of directors has issued 3,475,000 shares on the occasion of the follow-on U.S. public offering in September 2018, and as of December 31, 2018, the existing authorization covered the issuance of up to 3,012,896 shares.

4.9 Share-based payments

The Company has a stock options scheme for the employees of the Company and its subsidiaries. In accordance with the terms of the plan, as approved by shareholders, employees may be granted options to purchase ordinary shares at an exercise price as mentioned below per ordinary share.

The Company has granted on June 28, 2018 a total of 178,900 stock options and on December 21, 2018 a total of 861,575 stock options to its employees, Board members and consultants. The total number of stock options outstanding on December 31, 2018 totaled 3,536,651 compared to 2,862,216 on December 31, 2017 and 2,293,636 on December 31, 2016. No stock options were expired in the years ended December 31, 2018, 2017 and 2016. 319,671 stock options have been exercised in the year ended December 31, 2018 compared to 203,412 in the year ended December 31, 2017 and 140,292 in the year ended December 31, 2016. A total of 46,369 stock options have been forfeited in the year ended December 31, 2018 compared to 2,369 in the year ended December 31, 2017 and 31,174 in the year ended December 31, 2016.

The stock options are granted to employees, consultants or directors of the Company and its subsidiaries. The stock options have been granted free of charge. Each employee's stock option converts into one ordinary share of the Company upon exercise. No amounts are paid or payable by the recipient on receipt of the option. The options carry neither rights to dividends nor voting rights. Options may be exercised at any time from the date of vesting to the date of their expiry.

The stock options granted vest, in principle, as follows:

- 1/3rd of the stock options granted will vest on the first anniversary of the granting of the stock options, and
- 1/24th of the remaining 2/3rd of the stock options granted will vest on the last day of each of the 24 months following the month of the first anniversary of the granting of the stock options.

No other conditions are attached to the stock options.

The following share-based payment arrangements were in existence during the current and prior years and which are exercisable at the end of each period presented:

Expiry date	Exercise price per stock options (in €)	Outstanding stock options on December 31,		
		2018	2017	2016
2020	€ 3.95	18,200	36,960	112,738
2021	3.95	—	2,850	3,800
2023	2.44	294,400	314,593	360,787
2024	2.44	117,733	135,890	169,926
2024	3.95	6,895	15,692	55,746
2024	7.17	407,061	516,100	522,500
2024	2.44	26,970	83,820	83,820
2025	11.44	39,000	39,000	39,000
2025	10.34	3,000	3,000	3,000
2025	9.47	226,323	235,514	235,733
2026	11.38	50,415	60,000	60,000
2026	11.47	257,616	282,310	283,360
2026	14.13	315,102	362,126	363,226
2027	18.41	114,019	120,536	—
2027	21.17	628,292	653,825	—
2023	80.82	94,600	—	—
2028	80.82	75,450	—	—
2023/2028 (1)	€ 86.32	861,575	—	—
		3,536,651	2,862,216	2,293,636

- (1) On December 21, 2018, the Company granted options for which the beneficiaries had a 60-day period to choose between a contractual term of five or ten years.

	2018		2017		2016	
	Number of stock options	Weighted average exercise price	Number of stock options	Weighted average exercise price	Number of stock options	Weighted average exercise price
Outstanding at January 1	2,862,216	€ 11.54	2,293,636	€ 7.72	1,752,926	€ 5.37
Granted	1,040,475	85.37	774,361	20.74	712,176	12.82
Exercised	(319,671)	7.02	(203,412)	3.46	(140,292)	3.52
Forfeited	(46,369)	30.44	(2,369)	12.52	(31,174)	10.90
Outstanding at December 31,	3,536,651	33.42	2,862,216	11.54	2,293,636	7.72
Exercisable at December 31,	1,859,315	€ 9.62	1,598,829	€ 6.80	1,257,091	€ 4.68

The weighted average remaining contractual life of the stock options outstanding amounted to 7.82 years on December 31, 2018 compared to 8.03 years on December 31, 2017 and 8.09 years on December 31, 2016. The table below shows the weighted average remaining contractual life for each range of exercise price:

Exercise price (in €)	Outstanding on December 31, 2018	Weighted average remaining contractual life (in years)
2.44-3.95	464,198	4.83
7.17-9.47	633,384	6.32
10.34-14.13	665,133	7.61
18.41-21.17	742,311	8.88
80.82-86.32	1,031,625	9.44

The fair market value of the stock options has been determined based on the Black and Scholes model. The expected volatility in the model is based on the historical volatility of peer companies and historical volatility of the Company since its initial public offering.

Below is an overview of the parameters used in relation to the grants during 2018:

Stock options granted in	June 2018	Dec 2018
Number of options granted	178,900	861,575
Average fair value of options (in EUR)	€ 32.12	€ 44.49
Share price (in EUR)	€ 72.00	€ 82.20
Exercise price (in EUR)	€ 80.82	€ 86.32
Expected volatility	45.5 %	46.2 %
Average expected option life (in years) (1)	7.36	10
Risk-free interest rate	0.72 %	0.77 %
Expected dividends	— %	— %

- (1) On December 21, 2018, the Company granted a total of 861,575 stock options. The beneficiary can choose between a contractual term of five or ten years. The average expected option life is currently estimated at ten years. This estimate will be reassessed once the acceptance period of 60 days has passed and the beneficiaries will have made a choice between a contractual term of five or ten years. The total fair value of the grant would range from €27.7 million (100% of the stock options at an expected option life of five years) to €38.3 million (100% of the stock options at an expected option life of ten years).

Below is an overview of the parameters used in relation to the grants during 2017:

Stock options granted in	June 2017	Dec 2017
Number of options granted	120,536	653,825
Average fair value of options (in EUR)	€ 7.90	€ 37.10
Share price (in EUR)	€ 17.76	€ 53.50
Exercise price (in EUR)	€ 18.41	€ 21.17
Expected volatility	36.6 %	36.1 %
Average expected option life (in years)	10	10
Risk-free interest rate	0.61 %	0.53 %
Expected dividends	— %	— %

Below in an overview of the parameter used in relation to the grants during 2016:

Stock options granted in	May 2016	June 2016	Dec 2016
Number of options granted	288,950	60,000	363,226
Average fair value of options (in EUR)	€ 5.32	€ 5.46	€ 7.25
Share price (in EUR)	€ 11.10	€ 11.36	€ 14.96
Exercise price (in EUR)	€ 11.47	€ 11.38	€ 14.13
Expected volatility	40.2 %	39.6 %	38.0 %
Average expected option life (in years)	10	10	10
Risk-free interest rate	0.52 %	0.46 %	0.67 %
Expected dividends	— %	— %	— %

The total share-based payment expense recognized in the consolidated statement of comprehensive income totaled €19.2 million for the year ended December 31, 2018, compared to €4.3 million for the year ended December 31, 2017 and €2.3 million for the year ended December 31, 2016.

4.10 Defined benefit plans

Our personnel in Belgium participated in a defined contribution plan (extra-legal pension). The Belgian defined contribution pension plans were by law subject to minimum guaranteed rates of return, 3.25% on employer contributions and 3.75% on employee contributions. These rates, which apply as an average over the entire career, may be modified by Royal Decree. Therefore, those plans were basically accounted for as defined contribution plans.

As a consequence of the law of December 18, 2015, minimum returns were guaranteed by the employer as follows: (a) for the contributions paid as from January 1, 2016, a new variable minimum return based on OLO rates, with a minimum of 1.75% and a maximum of 3.75%. In review of the low rates of the OLO in the last years, the

return has been initially set to 1.75%; (b) for the contributions paid until end of December 2015, the previously applied legal returns as mentioned above, continue to apply until the leaving of the employees.

In view of the minimum returns guarantees, the Belgian defined contribution plans classify as defined benefit plans as from end December 2015.

As at December 31, 2016, a net liability of €1 thousand was recognized in the balance sheet as the minimum rates of return to be guaranteed by the employer were closely matched by the rates of return guaranteed by the insurer. As at December 31, 2017 and 2018, a net defined benefit obligation of respectively €25 thousand and €7 thousand was recorded.

The amounts recognized in the balance sheet are as follows:

(in thousands of €)	2018	2017	2016
Defined benefit obligation	€ 1,277	€ 1,007	€ 670
Fair value of plan assets	1,270	982	669
Deficit / surplus (-) of funded obligations	7	25	1
Net liability (asset)	€ 7	€ 25	€ 1

The movement in the defined benefit obligation, plan assets, net liability and asset over the year is as follows:

(in thousands of €)	2018	2017	2016
Defined benefit obligation at January 1	€ 1,007	€ 670	€ 486
Service cost	336	352	113
Interest expense	15	11	6
Contributions by plan participants	(116)	(148)	(64)
Actuarial gains (-) / losses (+)	35	124	131
Benefits paid / transfers out	—	(2)	(2)
Defined benefit obligation at December 31	€ 1,277	€ 1,007	€ 670

(in thousands of €)	2018	2017	2016
Fair value of plan assets at January 1	€ 982	€ 669	€ 486
Interest income	16	10	7
Administrative costs & taxes	(32)	(46)	(19)
Contributions by company & participants	328	423	176
Contributions by plan participants	(116)	(148)	(64)
Actuarial gains (+) / losses (-)	92	76	85
Benefits paid / transfers out	—	(2)	(2)
Fair value of plan assets at December 31	€ 1,270	€ 982	€ 669

In the income statement, current service cost and interest expense or income are included in the operating loss.

The Company's estimated employer contributions for 2018 amount to €0.2 million compared to €0.3 million in 2017 and €0.1 million in 2016. Plan assets on December 31, 2018, 2017 and 2016 consisted fully of insurance contracts and did not include direct positions in the Company's shares or bonds, nor do they include any property used by the Company. As the insurance contracts match the benefits payable by the plan, the plan assets correspond to the present value of the related obligations.

The principal actuarial assumption on the balance sheet date (weighted averages based on outstanding defined benefit obligation) was:

Actuarial assumption	2018	2017	2016
Discount rate	1.3 %	1.3 %	1.3 %

The weighted average duration of the benefit obligations equals 18 years. Sensitivity analyses show the following effects:

Sensitivity analysis (in thousands of €)	Change in assumption	Impact on defined- benefit obligation	%
Discount rate	-1.00%	Increase by 198.1	15.51 %
Discount rate	1.00 %	Decrease by 57.1	(4.47)%

The above analyses were done on a mutually exclusive basis, and holding all other assumptions constant. Through its defined benefit plan, the Company is exposed to a number of risks, the most significant of which are detailed below:

Asset volatility	The plan liabilities are calculated using a discount rate set with reference to corporate bond yields; if plan assets underperform this yield, this will create a deficit.
Changes in bond yields	A decrease in corporate bond yields will increase plan liabilities, although this will be partially offset by an increase in the value of the plan's bond holdings.
Salary risk	The majority of the plan's benefit obligations are calculated by reference to the future salaries of plan members. As such, a salary increase of plan members higher than expected will lead to higher liabilities.
Longevity risk	Belgian pension plans provide for lump sum payments upon retirement. As such there is limited or no longevity risk.

The weighted average age of the plan participants equals 43.8 years on December 31, 2018, compared to 46 years on December 31, 2017 and 48 years on December 31, 2016.

4.11 Trade and other payables

(in thousands of €)	Year Ended December 31,		
	2018	2017	2016
Trade payables	€ 6,007	€ 4,395	€ 4,385
Accruals for invoices to be received	18,145	4,046	5,444
Short-term employee benefits	12,920	6,844	2,362
	€ 37,072	€ 15,285	€ 12,191

Trade payables correspond primarily to clinical and manufacturing activities. The fair value of trade payables approximates their carrying amount.

The accruals for invoices to be received amount to €18.1 million for the year ended December 31, 2018 and relate to invoices to be received from clinical manufacturing organizations for the manufacturing of drug products to be used in clinical trials and from clinical research.

Short-term employee benefits include payables and accruals for salaries and bonuses to be paid to the employees of the Company.

4.12 Current tax liability

The current tax liability amounts to €0.8 million for the year ended December 31, 2018 and corresponds primarily to the tax payable on the result of argenx SE and on the result of argenx US, Inc. in view of the transfer price agreements set up between argenx BVBA and argenx US, Inc.

As part of its business restructuring, the Company transferred the legal ownership of its intellectual property rights from the Dutch argenx SE to its wholly owned Belgian subsidiary, argenx BVBA effective as of January 1, 2017. There is a tax ruling pending in Belgium, and if approved as currently proposed, the restructuring will result in additional tax deductible costs for argenx BVBA of €79.9 million. The Company cannot assure that it

will obtain the tax ruling from the Belgian tax authorities, and it may not be allowed to treat the aforementioned amount as a tax deductible cost in the Belgian subsidiary.

4.13 Deferred revenue

Deferred revenue relates to cash received from collaboration and strategic alliances prior to completion of the earnings process. On December 31, 2018, current and non-current deferred revenue amounted to €2.2 million compared to €10.1 million at the same date in 2017, and included €2.0 million related to the upfront and milestone payments received from AbbVie in 2018, 2017 and 2016, and €0.2 million related to the upfront and milestone payments received from LEO Pharma in 2018, 2017 and 2016. These payments are recognized as revenue over the estimated duration of the Company's involvement in the research and development programs provided for under the terms of the agreements.

5. Notes to consolidated statement of profit and loss and other comprehensive income

5.1 Revenue

(in thousands of €)	Year Ended December 31,		
	2018	2017	2016
Upfront payments	€ 8,635	€ 20,137	€ 9,103
Milestone payments	11,440	9,677	500
Research and development service fees (FTE)	1,407	6,601	5,110
	€ 21,482	€ 36,415	€ 14,713

For the years ended December 31, 2018 and 2017, the majority of the revenue was generated under the agreements with LEO Pharma and AbbVie, each as described below. These agreements comprise elements of upfront payments, milestone payments based on development criteria and research and development funding on an agreed FTE basis.

The upfront payments received in the year ended December 31, 2018 corresponded principally to the partial recognition in revenue over the year of the upfront payment received following the signatures of a collaboration agreement with AbbVie in April 2016 and with LEO Pharma in May 2015.

The milestone payments of €11.4 million recognized in the year ended December 31, 2018 mainly related to milestone payments received under the AbbVie and LEO Pharma collaborations.

The upfront and milestone payments are recognized as revenue over the estimated period of the Company's continuing involvement in the research and development activities provided for under the terms of these agreements.

The research and development service fees (FTE) for the year ended December 31, 2018 corresponded to FTE payments received under the collaboration agreements of €0.5 million from Shire, €0.5 million from Staten Biotechnology B.V. (Staten) and €0.4 million from LEO Pharma.

We adopted IFRS 15 - Revenue from contracts with customers on January 1, 2018 using the modified retrospective approach. For more information on the impact of adopting IFRS 15, see note 2.22.

In our current arrangements, the Company is licensing certain of its intellectual property to collaborative entities and conducts research and development activities. Such activities result in a service that is the output of the Company's ordinary activities. The Company generates revenue through a number of these arrangements, which include license fees, milestone payments, reimbursement income and future sales-based milestones and sales-based royalties. The Company assessed that the revenues from the current material licensing and collaboration agreements are in the scope of IFRS 15.

With regard to its collaboration with AbbVie and LEO Pharma, the Company concluded as follows:

- There is one single performance obligation under the new standard of IFRS 15, that being the transfer of a license combined with performance of research and development activities. The Company concluded that the license is not distinct in the context of the contract.
- The transaction price of these two agreements is currently composed of a fixed part, that being an upfront license fee, and a variable part, that being milestone payments and cost reimbursements of research and development activities delivered. Milestone payments are included in the transaction price of the arrangement only when achieved. Sales-based milestones and sales-based royalties are a part of the Company's arrangements but are not yet included in its revenues, as its programs with AbbVie and LEO Pharma are still in the development phase.
- The transaction price has been allocated to the single performance obligation, and revenues have been recognized over the estimated service period based on a pattern that reflects the transfer of the license and progress to complete satisfaction of the research and development activities. This is because the transfer of the license is considered to be combined with the performance of research and development activities. Therefore, research and development milestone payments are variable considerations that are entirely allocated to the single performance obligation.
- The Company has chosen an input model to measure the satisfaction of the single performance obligation that considers percentage of costs incurred for these programs (percentage of completion method).
- Cost reimbursements received could be recognized in revenues when costs are incurred and agreed by the parties, as the Company is acting as a principal in the scope of its stake of the research and development activities of its ongoing license and collaboration agreements.

For the year ended December 31, 2018, €10.5 million of milestone revenue associated with the AbbVie collaboration agreement was recognized, of which (i) €8.3 million is related with the recognition of a preclinical milestone obtained in 2018 and (ii) €2.2 million is related with deferred revenue that was already recognized in previous periods under the former IAS 18 standard.

For the year ended December 31, 2018, €0.6 million of milestone revenue associated with the LEO Pharma collaboration agreement was recognized, of which (i) €0.5 million is related with the recognition of a preclinical milestone obtained in 2018 and (ii) €0.1 million is related with deferred revenue that was already recognized in previous periods under the former IAS 18 standard.

Below are summaries of the key collaborations.

AbbVie

In April 2016, the Company entered into a collaboration agreement with AbbVie S.À.R.L. (AbbVie) to develop and commercialize ARGX-115 (ABBV-151). Under the terms of the collaboration agreement, the Company was responsible for conducting and funding all ARGX-115 (ABBV-151) research and development activities up to completion of IND enabling studies.

The Company granted AbbVie an exclusive option, for a specified period following completion of IND enabling studies, to obtain a worldwide, exclusive license to the ARGX-115 (ABBV-151) program to develop and commercialize products. The Company received an upfront, nonrefundable, non-creditable payment of \$40 million (€35.1 million as of the date the payment was received) from AbbVie for the exclusive option to license ARGX-115 (ABBV-151), and we achieved two preclinical milestones, each of which triggered a \$10.0 million payment (€8.9 million based on the exchange rate in effect as of the date the first milestone payment was received, and €8.7 million based on the exchange rate in effect as of the date the second milestone payment was received).

In August 2018, AbbVie exercised its option and has now assumed certain development obligations, being solely responsible for all research, development and regulatory costs relating to ARGX-115 based products. Subject to the continuing progress of ARGX-115 (ABBV-151) by AbbVie, the Company is eligible to receive development,

regulatory and commercial milestone payments in aggregate amounts of up to \$110 million, \$190 million and \$325 million, respectively, as well as tiered royalties on sales at percentages ranging from the mid-single digits to the lower teens, subject to customary reductions.

The Company has the right, on a product-by-product basis to co-promote ARGX-115 (ABBV-151) based products in the European Economic Area and Switzerland and to combine the product with the Company's own future immuno-oncology programs. The co-promotion effort would be governed by a co-promotion agreement negotiated in good faith by the parties. AbbVie will fund further GARP-related research by the Company for an initial period of two years. AbbVie will have the right to license additional therapeutic programs emerging from this research, for which the Company could receive associated milestone and royalty payments.

Leo Pharma

In May 2015 the Company and LEO Pharma A/S (LEO Pharma), a global healthcare company dedicated to helping people achieve healthy skin, entered into an alliance in which they collaborate to develop innovative antibody-based solutions for the treatment of chronic inflammation underlying many skin conditions.

Under the terms of the agreement, LEO Pharma received exclusive access to an existing argenx antibody. The Company received pre-IND payments of €4.5 million, including an upfront payment. The companies co-funded product development costs up to clinical trial application (CTA) filing, which was obtained in April 2018.

The Company is also eligible to receive clinical, regulatory, and sales milestone payments, as well as tiered royalties on sales of resulting products at percentages ranging from the low single digits to the low teens, which are, as of the reporting date, considered contingent revenue.

5.2 Other operating income

(in thousands of €)	Year Ended December 31,		
	2018	2017	2016
Grants	€ 1,842	€ 422	€ 779
Research and development incentives	2,151	983	641
Payroll tax rebates	3,756	3,436	1,019
	€ 7,749	€ 4,841	€ 2,439

Grants

The Flanders Innovation and Entrepreneurship Agency provided the Company with several grants.

On December 31, 2018, the situation of the grants received by the Company reflected the expenses incurred by the Company in the various research and development projects sponsored by Flanders Innovation and Entrepreneurship Agency. On December 31, 2018, the Company had two ongoing grant research projects:

(Amounts presented in thousands of €)

Flanders Innovation & Entrepreneurship - VLAIO 1

Grantor: Flanders Innovation & Entrepreneurship Agency

Start date: 11/01/2017

End date: 31/10/2020

Amount granted and approved: € 2,527

Amount recognized: 982

Flanders Innovation & Entrepreneurship - VLAIO 2		
Grantor: Flanders Innovation & Entrepreneurship Agency		
Start date:		01/05/2018
End date:		31/10/2020
Amount granted and approved:	€	2,634
Amount recognized:		740

No conditions related to the above government grants were unfulfilled, nor were there any contingencies related thereon at the date of the approval of these consolidated financial statements, except for those described in note 7.2 of this report.

Other Incentives

Research and development incentives

The Company has accounted for a tax receivable of €2.2 million in the year ended December 31, 2018, compared to €1.0 million in the year ended December 31, 2017, following a research and development tax incentive scheme in Belgium according to which the incentive will be refunded after a 5 year period, if not offset against the current tax payable over the period (see also note 4.3).

Payroll tax rebates

The Company accounted for €3.8 million payroll tax rebates in the year ended December 31, 2018, compared to €3.4 million in the year ended December 31, 2017, as a reduction in withholding income taxes for its highly-qualified personnel employed in its research and development department.

5.3 Segment reporting

The Company operates from the Netherlands, Belgium and the United States of America. Revenues are invoiced by the subsidiary in Belgium and are generated by clients geographically located as shown in the table below.

(in thousands of €)	Revenue from external customers		
	Year ended December 31,		
	2018	2017	2016
Netherlands	€ 470	€ 628	€ 548
Germany	—	—	311
Denmark	1,136	6,240	3,066
Switzerland	912	2,486	3,315
United States	—	1	47
Luxembourg	18,964	27,060	7,426
Total	€ 21,482	€ 36,415	€ 14,713

Information about major clients:

The Company received €21.5 million of revenue from its external customers in the year ended December 31, 2018 compared to €36.4 million over the same period in 2017, of which €19.0 million came from the Company's largest client, €1.1 million from its second largest client and €0.9 million from its third largest client, compared to respectively €27.1 million, €6.2 million and €2.5 million in the year ended December 31, 2017. For a detailed description of our key collaborations, see note 5.1.

5.4 Research and development expenses

(in thousands of €)	Year Ended December 31,		
	2018	2017	2016
Personnel expense	€ 26,519	€ 16,473	€ 9,844
External research and development expenses	48,859	27,893	17,562
Materials and consumables	1,464	1,562	1,180
Depreciation and amortization	494	446	335
Other expenses	6,273	5,366	2,636
	€ 83,609	€ 51,740	€ 31,557

5.5 Selling, general and administrative expenses

(in thousands of €)	Year Ended December 31,		
	2018	2017	2016
Personnel expense	€ 18,292	€ 6,745	€ 3,256
Consulting fees	5,472	3,289	2,563
Supervisory board	1,088	621	446
Office costs	2,619	1,793	746
	€ 27,471	€ 12,448	€ 7,011

5.6 Personnel expenses

The personnel expenses which exclude consultants mentioned above are as follows:

(in thousands of €)	Year Ended December 31,		
	2018	2017	2016
Short-term employee benefits—Salaries	€ 18,617	€ 12,149	€ 8,527
Short-term employee benefits—Social Security	2,213	1,504	1,027
Post-employment benefits	441	291	175
Termination benefits	96	8	86
Share-based payment	18,527	3,985	2,849
Employer social security contributions stock options	4,918	5,281	436
	€ 44,812	€ 23,218	€ 13,100

The post-employment benefits relate to the pension plans the Company has in place for its employees.

The number of full-time equivalents (FTE) employees by department is presented below:

Number of FTE	Year Ended December 31,		
	2018	2017	2016
Research and development	74.4	56.8	46.9
Selling, general and administrative	29.5	14.7	9.9
	103.9	71.5	56.8

These FTE's are working outside the Netherlands.

5.7 Operating leases

Operating lease payments recognized as an expense in the statement of profit and loss and other comprehensive income amount to €1.5 million for the year ended December 31, 2018 (of which €1.1 million is presented as research and development expenses and €0.4 million is included under selling, general and administrative expenses) versus €1.2 million for the year ended December 31, 2017 (of which €0.3 million is

presented as research and development expenses and €0.9 million is included under selling, general and administrative expenses). The Company's future operating lease commitments are as follows:

Operating lease commitments (in thousands of €)	Year Ended December 31,		
	2018	2017	2016
Less than 1 year	€ 1,028	€ 1,028	€ 915
1-3 years	1,766	465	1,159
3-5 years	210	33	24
More than 5 years	—	—	—
	€ 3,004	€ 1,526	€ 2,098

The Company has a lease plan for the Company's cars with maturity dates up to four years.

For the laboratory and office space, the Company has a lease agreement in Zwijnaarde Belgium for a period of nine years starting from April 1, 2016, with the possibility to terminate the lease by giving a notice of at least twelve months in advance at the occasion of the third and sixth anniversary of the agreement (see also note 7.6).

For its offices in the Netherlands and the United States of America, the Company has a lease agreement renewable on an annual base.

No purchase options were in effect under the lease agreements described above.

5.8 Financial result and exchange gains/(losses)

(in thousands of €)	Year Ended December 31,		
	2018	2017	2016
Interest income on bank deposits	€ 1,371	€ 165	€ 61
Net gains on current financial assets at FVTPL	2,323	210	12
Realized gain on non-current financial assets	—	875	—
Financial income	3,694	1,250	73
Realized exchange gains/(losses)	1,355	—	—
Unrealized exchange gains/(losses)	10,953	(5,797)	(31)
Exchange gains/(losses)	12,308	(5,797)	(31)

The exchange gains of €12.3 million for the year ended December 31, 2018 were primarily attributable to unrealized exchange rate gains on our cash and cash equivalents and current financial assets position in USD due to the favorable fluctuation of the USD exchange rate over the period.

5.9 Income taxes

The income tax expense for the year can be reconciled to the accounting loss as follows:

(in thousands of €)	Year Ended December 31,		
	2018	2017	2016
Loss before taxes	(65,847)	(27,479)	(21,374)
Income tax calculated at 25%	16,462	6,870	5,344
Effect of expenses and gains that are not deductible in determining taxable results	(3,934)	(1,141)	(755)
Effect of stock issue expenses that are not deductible in determining taxable results	3,716	5,754	462
Effect of concessions (R&D incentives and grants)	430	453	463
Effect of tax losses carried forward not recognized (Netherlands)	—	—	(5,551)
Effect of usage of tax losses carried forward not previously recognized (Netherlands)	—	19,378	—
Effect of tax losses carried forward not recognized (Belgium)	(5,511)	(27,413)	—
Effect of usage of tax losses carried forward not previously recognized (Belgium)	—	—	195
Effect of change in corporate tax rate on deferred tax asset not previously recognized (Belgium)	—	373	—
Effect of different tax rates in jurisdictions in which the company operates	(15)	(517)	(180)
Deferred tax asset other than loss carryforwards not recognized	(11,968)	(4,363)	—
Other	26	9	22
Income tax expense recognized in the consolidated statement of profit and loss	€ (794)	€ (597)	€ 0

The tax rate used for the 2018, 2017 and 2016 reconciliations above is the corporate income tax rate of 25% payable by corporate entities in the Netherlands.

The unrecognized deferred tax asset on deductible temporary differences and unused tax losses amounts to €29.3 million on December 31, 2018, compared to €28.4 million on December 31, 2017. Deferred tax have been measured using the effective rate that will apply in Belgium (25%). The Company has unused tax loss carried forwards for an amount of €117.1 million on December 31, 2018. This, combined with other temporary differences, resulted in a net deferred tax asset position. Due to the uncertainty surrounding the Company's ability to realize taxable profits in the near future, the Company did not recognize any deferred tax assets.

As part of its business restructuring, the Company transferred the legal ownership of its intellectual property rights from the Dutch argenx SE to its wholly owned Belgian subsidiary, argenx BVBA, effective as of January 1, 2017. There is a tax ruling pending in Belgium, and if approved as currently proposed, the restructuring will result in additional tax deductible costs for argenx BVBA of €79.9 million. The Company cannot guarantee that it will obtain the tax ruling from the Belgian tax authorities, and it may not be allowed to treat the aforementioned amount as a tax deductible cost in the Belgian subsidiary. Accordingly, no deferred tax asset has been recognized in respect of these tax operating losses (see note 4.12).

5.10 Loss per share

(in thousands of €)	Year Ended December 31,		
	2018	2017	2016
Loss of the year	€ (66,641)	€ (28,076)	€ (21,374)
Weighted average number of shares outstanding	33,419,356	24,609,536	18,820,612
Basic and diluted loss per share (in €)	€ (1.99)	€ (1.14)	€ (1.14)

Earnings/losses per ordinary share are calculated by dividing the loss for the period by the weighted average number of ordinary shares during the year.

As the Company is suffering operating losses, options have an anti-dilutive effect. As such, there is no difference between basic and diluted earnings/losses per ordinary share. There are no other instruments that could potentially dilute earnings per ordinary share in the future.

6. Financial instruments and financial risk management

6.1 Overview of financial instruments

The Company adopted IFRS 9 on January 1, 2018. On the date of initial application, the financial instruments of the Company were as follows:

(in thousands of €)	Measurement category		Carrying amount	
	Original IAS 39	New IFRS 9	Original IAS 39	New IFRS 9
Financial assets — non-current	Available for sale	FVTPL	€ 1	€ 1
Research and development incentive receivables — non-current	Amortised cost	Amortised cost	3,033	3,033
Restricted cash — non-current	Amortised cost	Amortised cost	256	256
Trade and other receivables	Amortised cost	Amortised cost	2,842	2,842
Prepaid expenses	Amortised cost	Amortised cost	2,338	2,338
Financial assets—current	FVTPL	FVTPL	168,907	168,907
Research and development incentive receivables — current	Amortised cost	Amortised cost	158	158
Restricted cash — current	Amortised cost	Amortised cost	1,692	1,692
Cash and cash equivalents	Amortised cost	Amortised cost	190,867	190,867
Trade and other payables	Amortised cost	Amortised cost	15,285	15,285

Current financial assets included collective investment funds nominated in € and \$ that are not considered as cash equivalents and of which the underlying investments include bonds and other international debt securities. The average credit rating of the underlying instruments is BBB or higher. The maximum exposure to credit risk is the carrying value at reporting date. These investment funds are recognized at fair value in the Company's consolidated financial statements (level 1). The fair value corresponds to the quoted market price and can therefore be classified as a level 1 fair value measurement. The net asset value (NAV) of the funds is available on a daily basis. Any difference between amounts invested and fair value at reporting date is booked in Profit & Loss.

Due to the current nature of the financial liabilities, the nominal value of all financial liabilities presented above approximates their fair value.

The Company carried the following assets at fair value on December 31, 2018, 2017 and 2016 respectively:

(in thousands of €)	At December 31, 2018		
	Level 1	Level 2	Level 3
Non-current financial assets	€	€	€ 1
Current financial assets	283,529		
Assets carried at fair value	€ 283,529	€ —	€ 1

(in thousands of €)	At December 31, 2017		
	Level 1	Level 2	Level 3
Non-current financial assets	€	€	€ 1
Current financial assets	168,907		
Assets carried at fair value	€ 168,907	€ —	€ 1

(in thousands of €)	At December 31, 2016		
	Level 1	Level 2	Level 3
Non-current financial assets	€	€	€ 1
Current financial assets	6,831		
Assets carried at fair value	€ 6,831	€ —	€ 1

During the disclosed calendar year no transfers occurred between the applicable categories. Given the insignificant value of the Company's assets categorized as Level 3, the additional Level 3 disclosures have been omitted.

6.2 Capital risk

The Company manages its capital to ensure that it will be able to continue as a going concern. The capital structure of the Company consists of equity attributed to the holders of equity instruments of the Company, such as capital, reserves and accumulated losses as mentioned in the consolidated statement of changes in equity. The Company makes the necessary adjustments in the light of changes in the economic circumstances, risks associated to the different assets and the projected cash needs of the current and projected research activities. On December 31, 2018 cash and cash equivalents amounted to €281.0 million and total capital amounted to €677.1 million. The current cash situation and the anticipated cash generation are the most important parameters in assessing the capital structure. The Company's objective is to maintain the capital structure at a level to be able to finance its activities for at least twelve months. Cash income from existing and new partnerships is taken into account and, if needed and possible, the Company can issue new shares or enter into financing agreements.

6.3 Credit risk

Credit risk refers to the risk that a counterparty will default on its contractual obligations resulting in financial loss to the Company. The Company has adopted a policy of only dealing with creditworthy counterparties and obtaining sufficient collateral, where appropriate, as a means of mitigating the risk of financial loss from defaults. Concentrations in credit risk are determined based on an analysis of counterparties and their importance on the overall outstanding contractual obligations at year end.

The Company has a limited number of collaboration partners and therefore has a significant concentration of credit risk. However, it has policies in place to ensure that credit exposure is kept to a minimum and significant concentrations of credit exposure are only granted for short periods of time to high credit quality collaboration partners.

Credit exposure is controlled by counterparty limits that are reviewed and approved by management annually.

Cash and cash equivalents and short-term deposits are invested with several highly reputable banks and financial institutions. The Company holds its cash and cash equivalents mainly with different banks which are independently rated with a minimum rating of 'BBB'.

The Company also holds short term investment funds in the form of money market funds with a recommended investment horizon of 6 months or shorter but with a low historical volatility. These money market funds are highly liquid investments, can be readily convertible into a known amount of cash. Since they are a basket of funds there is no individual credit risk involved.

The average credit rating of the underlying instruments for the investment funds is BBB or higher.

The maximum credit risk, to which the Company is theoretically exposed as at the balance sheet date, is the carrying amount of the financial assets.

At the end of the reporting period no financial assets were past due, consequently no financial assets were subject to impairment.

6.4 Liquidity risk

The Company manages liquidity risk by maintaining adequate reserves, by continuously monitoring forecast and actual cash flows, and by matching the maturity profiles of financial assets and liabilities.

The Company's main sources of cash inflows are obtained through capital increases and collaboration agreements. This cash is invested in savings accounts, term accounts and short term investment funds in the form of money market funds. These money market funds represent the majority of the Company's available sources of liquidity however since all of these are immediately tradable and convertible in cash they have a limited impact on the liquidity risk.

All financial liabilities (principally trade and other payables as disclosed in note 6.1) have a maturity within 3 months unless otherwise disclosed in these consolidated financial statements.

6.5 Interest rate risk

The Company is currently not exposed to significant interest rate risk. The only interest-bearing financial assets are cash at banks on deposit and term accounts.

Given the short-term nature of these investments the sensitivity towards interest rate fluctuations is deemed not to be significant. For the year ended December 31, 2018, if applicable interest rates would increase/decrease by 25 basis points, this would have a positive/negative impact of €0.3 million (compared to €0.3 million for the year ended December 31, 2017 and €0.1 million for the year ended December 31, 2016).

6.6 Foreign exchange risk

The Company undertakes transactions denominated in foreign currencies; consequently, exposures to exchange rate fluctuations arise.

The Company is mainly exposed to the US Dollar and GBP.

The net exposure to exchange differences of the monetary assets (being cash, cash equivalents and current financial assets) of the Company at the end of the reporting period are as follows:

(in thousands of €)	At December 31,		
	2018	2017	2016
USD	312,831	147,169	624
GBP	2	406	—

On December 31, 2018, if the USD/EUR exchange rate would have increased/decreased by 10%, this would have had a negative/positive impact of €28.44 million (compared to €13.38 million on December 31, 2017). On December 31, 2018, if the GBP/EUR exchange rate would have increased/decreased by 10%, this would have had no significant impact.

7. Other disclosures

7.1 Related party transactions

Amongst the shareholders of the Company, there are minority investors and venture capitalist funds which individually do not hold a significant influence on the Company. Balances and transactions between the Company and its subsidiaries, which are related parties of the Company, have been eliminated on consolidation and are not disclosed in this note. There were no significant transactions with related parties during the period, other than compensation of key management personnel.

Compensation of key management personnel

Key management personnel of the Company is composed of the Chief Executive Officer, the Chief Financial Officer, the Chief Operating Officer, the Chief Scientific Officer, the Chief Development Officer, the Chief Medical Officer, the Senior Vice President of Business Development and the General Counsel.

The remuneration of the key management personnel during the year was as follows:

(in thousands of €)	Year Ended December 31,		
	2018	2017	2016
Short term employee benefits	€ 4,236	€ 3,126	€ 1,832
Post employment benefits	153	115	125
Termination benefits	—	—	—
Share-based payment (1)	13,363	12,041	2,261
Employer social security contributions stock options (2)	2,792	3,073	436
	€ 20,544	€ 18,355	€ 4,654

- (1) Amount shown represents the expenses, recorded with respect to the option awards granted in the year, measured using the Black Scholes formula.
- (2) The Company incurs employer social security costs with respect to the option awards granted to certain members of the executive management. The amount of employer social security costs depends on the actual economic value realized and therefore varies based on our stock price. At each reporting date, the Company makes a calculation of the exposure.

Remuneration of the executive directors

The tables below show the remuneration received by executive directors for the years ended December 31, 2018, 2017 and 2016 (in €). Eric Castaldi served as a member of our board until April 26, 2017. A scenario analysis based on best practice clause II.2.1. of the Dutch Corporate Governance Code was made. Both executive directors have met each of their bonus targets previously established by the non-executive directors during the years ended December 31, 2018, 2017 and 2016 and the full bonus was granted in the same year.

2016	Base salary	Bonus	Pension contributions	Social security costs	ESOP (1)	Other (2)	Total
Tim Van Hauwermeiren	253,284	101,314	11,929	10,284	488,020	9,184	874,015
Eric Castaldi	235,952	82,583	84,972	136,124	786,035	—	1,325,666
Total	489,236	183,897	96,901	146,408	1,274,055	9,184	2,199,681

2017	Base salary	Bonus	Pension contributions	Social security costs	ESOP (1)	Other (2)	Total
Tim Van Hauwermeiren	303,941	301,635	14,315	9,459	2,968,195	9,601	3,607,146
Eric Castaldi	271,344	173,284	62,335	254,732	4,089,209	14,979	4,865,883
Total	575,285	474,919	76,650	264,191	7,057,404	24,580	8,473,029

2018	Base salary	Bonus	Pension contributions	Social security costs	ESOP (1)	Other (2)	Total
Tim Van Hauwermeiren	500,000	284,600	15,102	10,011	3,559,200	33,855	4,402,768
Total	500,000	284,600	15,102	10,011	3,559,200	33,855	4,402,768

- (1) Amount shown represents the expenses, recorded with respect to the option awards granted in the year, measured using the Black Scholes formula, and the employer social security costs with respect to the option awards granted to certain members of the executive management. The amount of employer social security costs depends on the actual economic value realized and therefore varies based on our stock price. At each reporting date, the Company makes a calculation of the exposure.

- (2) Consists of rent paid by the Company, costs attributable to the lease of a company car and employer-paid medical insurance premiums.

The table below shows the number of stock options granted to the executive directors during the years ended December 31, 2018, 2017 and 2016 and their exercise price equal to the fair market value upon date of grant, and the stock options exercised during 2018, 2017 and 2016.

2016	ESOPs	Term	Exercise price	Exercised
Tim Van Hauwermeiren	50,000	10 years	11.47	
	30,600	10 years	14.13	
			3.95	53,092
			2.44	72,200
Eric Castaldi	28,200	10 years	11.47	
	28,200	10 years	14.13	
Total	137,000			125,292
2017	ESOPs	Term	Exercise price	Exercised
Tim Van Hauwermeiren	80,000	10 years	21.17	
			2.44	65,380
Eric Castaldi	43,200	10 years	21.17	
Total	123,200			65,380
2018	ESOPs	Term	Exercise price	Exercised
Tim Van Hauwermeiren (1)	80,000	5 / 10 years	86.32	
			7.17	40,000
Total	80,000			40,000

- (1) On December 21, 2018, the Company granted options for which the beneficiary had a 60-day period to choose between a contractual term of five or ten years.

The table below shows the stock options held at the start of the year ended December 31, 2018, the stock options granted to executive directors which have vested during the year ended December 31, 2018 and the stock options to vest in the years until 2021.

Name	Total options held on January 1, 2018	options granted in 2018	options exercised in 2018	Total options held on December 31, 2018	Options vested until 2017	Exercise price	Options vested in 2018	Exercise price	Options to vest 2019	Exercise price	Options to vest 2020	Exercise price	Options to vest 2021	Exercise price
Tim Van Hauwermeiren	296,200	80,000	(40,000)	336,200	65,000	7.17	20,400	9.47	10,200	9.47	6,944	11.47	10,200	14.13
					26,389	11.47	16,667	11.47	26,667	21.17	26,667	21.17	26,667	86.32
					10,200	14.13	10,200	14.13	26,667	21.17	26,667	21.17	26,667	86.32
							26,667	21.17	26,667	21.17	26,667	21.17	26,667	86.32

The table below shows the remaining term of the options held by the executive directors on December 31, 2018.

Name	Number of options	Remaining term at December 31, 2018 (rounded up)
Tim Van Hauwermeiren	65,000	6.0 years
	30,600	7.0 years
	50,000	7.5 years
	30,600	8.0 years
	80,000	9.0 years
	80,000	5.0 / 10.0 (1)years

- (1) On December 21, 2018, the Company granted options for which the beneficiary had a 60-day period to choose between a contractual term of five or ten years.
Stock options are granted to the executive directors by the Board based on the recommendation of the Remuneration and Nomination Committee and the option allocation scheme established by the Board pursuant to the argenx Employee Stock Option Plan.

Remuneration of non-executive directors

The following table sets forth the information regarding the compensation earned by our non-executive directors during the years ended December 31, 2018, 2017 and 2016:

	2018	2017	2016
Peter Verhaeghe	€ 77,500	€ 77,500	€ 55,000
David L. Lacey	50,000	50,000	45,930
Werner Lanthaler	55,000	55,000	45,000
Pamela Klein	42,500	42,500	35,000
Don Debethizy	52,500	52,500	43,000
A.A. Rosenberg	42,500	42,500	—
James M. Daly	35,000	—	—
Total	€ 355,000	€ 320,000	€ 223,930

The table below shows the number of stock options granted to the non-executive directors during the years ended December 31, 2018, 2017 and 2016 and their exercise price, based on the 30 day average stock price prior to their date of grant, and the stock options exercised during the years ended December 31, 2018, 2017 and 2016.

2016	ESOPs	Term	Exercise price	Exercised
Peter Verhaeghe	10,000	10 years	11.38	
David L. Lacey	10,000	10 years	11.38	
Werner Lanthaler	10,000	10 years	11.38	
Don Debethizy	10,000	10 years	11.38	
Pamela Klein	10,000	10 years	11.38	
A.A. Rosenberg (1)	15,000	10 years	14.13	
Total	65,000			—

- (1) 15,000 stock options were granted to Msc. A.A. Rosenberg in December 2016 in his capacity of consultant to the Company. Msc. A.A. Rosenberg was appointed as a member of our board of directors at our Annual General Meeting in April 2017.

2017	ESOPs	Term	Exercise price	Exercised
David L. Lacey	15,000	10 years	21.37	
Total	15,000			—

2018	ESOPs	Term	Exercise price	Exercised
James M. Daly	15,000	10 years	80.82	
Peter Verhaeghe	10,000	10 years	86.32	
David L. Lacey	10,000	10 years	86.32	
Werner Lanthaler	10,000	10 years	86.32	
			2.44	3,566
			7.17	5,000
			2.44	10,850
			11.38	5,556
Don Debethizy	10,000	10 years	86.32	
Pamela Klein	10,000	10 years	86.32	
A.A. Rosenberg	10,000	10 years	86.32	
James M. Daly	10,000	10 years	86.32	
Total	85,000			24,972

The table below shows the stock options held at the start of the year ended December 31, 2018 and the stock options granted to the non-executive directors which have vested during the year ended December 31, 2018, as

well as the stock options to vest in the years ending December 31, 2019, December 31, 2020 and December 31, 2021 (in number of stock options), and the respective exercise price of such stock options:

Name	Total options held on January 1, 2018	Options granted in 2018	Options exercised in 2018	Total options held on December 31, 2018	Options vested until 2017	Exercise price	Options vested in 2018	Exercise price	Options to vest in 2019	Exercise price	Options to vest in 2020	Exercise price	Options to vest in 2021	Exercise price
Peter Verhaeghe	34,585	10,000		44,585	11,626	€ 2.44								
					7,959	€ 3.95								
					5,000	€ 7.17								
					5,000	€ 11.38	3,333	€ 11.38	1,667	€ 11.38	3,334	€ 86.32	3,333	€ 86.32
David L. Lacey	44,443	10,000		54,443	6,643	€ 2.44								
					12,800	€ 7.17								
					5,000	€ 11.38	3,333	€ 11.38	1,667	€ 11.38	5,000	€ 21.17	3,333	€ 86.32
							5,000	€ 21.17	3,333	€ 86.32	3,334	€ 86.32	3,333	€ 86.32
Werner Lanthaler	29,416	10,000	(24,972)	14,444	—	€ 2.44								
					—	€ 7.17								
					—	€ 11.38	2,777	€ 11.38	1,667	€ 11.38	3,334	€ 86.32	3,333	€ 86.32
J. Donald deBethizy	25,000	10,000		35,000	12,500	€ 11.44	2,500	€ 11.44	1,667	€ 11.38	3,334	€ 86.32	3,333	€ 86.32
					5,000	€ 11.38	3,333	€ 11.38	3,333	€ 86.32	3,334	€ 86.32	3,333	€ 86.32
Pamela Klein	25,000	10,000		35,000	12,500	€ 11.44	2,500	€ 11.44	1,667	€ 11.38	3,334	€ 86.32	3,333	€ 86.32
					5,000	€ 11.38	3,333	€ 11.38	3,333	€ 86.32	3,334	€ 86.32	3,333	€ 86.32
A.A. Rosenberg	15,000	10,000		25,000	5,000	€ 14.13	5,000	€ 14.13	5,000	€ 14.13	3,334	€ 86.32	3,333	€ 86.32
									3,333	€ 86.32	3,334	€ 86.32	3,333	€ 86.32
James M. Daly	—	25,000		25,000					7,500	€ 80.82	5,000	€ 80.82	2,500	€ 80.82
									3,333	€ 86.32	3,334	€ 86.32	3,333	€ 86.32

The table below shows the remaining term of the stock options held by the non-executive directors on December 31, 2018.

Name	Number of stock options	Remaining term on December 31, 2018 (rounded up)
Peter K.M. Verhaeghe	3,650	1.5 years
	2,340	2.0 years
	5,560	4.5 years
	3,181	5.0 years
	9,854	6.0 years
	10,000	7.5 years
	10,000	10.0 years
David L. Lacey	3,180	4.5 years
	1,818	5.0 years
	14,445	6.0 years
	10,000	7.5 years
	15,000	9.0 years
	10,000	10.0 years
Werner Lanthaler	4,444	7.5 years
	10,000	10.0 years
J. Donald deBethizy	15,000	6.5 years
	10,000	7.5 years
	10,000	10.0 years
Pamela Klein	15,000	6.5 years
	10,000	7.5 years
	10,000	10.0 years
A.A. Rosenberg	15,000	8.0 years
	10,000	10.0 years
James M. Daly	15,000	9.5 years
	10,000	10.0 years

Stock options are granted to the non-executive directors by the Board based on the recommendation of the Remuneration and Nomination Committee, and the option allocation scheme established by the board pursuant to the argenx Employee Stock Option Plan.

7.2 Contingencies

The Company is currently not facing any outstanding claims or litigations that may have a significant adverse impact on the Company's financial position.

As described in note 5.2 the Company has received several types of government grants which are granted subject to a certain number of conditions that need to be met at grant date and in the future. The Company recognizes grant income from Belgian and Flemish grant bodies when all contractual conditions are met. These government institutions may however subsequently perform an audit which may result in a (partial) claw back of the grant. The Company deems that the claw back risk is remote in view of the continuous monitoring of the contractual conditions. In September 2018, the Company was awarded a grant from the Flanders Innovation and Entrepreneurship Agency ("the VLAIO 2 grant"). The award of this grant is linked to the fulfillment of a specific condition in which our subsidiary argenx BVBA has to demonstrate that it does no longer meet the criteria of Article 2.18 of EU regulation nr. 651/2014 with regard to "undertakings in difficulty". The deadline for providing supporting evidence that argenx BVBA is no longer an "undertaking in difficult" was determined on May 31, 2019 and will be based on the audited statutory accounts of argenx BVBA for the year ending December 31, 2018. Until then, all payments in respect of the VLAIO 2 grant have been suspended. The Company has recognized grant income in respect of this VLAIO 2 grant for the year ended December 31, 2018, as the equity of its subsidiary argenx BVBA has been restored and as such does no longer meet the criteria of Article 2.18 of EU regulation nr. 651/2014 with regard to "undertakings in difficulty". The Company has fulfilled all remaining existing conditions relating to the recognition of its grant income.

Contracts with these grant bodies also typically include clauses that define the need for future validation of the project results after completion of the initial grant term during which the subsidized expenses or investments have been incurred and for which the grant was earned. Should this validation not occur or be deemed inadequate, the grant bodies have the right to reclaim funds previously granted.

As described in note 4.9, in 2018, the Company granted a total of 1,040,475 stock options to certain of its employees, Board members and consultants. As part of the grant of these stock options, the Company has undertaken to compensate Belgian taxes that are paid upon the grant of these stock options if and when at the end of the exercise period, the stock price would be lower than the exercise price, as increased with these taxes. The Company has applied for a tax ruling on this subject that would cover the stock option grants as from June 28, 2018. The exposure that the Company could face at the end of the exercise period for the stock options granted in 2018 ranges from €2.9 million to €3.5 million.

7.3 Commitments

At balance sheet date, there were no commitments signed for the acquisition of property, plant and equipment or intangible assets.

The Company's manufacturing commitments with its drug substance manufacturing contractor Lonza relate to the ongoing execution of the BLA services for efgartigimod and the ongoing manufacturing activities related to the start-up of Lonza Singapore as a potential future commercial manufacturing site. In December 2018, the Company signed its first commercial supply agreement with Lonza related to the reservation of commercial drug substance supply capacity for efgartigimod. The total commitment under this commercial supply agreement amounts to a minimum commitment of €25.3 million over a period of five years starting from 2020. In the aggregate, the Company has outstanding commitments for efgartigimod of approximately €42.2 million. In addition to the obligations for efgartigimod, the Company also has contractual obligations for cusatuzumab of approximately €4.5 million starting from 2019.

For information on the operating leases, see note 5.7.

7.4 Audit Fees

The following auditors' fees were expensed in the income statement:

Fees	Year Ended December 31,		
	2018	2017	2016
	in thousands of €		
Audit fees (1)	€ 648	€ 179	€ 85
Audit-related fees	143	724	65
Tax and other services (2)	—	—	2
Total	€ 791	€ 903	€ 152

- (1) Audit services performed by Deloitte Accountants B.V. as the external auditor referred to in Section 1 of the Dutch Accounting Firms Oversight Act (Wta) as well as by the Deloitte network.
- (2) Tax and other services performed conducted by the Deloitte network.

7.5 Overview of consolidation scope

The parent company argenx SE is domiciled in the Netherlands. The Company, argenx SE, has one subsidiary, argenx BVBA, based in Belgium. Since October 2017, argenx BVBA has also one subsidiary, argenx US Inc., based in the United States of America. Details of the Company's consolidated entities at the end of the reporting period are as follows:

List of consolidated companies.

Name	Registration number	Country	Participation	Main activity
argenx SE	COC 24435214	The Netherlands	100.00 %	Holding company Biotechnical research on drugs and pharma processes
argenx BVBA	0818292196	Belgium	100.00 %	Pharmaceuticals and pharmacy supplies merchant wholesalers
argenx US, Inc.	36-4880497	USA	100.00 %	

7.6 Events after the balance sheet date

The Company signed a new lease agreement effective January 2, 2019 for approximately 560 square meters of additional office space in Zwijnaarde, Belgium. This lease agreement will automatically expire on the same date as the lease agreement for our current office and laboratory space, being March 31, 2025. The new lease agreement increases the future commitments with €0.7 million.

On January 18, 2019, the Company announced the closing of an exclusive global collaboration and license agreement for cusatuzumab with Janssen. The collaboration agreement became effective following expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act and the closing of the private placement of 1,766,899 new argenx shares at a price of €100.02 per share to Johnson & Johnson Innovation Inc. (JJDC, Inc). argenx and Janssen have agreed to a joint global clinical development plan to evaluate cusatuzumab in acute myeloid leukemia, myelodysplastic syndromes and other potential future indications. Under the terms of the agreement, Janssen has paid argenx \$300 million in an upfront payment. argenx will be eligible to receive potentially up to \$1.3 billion in development, regulatory and sales milestones, in addition to tiered royalties, ranging from the low double digits to the high teens. Janssen will be responsible for commercialization worldwide. argenx retains the option to participate in commercialization efforts in the U.S., where the companies have agreed to share royalties on a 50/50 basis, and outside the U.S., Janssen will pay double-digit sales royalties to argenx.

On February 4, 2019, the Company announced that it entered into a global collaboration and license agreement with Halozyme that enables use by argenx of Halozyme's ENHANZE® drug delivery technology to develop multiple subcutaneous product formulations for current or future argenx product candidates. Under the terms of the agreement, argenx will pay an upfront payment of \$30 million to Halozyme, \$10 million per target for future target nominations and potential future payments of up to \$160 million per selected target, subject to achievement of specified development, regulatory and sales-based milestones. Halozyme will also receive mid-single digit royalties on sales of commercialized products.

On March 14, 2019, the Company announced that ABBV-151, an antibody product candidate formerly named ARGX-115 and exclusively licensed to AbbVie, has commenced clinical development with the initiation of a first-in-human clinical trial. The attainment of this development milestone triggers a \$30 million payment by AbbVie.

On March 20, 2019, the Company signed a new lease agreement for approximately 580 square meters of additional office space in Boston, USA. This lease agreement will expire in July 2024. The new lease agreement increases the future commitments with \$2.2 million.

(This page has been left blank intentionally.)

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH “[...*...]” A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE U.S. SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 24b-2 UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

COLLABORATION AND LICENSE AGREEMENT

BY AND AMONG

ARGENX BVBA

AND

ARGENX SE (SOLELY FOR PURPOSES OF SECTIONS 16.2 AND 16.3)

AND

CILAG GMBH INTERNATIONAL

COLLABORATION AND LICENSE AGREEMENT

This Collaboration and License Agreement (the “**Agreement**”) is made and effective as of December 2, 2018 (the “**Execution Date**”) by and between argenx BVBA, a Belgian company (“**argenx**”) and, solely for purposes of Sections 16.2 and 16.3, argenx SE, a Societas Europaea (“**Parent**”), on the one hand, and Cilag GmbH International, a Swiss company (“**Janssen**”), on the other hand.

INTRODUCTION

1. argenx is developing cusatuzumab and controls certain patents, know-how and other rights related to the Licensed Compounds and Licensed Products;
2. Janssen has considerable knowledge and experience in developing and commercializing products in the oncology field throughout the world;
3. argenx and Janssen believe that a collaboration and license arrangement between the Parties regarding the Licensed Compounds and Licensed Products would be desirable; and
4. argenx and Janssen therefore desire to provide for the development, manufacture and commercialization of the Licensed Compounds and Licensed Products in the Field on and subject to the terms and conditions set forth herein;

NOW, THEREFORE, for and in consideration of the mutual covenants contained herein, argenx and Janssen hereby agree as follows:

ARTICLE I DEFINITIONS

As used in this Agreement, the following terms shall have the meanings set forth below:

1.1 “Acquirer” means any Third Party that is a counterparty in any Change of Control transaction and any of such Third Party’s Affiliates.

1.2 “Action” means any claim, action, cause of action or suit (whether in contract or tort or otherwise), litigation (whether at law or in equity, whether civil or criminal), controversy, assessment, arbitration, investigation, hearing, charge, complaint, demand, notice or proceeding of, to, from, by or before any Governmental Authority.

1.3 “Affiliate” means, with respect to a Person, any other Person directly or indirectly controlling, controlled by, or under common control with, such first Person at any time for so long as such Person controls, is controlled by or is under common control with such first Person. For purposes of this definition, the term “control” (including the correlative meanings of the terms “controlled by” and “under common control with”), as used with respect to any Person, means (i) in the case of a Person that is a corporate entity, direct or indirect ownership of 50% or more of the stock or shares having the right to vote for the election of directors and (ii) in the case of a Person that is an entity, but is not a corporate entity, the possession, directly or

indirectly, of the power to direct or cause the direction of the management policies of such Person, whether through the ownership of voting securities, or by contract, or otherwise.

1.4 “Allocable Global Strategy Costs Benchmark Amount” means, with respect to each of the following Calendar Years, the following amounts (where “launch year” means the Calendar Year during which the Parties expect the First Commercial Sale of a Licensed Product to occur in the U.S.) as further described in Section 6.1.2(b):

[...***...]

1.5 “Antibody” means any antibody or other immunoglobulin protein comprising at least one complementarity determining region (CDR) portion thereof or similar binding protein moiety (including bispecific antibodies, single chain antibodies, domain antibodies, immunoconjugated and chimeric antigen receptor (CAR-T) associated antibodies), whether polyclonal, monoclonal, human, humanized, chimeric, murine, camelid, synthetic or from any other source.

1.6 “Anti-CD70 Antibody” means any Antibody that has been raised, engineered or otherwise optimized to specifically bind to the CD70 Antigen (in addition to any other target or receptor such antibody may bind to).

1.7 “argenx Housemarks” means (a) the corporate logo of argenx, (b) the trademark “argenx”, (c) any other trademark, trade name or service mark (whether registered or unregistered) of argenx or its Affiliates, which is not a Product Trademark, and (d) all intellectual property rights residing in any of the foregoing.

1.8 “argenx Intellectual Property” means argenx Know-How and argenx Patent Rights, collectively.

1.9 “argenx Know-How” means any Know-How that is Controlled by argenx or any of its Affiliates as of the Execution Date or during the Term the practice of which is necessary or useful for, or that is actually used in, the Exploitation of Licensed Compounds or Licensed Products.

1.10 “argenx Patent Rights” means any Patent Rights Controlled by argenx or any of its Affiliates as of the Execution Date or during the Term that Cover any Licensed Compound or Licensed Product or the Exploitation of Licensed Compounds or Licensed Products. argenx Patent Rights shall include: (a) the Patent Rights set forth in Schedule 1.10; and (b) the Patent Rights licensed to argenx under the Lonza Manufacturing Agreement, the Manufacturing License Agreement, [...***...], to the extent the terms of such agreement permit argenx to grant sublicenses under such Patent Rights and subject to the terms and conditions of such agreement. Upon Janssen’s request, from time to time at reasonable intervals, argenx shall provide to Janssen an updated list of then existing argenx Patent Rights.

1.11 [...***...].

1.12 [...***...].

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

1.13 “Business Day” means a day on which banking institutions in New York, New York and Brussels, Belgium are open for business.

1.14 “Calendar Quarter” means a quarter based on the Johnson & Johnson Universal Calendar for that quarter (a copy of which is attached hereto as Exhibit A).

1.15 “Calendar Year” means a year based on the Johnson & Johnson Universal Calendar for that year (a copy of which is attached hereto as Exhibit A).

1.16 “CD70 Antigen” means the antigen as described by UniProtKB/Swiss-Prot entry UniProtKB-P32970 (CD70_HUMAN)
<https://www.ncbi.nlm.nih.gov/gene?Db=gene&Cmd=DetailsSearch&Term=970>.

1.17 “CFDA” means the China Food and Drug Administration in China.

1.18 “Change of Control” means, with respect to a Person:

(a) completion of a merger, reorganization, amalgamation, arrangement, share exchange, consolidation, tender or exchange offer, private purchase, business combination, recapitalization or other transaction involving such Person as a result of which either (i) the stockholders of such Person immediately preceding such transaction hold less than 50% of the outstanding shares, or less than 50% of the outstanding voting power, respectively, of the ultimate company or entity resulting from such transaction immediately after consummation thereof (including a company or entity which as a result of such transaction owns the then outstanding securities of such Person or all or substantially all of such Person’s assets, including such Person’s assets related to Licensed Compounds and Licensed Products, either directly or through one or more subsidiaries), or (ii) any single Third Party person or group (within the meaning of the U.S. Securities Exchange Act of 1934 and the rules of the SEC thereunder as in effect, referred to as a “**Group**”) holds 50% or more of the outstanding shares or voting power of the ultimate company or entity resulting from such transaction immediately after the consummation thereof (including a company or entity which as a result of such transaction owns the then outstanding securities of such Person or all or substantially all of such Person’s assets either directly or through one or more subsidiaries);

(b) the direct or indirect acquisition (including by means of a tender offer or an exchange offer) by any Third Party person or Group of beneficial ownership (within the meaning of the U.S. Securities Exchange Act of 1934 and the rules of the SEC thereunder as in effect), or the right to acquire beneficial ownership, or formation of any Third Party Group which beneficially owns or has the right to acquire beneficial ownership, of 50% or more of either the outstanding voting power or the then outstanding shares of such Person, in each case on a fully diluted basis;

(c) individuals who are employed by, serve on the Board of Directors of, or are otherwise affiliated with or designated by a single company that directly or indirectly (through wholesalers, distributors or pharmacies) sells therapeutic or pharmaceutical products to patients or physicians who are treating patients in clinical or institutional settings, for any reason constitute at least a majority of the Board of Directors of such Person;

(d) the sale or disposition to a Third Party of all or substantially all the assets of such Person (determined on a consolidated basis), including such Person's assets related to the Licensed Compounds and Licensed Products; or

(e) the sale or disposition to a Third Party of assets or businesses that constitute 50% or more of the total revenue or assets of such Person (determined on a consolidated basis), including such Person's assets or business related to the Licensed Compounds and Licensed Products,

[...***...].

1.19 "Clinical Study" means any study in which human subjects are dosed or treated with a drug or biological product, whether approved or investigational.

1.20 "CMC Development" means test method development and stability testing, process development, process validation, process scale-up, formulation development, delivery system development, quality assurance and quality control development, technology transfer and other related activities directed to establishing Manufacturing of a drug or biological product.

1.21 "Collaboration Indication" means (a) any Indication that is or has been the subject of a Clinical Study referred to in the initial GDP attached to this Agreement as Exhibit B; (b) any Indication that is the subject of a Clinical Study that is added to the GDP after the Effective Date pursuant to Section 4.1.3; and (c) any Indication that is the subject of an Independent Study with respect to which an Opt-In Event has occurred pursuant to Section 4.3.5.

1.22 "Collaboration Know-How" means any Know-How that is made, generated, obtained or invented during the Term by or on behalf of either Party, or by the Parties jointly, in the course of and as a result of Developing, Manufacturing or Commercializing the Licensed Compounds and Licensed Products pursuant to this Agreement.

1.23 "Combination Product" means (a) any product containing a Licensed Compound and one or more other active compounds or active ingredients in a fixed-dose formulation, or (b) any combination of a Licensed Product sold together with another drug or biological product in a single package or container for a single price.

1.24 "Combination Regimen" means the administration of two or more drugs or biological products together for the treatment, diagnosis or prophylaxis of any Indication, including a Licensed Product and at least one other distinct drug or biological product that is not a Licensed Product, where such Product and other drug or biological product are packaged and sold separately.

1.25 "Commercialization" or "Commercialize" means marketing, promoting, detailing, distributing, importing, exporting, offering for sale or selling a product, including Medical Affairs Activities, regulatory activities directed to obtaining pricing and reimbursement approvals, price calculations and related reporting to Governmental Authorities, and interacting with Regulatory Authorities with respect to the foregoing. Commercialization shall not include any activities that are Development activities or Manufacturing activities.

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

1.26 “Commercialization Approval” means, with respect to a Licensed Product and any country or regulatory jurisdiction: (a) approval of a Drug Approval Application for such Licensed Product by the applicable Regulatory Authority in such country or regulatory jurisdiction if the application for such Drug Approval Application included efficacy data from a Clinical Study referred to in the GDP; and (b) any pricing and reimbursement approvals that are necessary to conduct a launch of such Licensed Product in such country or regulatory jurisdiction (even if such approvals are not legally required to launch such Licensed Product in such country or regulatory jurisdiction). For purposes of illustration with respect to the Major European Countries, the following pricing and reimbursement approvals are examples of those that are currently necessary to conduct a launch of a drug or biological product: in France, publication of the reimbursed price level in the official journal and registration on a reimbursement list by or on behalf of Comité Economique des Produits de Santé or Haute Autorité de Santé (or a successor agency); in Italy, publication of reimbursement in the Government’s Official Gazette (by Agenzia Italiana del Farmaco or a successor agency); in Germany, execution of contract with the head association of sick funds (GKV-Spitzenverband, Gesetzlichen Krankenversicherung, or a successor agency); in Spain, authorization by La Comisión Interministerial de Precios de los Medicamentos or La Comisión Nacional para el Uso Racional de los Medicamentos (or a successor agency) for national patient access to reimbursement by or on behalf of a Governmental Authority; and in the United Kingdom, a recommendation by the National Institute for Health and Care Excellence (or a successor agency) to obtain mandatory funding to enable broad market access.

1.27 “Commercial FTE” means [...***...] hours of work devoted to or in direct support of the Commercialization of a Licensed Product in the U.S. (and, with respect to Commercial FTE Costs included in the Allocable Global Strategy Costs, the OUS Territory) that is carried out by one or more qualified employees, contractors or consultants of a Party or its Affiliates, but shall not include personnel performing administrative and corporate functions (including human resources, finance, legal and investor relations).

1.28 “Commercial FTE Costs” means, with respect to any period, the Commercial FTE Rate multiplied by the number of Commercial FTEs expended by a Party during such period; provided, however, that Commercial FTE Costs for sales representatives shall be calculated as set forth in the definition of Selling Costs in the Financial Exhibit.

1.29 “Commercial FTE Rate” means:

(a) with respect to any Commercial FTE other than a sales representative, [...***...] of a Party’s or its Affiliates’ employees, contractors or consultants who perform Commercialization activities with respect to the Licensed Products in the U.S. (and, with respect to Commercial FTE Costs included in the Allocable Global Strategy Costs, the OUS Territory); and

(b) with respect to any Commercial FTE that is a sales representative, [...***...] of a Party’s or its Affiliates’ sales representatives who Detail the Licensed Products in the U.S. [...***...].

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

The Commercial FTE Rate is “fully burdened” and will cover any automobile allowance, meal expenses, travel/housing for meetings and other incidental expenses incurred by such personnel in the ordinary course of employment (i.e., such amounts shall not be considered “salary” and shall not be considered Out-of-Pocket Costs, but shall be deemed reimbursed by means of the Commercial FTE Rate).

1.30 “Commercially Reasonable Efforts” means, [...***...].

1.31 “Control” or “Controlled” means, with respect to any Know-How, Patent Right, intellectual property right or other intangible property and subject to Section 16.2.2, the possession (whether by license (other than a license granted pursuant to this Agreement) or ownership, or by control over an Affiliate having possession by license or ownership) by a Party of the ability to grant to the other Party access or a license or sublicense as provided herein without violating the terms of any agreement with any Third Party or other arrangement with any Third Party in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such license or access.

1.32 “Cooperative Group” means any cooperative group that is funded by the U.S. National Cancer Institute Clinical Trials Cooperative Group Program or any similar cooperative group in any country outside the U.S.

1.33 “Cost of Goods” or “COGS” means a Party’s reasonable and necessary internal and Third Party costs incurred in manufacturing or acquisition of Licensed Compound or Licensed Product, determined in accordance with such Party’s standard cost accounting policies that are in accordance with GAAP and consistently applied across all of such Party’s manufacturing network to other products that the Party manufactures. COGS shall be calculated in accordance with Exhibit E.

1.34 “Cover,” “Covering” or “Covered” means, with respect to a Patent Right and a product or technology, that a Valid Claim of such Patent Right would (absent a license thereunder or ownership thereof) be Infringed by the Exploitation of such product or practice of such technology; provided, however, that in determining whether a Valid Claim that is a claim of a pending application would be Infringed, it shall be treated as if issued as then currently being prosecuted.

1.35 “CPI” means the Consumer Price Index-Urban Wage Earners and Clerical Workers, U.S. City Average, All Items, 1982-1984=100, published by the U.S. Department of Labor, Bureau of Labor Statistics (or its successor equivalent index) in the U.S.

1.36 “Currency Hedge Rate” means the Johnson & Johnson currency hedge rate, [...***...].

1.37 “Data” means any and all research data, results, pharmacology data, preclinical data, clinical data (including investigator reports (both preliminary and final), statistical analysis, expert opinions and reports, safety and other electronic databases), in any and all forms, including files, reports, raw data, source data (including patient medical records and original patient report forms, but excluding patient-specific data to the extent required by applicable

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

Laws) and the like, in each case directed to, or used in the Exploitation of any Licensed Compound or Licensed Product under this Agreement.

1.38 “Development” or “Develop” means:

(a) non-clinical and clinical research and drug development activities designed to generate data to support Commercialization Approval of a drug or biological product, including assay development, toxicology, pharmacology and other discovery efforts, data collection and management, statistical analysis, Clinical Studies (including post-approval commitments and post-marketing requirements mandated by or undertaken at the request of Governmental Authorities and Medical Affairs Studies) and development of companion diagnostics;

(b) CMC Development activities;

(c) regulatory activities relating to Clinical Studies and CMC Development activities, including the preparation and submission of IND/CTAs;

(d) regulatory activities in support of obtaining and maintaining Marketing Approval, including the preparation and submission of Drug Approval Applications, regulatory affairs, project management, drug safety surveillance and REMS programs as required by the FDA or other Regulatory Authorities;

(e) Early Access Programs; and

(f) pharmacovigilance activities with respect to a drug or biological product, including establishing, updating and maintaining of a global safety database.

1.39 “Development Costs” means [...*...].**

1.40 “Development FTE” means [...***...] hours of work devoted to or in direct support of the Development of Licensed Products that is carried out by one or more qualified employees or contractors or consultants of a Party or its Affiliates, including scientific, medical, technical and other personnel directly engaged in performing Development activities with respect to the Licensed Products (including the compound development teams and project management teams that support the Licensed Products). Development FTE shall not include work performed by personnel performing administrative and corporate functions (including human resources, finance, legal and investor relations).

1.41 “Development FTE Costs” means, with respect to any period, the Development FTE Rate multiplied by the number of Development FTEs expended by a Party during such period.

1.42 “Development FTE Rate” means a rate of [...***...] per Development FTE per Calendar Year (prorated for the period beginning on the Execution Date and ending on the last day of the first Calendar Year of the Term); provided, however, that such rate shall be increased or decreased annually beginning [...***...] by the percentage increase or decrease in the [...***...]. The Development FTE Rate is “fully burdened” and will cover employee salaries and

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

such facilities and equipment and other materials and services, including ordinary laboratory consumables procured from distributors of relevant products as they may use.

1.43 “Diligent Efforts” means, [...***...].

1.44 “Distributor” means a Third Party that acquires the entirety of its requirements for finished Licensed Products from the relevant Party or the relevant Party’s suppliers.

1.45 “Drug Approval Application” means (a) a Biologics License Application submitted to the FDA pursuant to Section 351(a) of the Public Health Service Act and the regulations promulgated thereunder (“**BLA**”); (b) an application for authorization to market and/or sell a biological product submitted to a Regulatory Authority in any country or jurisdiction other than the U.S., including, with respect to the European Union, a marketing authorization application filed with the EMA pursuant to the Centralized Approval Procedure or with the applicable Regulatory Authority of a country in the European Economic Area with respect to the decentralized procedure, mutual recognition or any national approval procedure (“**MAA**”); or (c) with respect to any biological product for which a BLA or MAA has been approved by the applicable Regulatory Authority, an application to supplement or amend such BLA or MAA to expand the approved label for such biological product to include use of such biological product for an additional indication (“**Supplemental Application**”).

1.46 “Drug Regulation Laws” means Laws regulating to drugs and biological products, including the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et. seq.*, the Public Health Service Act and regulations issued by the FDA, each as in effect and as amended from time to time , as well as similar Laws in the OUS Territory, each as in effect and as amended from time to time.

1.47 “Early Access Program” or “EAP” means any program to provide patients with a Licensed Product before receipt of Marketing Approval and before First Commercial Sale in the country in which the use of the Licensed Product is not primarily intended to obtain information about the safety or effectiveness of such Licensed Product, including Treatment INDs / Protocols, Named Patient Programs and Compassionate Use programs in other countries. For clarity, an EAP with respect to a Licensed Product may continue to be performed following receipt of Marketing Approval of such Product and costs may continue to be incurred in accordance with the performance of such EAP after Marketing Approval.

1.48 “Effective Date” means the Closing Date as defined in the Investment Agreement.

1.49 “EMA” means the European Medicines Agency or any successor agency thereto.

1.50 “European Union” or “EU” means the countries of the European Economic Area, as it is constituted on the Execution Date and as it may be modified from time to time after the Execution Date; provided that if the United Kingdom ceases to be a member of the European Union it shall continue to be treated as a country in the European Union for the purposes of this definition.

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

1.51 “**Executive Officers**” means [...***...]. In the event that the position of any of the Executive Officers identified in this Section no longer exists due to a corporate reorganization, corporate restructuring or the like that results in the elimination of the identified position, the applicable Executive Officer shall be replaced with another executive officer with responsibilities and seniority comparable to the eliminated Executive Officer.

1.52 “**Existing Academic Agreement**” means any agreement between argenx and a research or academic institution relating to a Licensed Compound or Licensed Product that is in effect on the Effective Date.

1.53 “**Existing Third Party Agreements**” means the agreements set forth on Exhibit C.

1.54 “**Exploitation**” or “**Exploit**” means to make, have made, use, have used, offer to sell, sell, have sold, import, export and otherwise practice or exploit, including to Develop, Manufacture and Commercialize.

1.55 “**FDA**” means the United States Food and Drug Administration or any successor agency thereto.

1.56 “**Field**” means the prevention, diagnosis and treatment of human diseases.

1.57 “**Financial Exhibit**” means Exhibit D attached hereto, as the same may be amended from time to time by the Parties.

1.58 “**First Commercial Sale**” means, with respect to a Licensed Product in a country, the first commercial sale of such Licensed Product in such country. Sales for Clinical Study purposes, Early Access Programs or similar uses shall not constitute a First Commercial Sale. In addition, sales of a Licensed Product by and between a Party and its Affiliates, licensees and Sublicensees, or between the Parties (or their respective Affiliates, licensees or Sublicensees) shall not constitute a First Commercial Sale. For the avoidance of doubt sales of a Licensed Product made on a named patient basis shall not constitute a First Commercial Sale for the purposes of this definition.

1.59 “**GAAP**” means U.S. generally accepted accounting principles applied on a consistent basis. Unless otherwise defined or stated, financial terms shall be calculated by the accrual method under GAAP.

1.60 “**Good Clinical Practice**” or “**GCP**” means the current standards for clinical trials for pharmaceuticals, as set forth in the applicable regulations and ICH guidance, including ICH E6, as amended from time to time, and such standards of good clinical practice as are required by the European Union and other organizations and governmental agencies in countries in which a Licensed Product is intended to be tested to the extent such standards are not less stringent than United States Good Clinical Practice.

1.61 “**Good Laboratory Practice**” or “**GLP**” means the current standards for laboratory activities for pharmaceuticals, as set forth in the FDA’s Good Laboratory Practice regulations at 21 C.F.R. Part 58 or the Good Laboratory Practice principles of the Organization

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

for Economic Co-Operation and Development, as amended from time to time, and such standards of good laboratory practice as are required by the European Union and other organizations and governmental agencies in countries in which a Licensed Product is intended to be sold, to the extent such standards are not less stringent than United States Good Laboratory Practice.

1.62 “Good Manufacturing Practice” or “GMP” means the part of quality assurance which ensures that products are consistently produced and controlled in accordance with the quality standards appropriate to their intended use as defined in 21 C.F.R. Parts 210 and 211, European Directive 2003/94/EC, Eudralex 4, Annex 16, and applicable United States, European Union, Canadian and ICH Guidance and/or regulatory requirements for a product.

1.63 “Governmental Authority” means any national, federal, state or local government, or political subdivision thereof, or any multinational organization or authority or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof), or any governmental arbitrator or arbitral body.

1.64 “Government Health Care Programs” means the Medicare program (Title XVIII of the Social Security Act), the Medicaid program (Title XIX of the Social Security Act), TRICARE, the Federal Employee Health Benefits Program, and other foreign, federal, state and local governmental health care plans and programs.

1.65 “Government Order” means any order, writ, judgment, injunction, decree, stipulation, ruling, determination or award entered by or with any Governmental Authority.

1.66 “Health Care Laws” means Laws relating to Government Health Care Programs, Private Health Care Plans, privacy and confidentiality of patient health information and human biological materials, including, in the United States, federal and state Laws pertaining to the federal Medicare and Medicaid programs (including the Medicaid rebate program); federal Laws pertaining to the Federal Employees Health Benefit Program, the TRICARE program and other Government Health Care Programs; federal and state Laws applicable to health care fraud and abuse, kickbacks, physician self-referral and false claims (including 42 U.S.C. § 1320a-7a, 42 U.S.C. § 1320a-7b, 42 U.S.C. § 1395nn and the federal Civil False Claims Act, 31 U.S.C. § 3729 *et. seq.*); the Health Insurance Portability and Accountability Act of 1996; and 45 C.F.R. Part 46, as well as similar Laws in the OUS Territory, each as in effect and as amended from time to time.

1.67 “HSR Act” means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rules and regulations promulgated thereunder.

1.68 “ICH” means the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

1.69 “IND/CTA” means an Investigational New Drug Application filed with FDA or a similar application filed with an applicable Regulatory Authority outside of the United States such as a clinical trial application or a clinical trial notification, or any other equivalent or related regulatory submission, license or authorization.

1.70 “Indication” means the diagnosis, treatment or prevention of a discrete clinically recognized form of a disease. For clarity, except in the case of [...***...], treatment of different subpopulations within a population of patients having a disease shall not be treated as separate Indications for purposes of this Agreement (e.g. front-line treatment, relapsed refractory treatment and maintenance treatment of the same disease shall not be considered different Indications).

1.71 “Infringe” or “Infringement” means any infringement as determined by Law, including direct infringement, contributory infringement or any inducement to infringe.

1.72 “Investment Agreement” means that certain Investment Agreement, dated the date hereof, between Parent and Johnson & Johnson Innovation – JJDC, Inc., as may be amended from time to time.

1.73 “Janssen Housemarks” means (i) the corporate logo of Janssen, (ii) the trademark “Janssen” or “Cilag”, (iii) any other trademark, trade name or service mark (whether registered or unregistered) of Janssen or its Affiliates which is not a Product Trademark, and (iv) all intellectual property rights residing in any of the foregoing.

1.74 “Janssen Intellectual Property” means Janssen Know-How and Janssen Patent Rights, collectively.

1.75 “Janssen Know-How” means any Know-How that is Controlled by Janssen or any of its Affiliates during the Term, the practice of which is necessary or useful for, or is actually used in, the Exploitation of Licensed Compounds or Licensed Products.

1.76 “Janssen Patent Rights” means any Patent Rights Controlled by Janssen or any of its Affiliates during the Term that Cover any Licensed Compound or Licensed Product.

1.77 “Joint Intellectual Property” means Joint Collaboration Inventions and Joint Collaboration Patent Rights, collectively.

1.78 “Know-How” means all technical, scientific and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulas, instructions, skills, techniques, procedures, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and other material, including Manufacturing procedures, test procedures, and purification and isolation techniques in written, electronic or any other form, and all other discoveries, developments, inventions (whether or not patented or patentable), and tangible embodiments of any of the foregoing, in each case that is not generally known to the public. Know-How shall be deemed to exclude Regulatory Documentation, but, for clarity, shall include Data, in each case that is not generally known to the public.

1.79 “Law” means any federal, state, local, foreign or multinational law, statute, standard, ordinance, code, rule, regulation, resolution or promulgation, or any order by any court, regulatory agency or other Governmental Authority, or any license, franchise, permit or similar right granted under any of the foregoing, or any similar provision having the force or effect of law.

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

1.80 “Lead Anti-CD70 Antibody” means the Antibody having the sequence set forth in Schedule 1.80, also denoted ‘cusatuzumab’ (referred to by argenx as ARGX-110), and any other Antibody molecule containing at least one CDR of cusatuzumab.

1.81 “Licensed Compound” means the (i) the Lead Anti-CD70 Antibody, (ii) any other Anti-CD70 Antibody developed by argenx, the sequence of which is disclosed in any of the argenx Patent Rights set forth in Schedule 1.10 as of the Execution Date that claims the composition of matter of the Lead Anti-CD70 Antibody; or (iii) any other Anti-CD70 Antibody that is otherwise claimed in any of the argenx Patent Rights set forth in Schedule 1.10 as of the Execution Date that claims the composition of matter of the Lead Anti-CD70 Antibody.

1.82 “Licensed Product” means any pharmaceutical or biological product in any form containing one or more Licensed Compounds as an active ingredient, in any dosage form, formulation or method of delivery.

1.83 “Lonza” means Lonza Sales AG.

1.84 “Lonza Manufacturing Agreement” means [...***...].

1.85 “Major European Countries” means France, Germany, Italy, Spain and the United Kingdom.

1.86 “Manufacturing” or “Manufacture” means activities directed to producing, manufacturing, processing, filling, finishing, packaging, labeling, quality assurance testing and release, shipping and storage of a product.

1.87 “Manufacturing Agreements” means the Lonza Manufacturing Agreement and the Patheon Manufacturing Agreement.

1.88 “Manufacturing License Agreement” means the [...***...].

1.89 “Marketing Approval” means approval of a Drug Approval Application by the applicable Regulatory Authority.

1.90 “Medical Affairs Activities” or “MAF Activities” means activities directed to interacting with physicians and other healthcare professionals who utilize or conduct research related to a drug or biological product, including: medical and scientific information; responding to external inquiries or complaints; pharmacovigilance activities; medical education; Health Economics and Outcomes Research (HECOR, HEMAR); speaker programs; advisory boards; grants, fellowships and sponsorships; drug safety; local country government affairs; deployment of field-based medical science liaisons (MSLs); MD’s in the field (separate from medical science liaisons); publications; medical communications; field medical education; registries; advocacy support; and slide libraries/kits, reprints and publication planning, but excluding activities directed toward the conduct or support of Medical Affairs Studies.

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

1.91 “**Medical Affairs Study**” means any of the following:

(a) any Clinical Study that is sponsored and conducted by a Cooperative Group as sponsor-investigator (a “**Cooperative Group Study**”) that is supported or enabled by a Party or one of its Affiliates or Sublicensees;

(b) any Clinical Study that is sponsored and conducted by a Third Party as a sponsor-investigator, other than a Cooperative Group Study (sometimes referred to as an “**Investigator Initiated Study**” or “**IIS**”) that is supported or enabled by a Party or one of its Affiliates or Sublicensees; or

(c) any Clinical Study that: (i) is sponsored and conducted by a Party or one of its Affiliates or Sublicensees as a sponsor; (ii) is not intended for use as a basis for obtaining Marketing Approval (e.g., for a further indication, label expansion or otherwise); and (iii) is not being conducted as a commitment made to or a requirement imposed by a Regulatory Authority as a condition of, or in connection with obtaining or maintaining, a Marketing Approval, including any Real World Evidence (RWE) study that is intended to support commercial efforts to secure and retain reimbursement.

1.92 “**Medical Affairs Study Budget Benchmark Amount**” means, with respect to each of the following Calendar Years, the following amounts (where “launch year” means the Calendar Year during which the Parties expect the First Commercial Sale of a Licensed Product to occur in the U.S.):

[...***...]

1.93 “**MHLW**” means the Ministry of Health, Labour and Welfare in Japan.

1.94 “**Net Sales**” means, [...***...].

1.95 “**Ongoing Phase 1/2 Clinical Study**” shall mean that certain Clinical Study of Licensed Product having the ClinicalTrials.gov identifier NCT03030612, entitled “ARGX-110 With AZA in AML or High Risk MDS”.

1.96 “**OUS Territory**” means the entire world and all countries, territories and possessions therein, excluding the U.S.

1.97 “**Out-of-Pocket Costs**” means [...***...].

1.98 “**Parties**” means argenx and Janssen.

1.99 “**Party**” means either argenx or Janssen.

1.100 “**Patent Rights**” means (a) all original (priority establishing) patent applications claiming one or more inventions filed anywhere in the world, including provisionals and nonprovisionals, and (b) any patent or patent application that claims, or is entitled to claim, direct or indirect priority to the patent applications described in clause (a), including any continuations, continuations-in-part, divisions, or substitute applications, any patents issued or granted from any such patent applications, and any reissues, reexaminations, renewals or extensions (including by virtue of any supplementary protection certificates) of any such patents, and any confirmation

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

patents or registration patents or patents of addition based on any such patents, and all foreign counterparts or equivalents of any of the foregoing.

1.101 “Patheon” means Patheon (UK) Limited.

1.102 “Patheon Manufacturing Agreement” means [...***...].

1.103 “Person” means any individual, corporation (including not-for-profit), general or limited partnership, limited liability company, joint venture, estate, trust, association, organization, Governmental Authority or other entity of any kind or nature.

1.104 “Phase 2 Study” means a clinical study of a Licensed Product (a) with the endpoint of evaluating its effectiveness for a particular Indication or Indications, its short term tolerance and safety, as well as its pharmacokinetic and pharmacodynamic information in patients with the Indications under study and is not intended to be pivotal to support Regulatory Approval for such Licensed Product; or (b) that meets the definition in 21 C.F.R. §312.21(b) or any of its foreign equivalents.

1.105 “Phase 3 Study” means a clinical study of a Licensed Product (a) on a sufficient number of patients, which trial (i) is designed to establish that such Licensed Product is safe and efficacious for its intended use, (ii) is designed to define warnings, precautions and adverse reactions that are associated with such Licensed Product in the dosage range to be prescribed, and (iii) is pivotal to support Regulatory Approval for such Licensed Product; or (b) that meets the definition in 21 C.F.R. §312.21(c) or any of its foreign equivalents.

1.106 “PPACA” means the U.S. Patient Protection and Affordable Care Act.

1.107 “Private Health Care Plans” means non-governmental Third Party health care payors and plans, including insurance companies, health maintenance organizations and other managed care organizations, Blue Cross and Blue Shield plans and self-funded employers.

1.108 “Product Domain Names and Websites” means any and all domain names and websites registered for use in association solely with the Licensed Products and the Product Trademarks, excluding website content.

1.109 “Product Trademarks” means any trademark, trade name or service mark (whether registered or unregistered) used on, with, or to refer to a Licensed Product or used with patient support or other information or services or promotional materials in association with a Licensed Product, and all intellectual property rights residing in the foregoing but in each case, excluding argenx Housemarks and Janssen Housemarks as applicable.

1.110 “Regulatory Authority” means any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity with authority over the marketing and sale of pharmaceutical products in a country, including FDA in the U.S. and EMA in the EU. Regulatory Authority also includes any non-governmental group licensed by an entity described in the preceding sentence to perform inspections, audits and/or reviews.

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

1.111 “Regulatory Documentation” means any documentation comprising or relating to or supporting any Regulatory License with respect to a drug or biological product, or its use or potential use in humans, including any documents or reports submitted to any Regulatory Authority and all supporting Data, including IND/CTAs, Drug Approval Applications and all correspondence with any Regulatory Authority with respect to any drug or biological product (including minutes of any meetings, telephone conferences or discussions with any Regulatory Authority).

1.112 “Regulatory Exclusivity” means any exclusive marketing rights or data protection or other exclusivity rights conferred by any Regulatory Authority with respect to a drug or biological product that prevent (i) such Regulatory Authority from granting any regulatory approval of a Third Party product that has an amino acid sequence that is the same as or substantially identical to the amino acid sequence of such biological product; and/or (ii) a Third Party from making a cross reference to data held by such Regulatory Authority including orphan drug exclusivity, pediatric exclusivity, rights conferred in the U.S. under Section 351 of the Public Health Service Act, 42 U.S.C. §262 (the “BPCIA”), the Drug Price Competition and Patent Term Restoration Act (21 U.S.C. §355), as amended (the “Hatch-Waxman Act”), the PPACA or in the European Union under Directive 2001/83/EC, as amended, and Regulation (EC) No. 1901/2006, as amended, or rights similar thereto in other countries or regulatory jurisdictions. If a Regulatory Authority confers more than one type of exclusivity with respect to a biological product in a country or jurisdiction (e.g., the FDA grants both biologic drug reference product exclusivity and orphan drug exclusivity with respect to such biological product), “Regulatory Exclusivity” will be deemed to apply to such biological product in such country or jurisdiction so long as any exclusivity granted to such biological product prevents such Regulatory Authority from granting any regulatory approval of a Third Party product that has an amino acid sequence that is the same as or substantially identical to the amino acid sequence of such biological product or making any cross reference to data held by such Regulatory Authority.

1.113 “Regulatory License” means any approval (including a Marketing Approval), license (including an import license), registration or authorization from any Regulatory Authority that is required under applicable Law or necessary to Exploit a drug or biological product in any country or jurisdiction for one or more uses, and all amendments and supplements thereto.

1.114 [...***...].

1.115 “Royalty-Bearing Agreement” means [...***...].

1.116 “Royalty Term” means, with respect to a Licensed Product in a particular country, the period of time beginning on the date of the First Commercial Sale of such Licensed Product in such country and ending on the later of: (a) the expiration of the last-to-expire Valid Claim of (i) an argenx Patent Right or Joint Collaboration Patent Right in such country that Covers the composition of matter or any method of use of such Licensed Product or (ii) a Specified Manufacturing Patent Right in such country that Covers any method of manufacture of such Licensed Product; (b) the expiration of Regulatory Exclusivity for such Licensed Product in such country, if any; or (c) the tenth (10th) anniversary of such First Commercial Sale in such country.

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

1.117 “Segregate” means, with respect to any given product or program, to use Diligent Efforts to segregate activities directed to the Exploitation of such product or program from activities directed to the Exploitation of Licensed Compounds or Licensed Products under this Agreement, including using Diligent Efforts to ensure that: (i) no personnel involved in Exploiting such product or program have access to non-public plans or information relating to the Exploitation of Licensed Compounds or Licensed Products (provided that management personnel may review and evaluate plans and information regarding both such product or program and the Exploitation of Licensed Compounds or Licensed Products in connection with portfolio decision-making); and (ii) no personnel involved in Exploiting Licensed Compounds or Licensed Products have access to non-public plans or information relating to the Exploitation of such product or program (provided that management personnel may review and evaluate plans and information regarding both such product or program and the Exploitation of Licensed Compounds or Licensed Products in connection with portfolio decision-making).

1.118 “Specified Manufacturing Patent Rights” means the argenx Patent Rights set forth on Schedule 1.118.

1.119 “Third Party” means any Person other than a Party or any of its Affiliates.

1.120 “U.S.” means the United States of America and its territories and possessions.

1.121 “U.S. Collaboration Results” has the meaning set forth on the Financial Exhibit.

1.122 “U.S. Commercialization Budget Benchmark Amount” means, with respect to each of the following Calendar Years, the following amounts (where “launch year” means the Calendar Year during which the Parties expect the First Commercial Sale of a Licensed Product to occur in the U.S.):

[...***...]

1.123 “U.S. Commercialization Option” means argenx’s option to participate in the Commercialization of the Licensed Product as described in the first sentence of Section 6.1.3(b).

1.124 “U.S. Commercialization Plan” means a written plan for Commercialization of the Licensed Products in the U.S. containing the information set out in Section 6.1.2.

1.125 “Valid Claim” means a claim (i) of any issued, unexpired patent that has not been revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken, or with respect to which an appeal is not taken within the time allowed for appeal, and that has not been disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise or (ii) of any patent application that has not been cancelled, withdrawn or abandoned, without being re-filed in another application in the applicable jurisdiction or has not been pending or filed more than seven years from the earliest possible priority date for said application; provided that if such claim is later issued, it shall from the issuance date forward, be deemed to be a Valid Claim, subject to paragraph (i).

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

1.126 Additional Definitions. The definitions of each of the following terms is set forth in the Section of this Agreement indicated below:

<u>Definition</u>	<u>Section</u>
1974 Convention	16.4
Accelerated Approval	0
Agreement	Preamble
Alliance Manager	2.10
Allocable Global Strategy Costs	6.1.2(b)
Allowable Expenses	Financial Exhibit
AML	8.2.1
Anti-Corruption Laws	11.12.1
Applicable Percentage	4.3.5
Approval Date	4.5
argenx	Preamble
argenx Indemnified Parties	12.2
Bankruptcy Code	13.4.2
BLA	1.45
BPCIA	1.112
Breaching Party	13.2
Charitable Contribution Costs	Financial Exhibit
Claim	12.3.1
Claim Amount	12.3.1
Claim Basis	12.3.1
CMC Plan	7.1.2
Collaboration Invention	9.1.2
Collaboration Losses	Financial Exhibit
Commercialization Wind-Down Period	13.6.2
Committee Matters	2.8.1(a)
Committees	2.6
Confidential Information	10.1.2
Controlling Party	12.4.5
Cooperative Group Study	1.91
Cost Report	8.4.2(c)
Detail or Detailing	Financial Exhibit
Development Budget	4.1.2(b)
Development Budget Forecast	4.1.2(d)
Development Reconciliation Procedures	8.4.2(b)
Disclosing Party	10.1.1
Dispute	15.1
Distribution Costs	Financial Exhibit
DOJ	14.2
Execution Date	Preamble
Expert	2.8.3
Expert Panel	2.8.3
First Position Detail	Financial Exhibit

Force Majeure Event	16.16
FTC	14.2
Global Development Plan or GDP	4.1.1
Global Publication Strategy	10.8.1
Group	1.18
Hatch-Waxman Act	1.112
Health Care Reform Fees	Financial Exhibit
HSR Clearance Date	14.1
HSR Conditions	14.1
ICDR	15.3.1
Indemnified Party	12.3.1
Indemnifying Party	12.3.1
Independent Study	4.3.4
Independent Study Proposal	4.3.2
Infringement Recovery	9.5.4
Insolvency Event	13.4.1
Inventory	13.6.2
Investigator Initiated Study or IIS	1.91
Janssen	Preamble
Janssen Indemnified Parties	12.1
JDC	2.2
JFC	2.4
JMC	2.5
Joint Collaboration Invention	9.1.2
Joint Collaboration Patent Rights	9.1.2
JSC	2.1
Losses	12.1
MAA	1.45
Major Country	6.2.2
Marketing Expenses	Financial Exhibit
MDS	8.2.1
Medical Affairs Expenses	Financial Exhibit
Medical Affairs Study Budget	4.1.2(c)
MHRA	8.2.1
Milestone Event	8.2.1
Milestone Payment	8.2.1
New Third Party License	8.7.2
Non-Exclusively Licensed Third Party Intellectual Property	3.1.5
Non-Breaching Party	13.2
Opt-In Event	4.3.5
Opt-In Payment	4.3.5
Other Commercialization Costs	Financial Exhibit
Other Detail	Financial Exhibit
Other Income	Financial Exhibit
OUS Third Party License	8.6.2
Parent	Preamble

Patent Representative	9.1.1
Payee	8.10.2
Payor	8.10.2
Pharmacovigilance Agreement	5.2
Potential Independent Study	4.3.1
Product Liability Costs	12.4.1
Product Trademark Costs	Financial Exhibit
Proposed Publications	10.8.2
Proposing Party	4.1.3
Public Official	11.12.4
Publishing Party	10.8.2
Recall Expenses	Financial Exhibit
Receiving Party	10.1.1
Registration Plan	4.1.2(a)
Regulatory Maintenance Costs	Financial Exhibit
Required Study	2.8.2(c)
Reviewing Party	10.8.2
Sales Milestone Event	8.3
Sales Milestone Payment	8.3
Second Position Detail	Financial Exhibit
Selling Costs	Financial Exhibit
Shared Product Liability Costs	12.4.2
Shared Third Party Products Liability Action	12.4.4
Sole Collaboration Invention	9.1.2
Subcommittee	2.6
Subcontract	4.2.4
Subcontractor	4.2.4
Sublicense	3.3.4
Sublicensee	3.3.4
Supplemental Application	1.45
Supply Costs	Financial Exhibit
Tax or Taxes	8.10.6
Tax Return	8.10.6
Term	13.1
Third Party Patent Challenge	9.7.2
Third Party Products Liability Action	12.4.4
Transactions	14.1
USCC	2.3
U.S. Collaboration Results	Financial Exhibit
U.S. Commercialization Budget	6.1.2
U.S. Commercialization Plan	6.1.2
U.S. Reconciliation Procedures	8.5.2(a)
Working Group	2.6

ARTICLE II
MANAGEMENT OF COLLABORATIVE ACTIVITIES

2.1 Joint Steering Committee. Within [...***...] after the Effective Date, argenx and Janssen shall establish a joint steering committee (the “**JSC**”), comprised of senior executives of each Party or their respective Affiliates, to: (i) review and approve the GDP, the Development Budget, the U.S. Commercialization Plan, the U.S. Commercialization Budget and any other budgets in accordance with Sections 4.1.2, 4.1.3 and 6.1.2; (ii) resolve matters on which the Committees do not reach consensus in accordance with Section 2.8.1(c); and (iii) perform the other functions that are expressly delegated to the JSC in this Agreement. The JSC shall have no oversight or authority with respect to Commercialization of the Licensed Products in the OUS Territory.

2.2 Joint Development Committee. Within [...***...] after the Effective Date, argenx and Janssen shall establish a joint development committee (the “**JDC**”) which shall: (i) oversee and make decisions with respect to the Parties’ Development of the Licensed Products in the U.S. and OUS Territory pursuant to this Agreement, to the extent provided in Article IV; and (ii) perform the other functions that are expressly delegated to the JDC in this Agreement. The JDC shall include individuals from each Party with reasonable expertise in the areas of product development, clinical research and regulatory matters.

2.3 U.S. Commercialization Committee. At a time agreed by the Parties but no less than [...***...] in advance of the first anticipated Marketing Approval of a Licensed Product in the U.S., argenx and Janssen shall establish a U.S. commercialization committee (the “**USCC**”) which shall: (i) oversee and make decisions with respect to the Parties’ Commercialization of the Licensed Products in the U.S. pursuant to this Agreement, to the extent provided in Article VI; and (ii) perform the other functions that are expressly delegated to the USCC in this Agreement. The USCC shall include individuals from each Party with reasonable expertise in the areas of finance, operations, sales and marketing. If this Agreement requires that any decision be made by the USCC before it is formed, such decision shall be made by the JSC.

2.4 Joint Finance Committee. Within [...***...] after the Effective Date, argenx and Janssen shall establish a joint finance committee (the “**JFC**”). The JFC shall: (i) coordinate and conduct the budgeting, accounting, reporting, reconciliation and other financial activities set forth in this Agreement to the extent provided in this Agreement; (ii) if requested by the JSC, develop and recommend to the JSC for approval a process for the development and approval of budgets contemplated by this Agreement, including Development Budgets and U.S. Commercialization Budgets to implement the provisions of Sections 4.1.2, 4.1.3 and 6.1.2; and (iii) perform the other functions that are expressly delegated to the JFC in this Agreement. The JFC shall include individuals from each Party with reasonable expertise in the areas of accounting, cost allocation, budgeting and financial reporting.

2.5 Joint Manufacturing Committee. Within [...***...] after the Effective Date, argenx and Janssen shall establish a joint Manufacturing committee (the “**JMC**”). The JMC shall: (i) oversee and coordinate CMC development and manufacturing matters with respect to the Lead Anti-CD70 Antibody and the Licensed Product containing the Lead Anti-CD70 Antibody, including technology transfer; (ii) promptly after the Effective Date, mutually agree

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

and update the draft CMC Plan attached hereto as Exhibit E; and (iii) perform the other functions that are expressly delegated to the JMC in this Agreement. The JMC shall include individuals from each Party with reasonable expertise in the area of Manufacturing of biological products.

2.6 Subcommittees and Working Groups. From time to time, the JSC, JDC, USCC, JFC and JMC (collectively, the “**Committees**”) may establish subcommittees (each, a “**Subcommittee**”) and working groups (each, a “**Working Group**”) to perform particular tasks and oversee particular projects or activities within the forming Committee’s authority. Each such Subcommittee shall operate in the same manner as the forming Committee, as described in Section 2.7, and each such Working Group shall be constituted and shall operate as the forming Committee determines, provided that no Subcommittee or Working Group shall have any decision-making authority, but shall instead make recommendations to the forming Committee with respect to such matters within its authority.

2.7 Membership of Committees, Subcommittees and Working Groups. Each Committee shall be composed of an equal number of representatives appointed by each Party. Each Committee shall be initially comprised of [...***...] representatives of each Party. Each Party shall have the right, but not be obligated, to appoint the same number of representatives to the Subcommittees and Working Groups as are appointed by the other Party. Each Party’s representatives to the Committees, Subcommittees or Working Groups shall be employees of such Party or its Affiliates. Each Party may replace any of its Committee, Subcommittee or Working Group representatives at any time upon written notice to the other Party. The Committees and the various Subcommittees and Working Groups shall be co-chaired by one designated representative of each Party. The co-chairpersons of each Committee, Subcommittee and Working Group shall not have any greater authority than any other representative on the Committee, Subcommittee or Working Group. The co-chairpersons shall be responsible for (i) calling meetings; (ii) preparing and circulating an agenda in advance of each meeting, provided that the co-chairpersons shall include any agenda items proposed by either Party on such agenda; (iii) ensuring that all decision-making is carried out in accordance with the voting and dispute resolution mechanisms set forth in this Agreement; and (iv) preparing and issuing minutes of each meeting within [...***...] thereafter, which will be approved in writing by each co-chairperson after the meeting.

2.8 Decision-Making.

2.8.1 Committee Actions and Decision-Making.

(a) Each Committee shall only have authority to determine, approve or resolve matters that such Committee is expressly authorized to determine, approve or resolve under this Agreement (“**Committee Matters**”). For clarity, no Committee shall have authority to: (1) amend this Agreement or amend or waive a Party’s rights or obligations under this Agreement; (2) determine that either Party has fulfilled or breached its obligations under this Agreement; (3) make any decision that expressly requires argenx’s or Janssen’s approval or agreement or the approval or agreement of both Parties under this Agreement; (4) resolve any dispute regarding whether a Milestone Event or Sales Milestone Event has been achieved or the amount of any payments owed by one Party to the other Party under this Agreement; or (5) resolve any dispute regarding whether a matter is a Committee Matter or subject to a Party’s

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

final decision-making authority or a Party's approval or agreement under this Agreement, or whether a matter is a Dispute under this Agreement. For clarity, a dispute regarding whether a matter is a Committee Matter, a Dispute under this Agreement or whether an exercise of final decision-making authority is made in accordance with Section 2.8.2 shall be resolved in accordance with Article XV.

(b) The Committees shall determine, approve or resolve Committee Matters by consensus, with the representatives of each Party collectively having one vote on behalf of such Party.

(c) If the JDC, USCC, JFC or JMC does not reach consensus on any Committee Matter within its authority within [...***...] after such matter is first presented to such Committee, either Party may refer such Committee Matter to the JSC for resolution.

(d) If the JSC does not reach consensus, (either with respect to any Committee Matter referred to it by the JDC, USCC, JFC or JMC or with respect to any Committee Matter within the JSC's authority), within [...***...] after such Committee Matter is first presented to the JSC, then, unless this Agreement expressly provides otherwise, either Party may refer such Committee Matter to the Executive Officers for resolution; provided, however, that (i) Committee Matters of the JFC shall be subject to resolution pursuant to Section 2.8.1(f) and (ii) Committee Matters of the JMC shall be subject to resolution pursuant to Section 2.8.2(f).

(e) If the Executive Officers do not reach consensus on a Committee Matter (other than a Committee Matter of the JFC) within [...***...] after such Committee Matter is referred to them, such Committee Matter shall, upon the written request of either Party, be resolved by an Expert Panel in accordance with Section 2.8.3 unless otherwise expressly set forth in Section 2.8.1(f), Section 2.8.2, Section 4.1.3(d) or another provision of this Agreement.

(f) If the members of the JSC do not reach consensus with respect to a Committee Matter of the JFC within [...***...] after such matter is first presented to the JSC, then either Party may refer such matter for resolution by an independent Third Party accounting firm and such Committee Matter of the JFC shall not be subject to resolution pursuant to Section 2.8.3. If either Party refers such matter for resolution by an independent Third Party accounting firm, the Parties shall mutually select and engage an independent Third Party accounting firm that has no auditing or other financial relationship with either Party or any of its Affiliates to resolve such matter. If the Parties are unable to agree on the identity of the Third Party accounting firm within [...***...] of the date on which a Party refers such matter for resolution pursuant to this paragraph (f), the Third Party accounting firm shall be one of the "big four" accounting firms that is not the external auditor of either Party. Such accounting firm shall, as soon as reasonably practicable after such firm is engaged and acting as expert and not an arbitrator, deliver a report to each Party with its analysis and determination of such matter. The accounting firm's determination shall be final and binding on the Parties, and the costs of such firm shall be shared equally by the Parties.

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

2.8.2 Resolution of Certain Committee Matters.

(a) *Initial Development Budget for a Calendar Year.* If the JSC or, after escalation, the Executive Officers do not reach consensus on an initial Development Budget (excluding the Medical Affairs Study Budget portion thereof) for a Calendar Year in accordance with Section 4.1.3(c) by [...***...] of the immediately preceding Calendar Year, then the initial default aggregate amount of the Development Budget (excluding the Medical Affairs Study Budget portion thereof) for such Calendar Year shall be [...***...]; and the JSC or, after subsequent escalation, the Executive Officers shall use Diligent Efforts to reach consensus on a definitive Development Budget (excluding the Medical Affairs Study Budget portion thereof) for such Calendar Year no later than [...***...] of such Calendar Year; provided that if the JSC previously approved a budgeted amount for an ongoing Clinical Study (excluding a Medical Affairs Study), such budgeted amount shall continue to apply to such Clinical Study.

(b) *Initial Medical Affairs Study Budget for a Calendar Year.* If the JSC or, after escalation, the Executive Officers do not reach consensus on an initial Medical Affairs Study Budget for a Calendar Year in accordance with Section 4.1.2(c) by [...***...] of the immediately preceding Calendar Year, then (i) if there is a Medical Affairs Study Budget Benchmark Amount for such Calendar Year, the initial default aggregate amount of the Medical Affairs Study Budget for such Calendar Year shall equal [...***...] or (ii) otherwise, the initial default aggregate amount of such Medical Affairs Study Budget for such Calendar Year shall equal [...***...]; and, in each case, the JSC or, after subsequent escalation, the Executive Officers shall use Diligent Efforts to reach consensus on a definitive Medical Affairs Study Budget for such Calendar Year no later than [...***...] of such Calendar Year.

(c) *Addition of a Clinical Study to GDP for a Collaboration Indication.* If the JSC or, after escalation, the Executive Officers do not reach consensus on a proposed amendment to the GDP to add a Clinical Study of a Licensed Product for a Collaboration Indication in accordance with Section 4.1.3, then the amendment will be added to the GDP if either (i) such Clinical Study is required by a Regulatory Authority in order to obtain or maintain Commercialization Approval of a Licensed Product for such Collaboration Indication, or (ii) a Regulatory Authority advises Janssen or its representatives at any meeting with such Regulatory Authority (as reflected in the minutes of such meeting) that such Clinical Study may be necessary or is advisable in order to obtain or maintain Marketing Approval of a Licensed Product for such Collaboration Indication (in either case ((i) or (ii)), a “**Required Study**”). Otherwise, the amendment will not be made to the GDP. If the JSC or, after escalation, the Executive Officers do not reach consensus as to whether or not a Clinical Study of a Licensed Product for a Collaboration Indication proposed to be added to the GDP is a Required Study, then (A) if the Regulatory Authority in question is the FDA, either Party may request that such Committee Matter be resolved by an Expert Panel in accordance with Section 2.8.3, and (B) if the Regulatory Authority in question is the applicable Regulatory Authority in a country or other regulatory jurisdiction in the OUS Territory, then such Committee Matter shall not be subject to resolution by an Expert Panel and [...***...] shall have the final decision-making authority with respect thereto.

(d) *Initial Commercialization Budget for a Calendar Year.* If the JSC or, after escalation, the Executive Officers do not reach consensus on a proposed initial U.S.

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

Commercialization Budget for a particular Calendar Year submitted to the JSC for approval in accordance with Section 6.1.2(c) or 6.1.2(d) by [...***...] of the immediately preceding Calendar Year, (i) if there is a U.S. Commercialization Budget Benchmark Amount for such Calendar Year, the initial default aggregate amount of the U.S. Commercialization Budget for such Calendar Year shall equal [...***...] or (ii) otherwise, the initial default aggregate amount of such U.S. Commercialization Budget for such Calendar Year shall equal [...***...]; and, in each case, the JSC or, after subsequent escalation, the Executive Officers shall use Diligent Efforts to reach consensus on a definitive U.S. Commercialization Budget for such Calendar Year no later than [...***...] of such Calendar Year

(e) *U.S. Commercialization Matters Relating to Booking of Sales.* If the USCC or, after escalation, the JSC or Executive Officers do not reach consensus on the pricing and reimbursement strategy for the Licensed Products in the U.S. in accordance with Section 6.1.6 or any other Committee Matter relating to aspects of distribution or pricing and reimbursement activities with respect to the Licensed Products in the U.S. described in Section 6.1.5, [...***...] shall have final decision-making authority on such Committee Matter.

(f) *CMC Development and Manufacturing.* If the JMC or, after escalation, the JSC does not reach consensus on any matter related to CMC Development or Manufacturing of the Licensed Compounds or Licensed Products (including CMC components of Regulatory Filings or quality matters related to the Licensed Compounds or Licensed Products), [...***...] shall have final decision-making authority on such Committee Matter, provided that [...***...] may not use such authority to increase amounts budgeted in the Development Budget for CMC Development activities (including, without limitation, budgeted argenx headcount (FTEs) for such activities).

2.8.3 Expert Resolution. If Section 2.8.1 or 2.8.2 provides that a Committee Matter will be resolved by an Expert Panel in accordance with this Section 2.8.3, then, upon the written request of either Party, such Committee Matter shall be resolved by final, binding expert determination using the following procedure:

(a) Each Party shall select one Third Party expert who is neutral, disinterested and impartial, and has experience relevant to the specific subject matter of the referred Committee Matter, within [...***...] after either Party requests resolution by an Expert Panel (each, an “**Expert**”). The Experts selected by the Parties shall jointly select a third Expert within three days thereafter (the three Experts together, the “**Expert Panel**”). If the Experts selected by the Parties are unable to agree on the identity of the third party within [...***...] of the date on which the Parties refers such matter to them pursuant to this paragraph (a), the third Expert shall be appointed by the ICC International Centre for ADR in accordance with the Rules for the Appointment of Experts and Neutrals of the International Chamber of Commerce.

(b) Within [...***...] after the Expert Panel has been selected, each Party shall provide to the Expert Panel and the other Party a written report setting forth its position on the referred Committee Matter. Each Party may update its own report within [...***...] after receiving the other Party’s report. If requested by the Expert Panel, each Party shall make oral submissions based on its written report and each Party shall have the right to be present during any such oral submissions.

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

(c) Within [...***...] after receiving the last report or, if requested by the Expert Panel, the oral submissions, the Expert Panel shall select one Party's position on the referred Committee Matter as its final decision. The Expert Panel shall not have the authority to modify either Party's position or to render any substantive decision other than to select one Party's position on the referred Committee Matter as set forth in such Party's written report most recently submitted to the Expert Panel (i.e., the version initially submitted, if not subsequently revised or as most recently revised in accordance with Section 2.8.3(b), if applicable). The decision of the Expert Panel shall be the Parties' sole, exclusive and binding resolution of the referred Committee Matter, and the Expert's decision shall become the decision of the JSC on the matter.

(d) The costs and fees of the Expert Panel shall be shared equally by the Parties. Each Party shall bear its own costs of participating in the proceeding.

(e) The Parties shall use, and shall direct the Expert Panel to use, Diligent Efforts to resolve the referred Committee Matter within [...***...] after either Party requests such resolution.

(f) Unless otherwise mutually agreed upon by the Parties, the in-person portion (if any) of such proceedings shall be conducted in Brussels, Belgium.

2.9 Meetings of the Committees, Subcommittees and Working Groups. The JSC shall hold meetings at such times as the JSC shall determine, and the JDC, USCC, JFC and JMC shall hold meetings at such times as the applicable Committee determines, but in no event shall such meetings of each Committee be held less frequently than [...***...]. Each Subcommittee or Working Group shall hold meetings at such times as the Subcommittee or Working Group agrees or as its forming Committee directs. Each Committee, Subcommittee and Working Group may meet in person or by audio or video conference as the Parties may mutually agree, [...***...]. With respect to in-person meetings of the Committees, Subcommittees and Working Groups, the representatives shall meet alternately at a location(s) designated by Janssen or argenx, [...***...]. Employees of the Parties and their Affiliates and, with the consent of the applicable Committee, Subcommittee or Working Group, consultants and other Third Parties involved in the Exploitation of the Licensed Products may attend such meetings of the Committees, Subcommittees or Working Groups as nonvoting observers. No action taken at a meeting of any Committee, Subcommittee or Working Group shall be effective unless a representative of each Party is present or participating.

2.10 Alliance Managers. Each Party shall designate one of its or its Affiliates' employees to serve as such Party's alliance manager for all of the activities contemplated under this Agreement ("**Alliance Manager**"). The Alliance Managers will facilitate communication between the Parties to support a successful relationship between the Parties. The Alliance Managers shall be the primary point of contact for the Parties regarding the activities contemplated by this Agreement and shall facilitate all such activities hereunder, except to the extent that such matters are coordinated by the JSC, another Committee or a Subcommittee or Working Group. Each Party may change its designated Alliance Manager from time to time upon notice to the other Party.

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

**ARTICLE III
LICENSE GRANTS**

3.1 argenx Grants to Janssen.

3.1.1 Development License. Subject to the terms and conditions of this Agreement, argenx hereby grants, and shall cause its Affiliates to grant, to Janssen, during the Term, a co-exclusive (with argenx) license under the argenx Intellectual Property and argenx's interest in Joint Intellectual Property to use, Develop and have Developed the Licensed Compounds and Licensed Products in the Field in the U.S. and OUS Territory.

3.1.2 Manufacturing License. Subject to the terms and conditions of this Agreement, argenx hereby grants, and shall cause its Affiliates to grant, to Janssen, during the Term, a co-exclusive (with argenx) license under the argenx Intellectual Property and argenx's interest in Joint Intellectual Property to make, have made and otherwise Manufacture the Licensed Compounds and Licensed Products in the Field in the U.S. and OUS Territory.

3.1.3 Commercialization License.

(a) U.S. Subject to the terms and conditions of this Agreement, argenx hereby grants, and shall cause its Affiliates to grant, to Janssen, during the Term, a co-exclusive (with argenx) license under the argenx Intellectual Property and argenx's interest in Joint Intellectual Property to sell, offer to sell, have sold, import and otherwise Commercialize the Licensed Compounds and Licensed Products in the Field in the U.S.

(b) OUS Territory. Subject to the terms and conditions of this Agreement, argenx hereby grants, and shall cause its Affiliates to grant, to Janssen, during the Term, an exclusive (except for the rights retained by argenx as set out in Section 3.1.3(c)) license under the argenx Intellectual Property and argenx's interest in Joint Intellectual Property to sell, offer to sell, have sold, import and otherwise Commercialize the Licensed Compounds and Licensed Products in the Field in the OUS Territory.

(c) argenx Retained Rights. Subject to the terms and conditions of this Agreement, argenx shall retain a right to import and export the Licensed Compounds and/or Licensed Products into and out of the OUS Territory to the extent necessary for argenx (i) to perform its obligations under Section 4.2.1 or Section 7.1, (ii) to conduct Independent Studies pursuant to Section 4.3 or (iii) to conduct a Clinical Study pursuant to Section 4.5. For clarity, argenx shall not otherwise Commercialize the Licensed Compounds and Licensed Products in the OUS Territory.

3.1.4 Sublicensing. The licenses granted by argenx to Janssen under this Section 3.1 shall be sublicensable only to the extent provided in Section 3.3.

3.1.5 Definition of Co-Exclusive. For purposes of this Section 3.1, "co-exclusive (with argenx)" means that argenx shall retain all of the same rights under the argenx Intellectual Property and argenx's interest in Joint Intellectual Property to Develop, Manufacture and Commercialize the Licensed Compounds and Licensed Products in addition to Janssen under Section 3.1.1, 3.1.2 or 3.1.3(a), and, save to the extent that argenx is permitted to grant

sublicenses pursuant to Section 3.3.2, argenx covenants not to grant to any Third Party a license under such retained rights to the argenx Intellectual Property and argenx's interest in Joint Intellectual Property to conduct the applicable licensed activities with respect to the Licensed Compounds and Licensed Products in the applicable territory. Further, for the avoidance of doubt, that to the extent that any argenx Intellectual Property licensed to Janssen on a co-exclusive or exclusive basis pursuant to this Section 3.1 is non-exclusively licensed to argenx by a Third Party ("**Non-Exclusively Licensed Third Party Intellectual Property**"), the rights granted by argenx to Janssen pursuant to this Section 3.1 under such Non-Exclusively Licensed Third Party Intellectual Property shall be co-exclusive or exclusive (as applicable) solely as between Janssen and argenx but shall otherwise be non-exclusive. argenx covenants not to grant any sub-licenses to a Third Party under such Non-Exclusively Licensed Third Party Intellectual Property other than in accordance with Section 3.3.2.

3.1.6 argenx Affiliates. If any of the argenx Intellectual Property and argenx's interest in Joint Intellectual Property licensed by argenx to Janssen pursuant to this Section 3.1 is Controlled by an Affiliate of argenx, argenx shall procure that such Affiliate grants the licenses to Janssen in accordance with this Section 3.1.

3.2 Janssen Grants to argenx.

3.2.1 Development License. Subject to the terms and conditions of this Agreement, Janssen hereby grants, and shall cause its Affiliates to grant, to argenx, during the Term, a co-exclusive (with Janssen) license under the Janssen Intellectual Property and Janssen's interest in Joint Intellectual Property to use, Develop and have Developed the Licensed Compounds and Licensed Products in the Field in the U.S. and OUS Territory.

3.2.2 Commercialization License. Subject to the terms and conditions of this Agreement, Janssen hereby grants, and shall cause its Affiliates to grant, to argenx, during the Term, a co-exclusive (with Janssen) license under the Janssen Intellectual Property, Janssen's interest in Joint Intellectual Property and the Product Trademarks to sell, offer to sell, have sold, import and otherwise Commercialize the Licensed Compounds and Licensed Products in the Field in the U.S.

3.2.3 Sublicensing. The licenses granted by Janssen to argenx under this Section 3.2 shall be sublicensable only to the extent provided in Section 3.3.

3.2.4 Definition of Co-Exclusive. For purposes of this Section 3.2, "co-exclusive (with Janssen)" means that Janssen shall retain all of the same rights under the Janssen Intellectual Property, Janssen's interest in Joint Intellectual Property and the Product Trademarks to Develop and Commercialize the Licensed Compounds and Licensed Products in addition to argenx under Section 3.2.1 or 3.2.2, and Janssen covenants not to grant to any Third Party a license under such retained rights to the Janssen Intellectual Property, Janssen's interest in Joint Intellectual Property and the Product Trademarks to conduct the applicable licensed activities with respect to the Licensed Compounds and Licensed Products in the applicable territory.

3.2.5 Janssen Affiliates. If any of the Janssen Intellectual Property and Janssen's interest in Joint Intellectual Property licensed by Janssen to argenx pursuant to this

Section 3.2 is Controlled by an Affiliate of Janssen, Janssen shall procure that such Affiliate grants the licenses to argenx in accordance with this Section 3.2.

3.3 Sublicensing.

3.3.1 Affiliates. Each Party shall have the right to grant sublicenses of the licenses granted to such Party pursuant to Section 3.1 or 3.2 to any of its Affiliates without the consent of the other Party, subject to the terms set out in Section 3.3.5.

3.3.2 Subcontractors. If a Party enters into a Subcontract in accordance with Section 4.2.4, 6.1.9 or 7.1.8, such Party shall have the right to grant sublicenses of the licenses granted to such Party pursuant to Section 3.1 or 3.2 to the applicable Subcontractor without the consent of the other Party, to the extent reasonably necessary to enable such Subcontractor to perform subcontracted activities with respect to the Licensed Compounds and Licensed Products under such Subcontract.

3.3.3 Third Parties. Janssen shall have the right to grant sublicenses of the licenses granted to Janssen pursuant to Section 3.1 without the consent of argenx to one or more Distributors in countries in the OUS Territory where it is customary for Janssen to use Distributors to Commercialize pharmaceutical products, to the extent reasonably necessary to enable such Distributors to Commercialize the Licensed Products in such countries.

3.3.4 Sublicense Requirements. Each sublicense granted by a Party to a Third Party pursuant to this Section 3.3 (a “**Sublicense**”) shall: (i) be in writing; (ii) be subject and subordinate to, and consistent with, the terms and conditions of this Agreement; (iii) require the applicable sublicensee (a “**Sublicensee**”) to comply with all applicable terms of this Agreement (except for the payment obligations, for which the sublicensing Party shall remain responsible); and (iv) prohibit further sublicensing, except on terms consistent with this Section 3.3.4. The Party granting a Sublicense shall remain responsible for its obligations under this Agreement and shall be responsible for the performance of the relevant Sublicensee. In addition, such Party shall ensure that each of its Sublicensees complies with all relevant provisions of this Agreement. No Sublicense shall diminish, reduce or eliminate any obligation of either Party under this Agreement. Upon reasonable request, the sublicensing Party shall provide the other Party with a copy of each Sublicense, provided that the sublicensing Party may redact any information from such Sublicense to the extent that such redactions do not reasonably impair the other Party’s ability to ascertain or ensure compliance with this Agreement.

3.3.5 Additional Restrictions. A Party shall not grant a sublicense pursuant to Section 3.3.1, 3.3.2 or 3.3.3 if such grant would cause adverse tax consequences to the other Party (or such Party’s Affiliates), as reasonably demonstrated by such other Party within [...***...] of being notified of a proposed sublicense. In the event a sublicense would so cause such adverse tax consequences, the Parties agree to cooperate reasonably to enable such sublicense in a manner reasonably satisfactory to the non-sublicensing Party, including, if appropriate, indemnification by the sublicensing Party.

3.4 Cross-License to Collaboration Know-How. Subject to the terms and conditions of this Agreement, each Party hereby grants, and shall cause its Affiliates to grant, to

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

the other Party, a non-exclusive, worldwide, perpetual, irrevocable, fully paid-up license, with the right to freely grant sublicenses through multiple tiers, under the Collaboration Know-How and the Joint Intellectual Property for all uses other than the Development, Manufacture and Commercialization of the Licensed Compounds and Licensed Products; in each case, without the duty of accounting to the other Party or seeking the other Party's consent to license, assign or otherwise exploit Joint Intellectual Property by reason of the joint ownership thereof pursuant to Section 9.1. Each Party hereby waives any right such Party may have under the Laws of any jurisdiction to require any such approval or accounting and, to the extent there are any applicable Laws that prohibit such a waiver, each Party will be deemed to have so consented. At the reasonable written request of a Party, the other Party will in writing grant such consents and confirm that no such accounting is required to effect the foregoing. For clarity, (a) the license granted by each Party to the other Party under this Section 3.4 excludes any license or right under any Patent Rights Controlled by such Party, with the sole exception of the Joint Collaboration Patent Rights – *i.e.*, the license granted by argenx under this Section 3.4 excludes any license or right under argenx Patent Rights (other than the Joint Collaboration Patent Rights), and the license granted by Janssen under this Section 3.4 excludes any license or right under Janssen Patent Rights (other than the Joint Collaboration Patent Rights); and (b) neither Party grants to the other Party under this Section 3.4 any license under any Know-How or Patent Rights that are licensed to such Party by any Third Party.

3.5 No Other Rights; No Conflicting Grants. No rights other than those expressly set forth in this Agreement are granted to either Party under this Agreement, and no additional rights shall be deemed granted to either Party by implication, estoppel or otherwise, with respect to any intellectual property rights. All rights not expressly granted by either Party or its Affiliates to the other under this Agreement are reserved. During the Term, neither Party nor any of its Affiliates shall grant or assign any right to any Third Party (including by transferring ownership of a Patent Right licensed to the other Party under this Article III) that would conflict with the rights granted to the other Party under this Agreement.

3.6 Technical Assistance. During the Term, argenx shall reasonably cooperate with Janssen to provide reasonable technical assistance, and to transfer to Janssen any argenx Know-How licensed to Janssen under Section 3.1, as requested by Janssen to facilitate the transfer of Development and Manufacturing efforts related to the Licensed Compounds and Licensed Products. Such cooperation will include providing Janssen with reasonable access by teleconference or in-person at argenx's facilities to any argenx personnel involved in the Development and Manufacturing of the Licensed Compounds and Licensed Products. argenx shall be compensated for the costs of providing such assistance at the Development FTE Rate and such costs shall be included as Development Costs.

ARTICLE IV DEVELOPMENT

4.1 GDP and Development Budget.

4.1.1 General. The Parties shall conduct Development of the Licensed Compounds and Licensed Products only in accordance with the Global Development Plan or to the extent permitted under another provision of this Agreement. **“Global Development Plan”** or

“GDP” means the written plan for the Parties’ Development of the Licensed Products in the U.S. and OUS Territory, as it may be amended from time to time in accordance with the terms of this Agreement. The GDP shall include the Development Budget, Registration Plan and Development Budget Forecast, as described below.

4.1.2 GDP Contents.

(a) The GDP shall include, with respect to each Licensed Product and each Collaboration Indication, all Development activities that are reasonably necessary to seek, obtain and maintain Commercialization Approval and to support and sustain Commercialization of such Licensed Product for such Collaboration Indication in the U.S. and OUS Territory. The GDP shall also include a written plan for preparing and submitting Drug Approval Applications and obtaining and maintaining Marketing Approvals in the U.S. and OUS Territory (the “**Registration Plan**”).

(b) The GDP shall include a rolling, [...***...] budget for Development Costs to be incurred by the Parties in conducting the Development activities described in the GDP that are scheduled to be commenced or conducted during the then-current Calendar Year and the [...***...] succeeding Calendar Years (with respect to such Calendar Years, the “**Development Budget**”). The Development Budget shall be broken down by Development activity and with a breakout of costs as determined by the JFC. In the case of the Development Budget for the first [...***...] of the Term, the first [...***...] of such Development Budget shall be binding on the Parties to the extent provided in Section 8.4, and the [...***...] of the Development Budget shall serve as non-binding guidance for the Parties. In the case of each subsequent Development Budget, the [...***...] of such Development Budget shall be binding on the Parties to the extent provided in Section 8.4, and the [...***...] of such Development Budget shall serve as non-binding guidance for the Parties.

(c) For each Licensed Product and each Collaboration Indication in the GDP, the GDP shall include Medical Affairs Studies that are reasonably necessary to seek, obtain and maintain pricing and reimbursement approvals for, and to support and sustain Commercialization of, such Licensed Product for such Collaboration Indication in the U.S. and OUS Territory. Following Marketing Approval of a Licensed Product for an initial Collaboration Indication, the GDP may also include IISs and Cooperative Group Studies to support Marketing Approval of such Licensed Product for other Collaboration Indications in the U.S. and OUS Territory. Each Development Budget shall include an amount for Medical Affairs Studies for each Calendar Year covered by such Development Budget (the “**Medical Affairs Study Budget**”), unless the JSC determines otherwise by consensus. As part of the annual update to the GDP pursuant to Section 4.1.3(b), the JDC shall prepare and recommend to the JSC: (i) the Medical Affairs Study Budget for the applicable Calendar Years; (ii) an allocation of the Medical Affairs Study Budget for such Calendar Years between the U.S. and OUS Territory; and (iii) which Medical Affairs Studies should be conducted during such Calendar Years. If the JDC does not make, or the JSC does not approve, any of such recommendations prior to [...***...] of the Calendar Year immediately preceding the first Calendar Year of each Development Budget, then: (w) Section 2.8.2(b) shall apply; (x) the Medical Affairs Study Budget for such Calendar Year shall be allocated [...***...] to the U.S. and [...***...] to the OUS Territory; (y) the JDC shall recommend, and the JSC shall approve, which Medical Affairs

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

Studies shall be conducted during such Calendar Year using the portion of the Medical Affairs Study Budget allocated to the U.S. in accordance with Section 4.1.3(d)-(f); and (z) [...] shall determine which Medical Affairs Studies shall be conducted during such Calendar Year using the portion of the Medical Affairs Study Budget allocated to the OUS Territory (and such determination shall not be subject to JDC or JSC approval).

(d) The GDP shall include a high-level forecast of the aggregate amount of the Development Budget for each Calendar Year covered by the GDP after the Calendar Years covered by the then-current Development Budget (the “**Development Budget Forecast**”).

4.1.3 Initial GDP; Updates and Amendments.

(a) The initial GDP is attached to this Agreement as Exhibit B. The GDP (including the Development Budget) may be updated and amended from time to time only with the approval of the JSC, as described in this Section 4.1.3.

(b) The JDC shall review the GDP annually and prepare any recommended updates. No later than [...***...], the JDC shall prepare (i) an updated Development Budget covering the next [...***...] period (in accordance with Section 4.1.2(b)) and (ii) an updated Development Budget Forecast that covers at least the [...***...].

(c) The JDC shall submit all such updates to the JSC for review and approval, as follows:

(i) The JSC shall use reasonable efforts to grant preliminary approval of such updates no later than [...***...].

(ii) Promptly after the JSC’s preliminary approval, such updates shall be submitted to each Party for its internal budgeting process.

(iii) After each Party performs its internal budgeting process, the JSC shall use reasonable efforts to grant final approval of such updates no later than [...***...] (or at a later time if agreed by the JSC), at which time any approved updates shall be set forth in writing in an amended version of the GDP.

(d) Either Party may submit a proposed update or amendment to the GDP to the JDC from time to time. The JDC shall discuss such proposal at its next meeting and make a recommendation to the JSC as to whether to approve such update or amendment. The JDC may also independently develop proposed updates and amendments to the GDP, which the JDC shall submit to the JSC for review and approval. Notwithstanding the foregoing, any updates and amendments submitted by Janssen to the Registration Plan with respect to the OUS Territory shall not require JSC approval.

(e) If the JSC approves an update or amendment to the GDP (including any corresponding update or amendment to the Development Budget), the GDP (including the Development Budget) shall be deemed to be amended accordingly on the date of

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

such approval. No update or amendment to the GDP shall become effective unless and until the JSC approves a corresponding update or amendment to the Development Budget.

(f) If the JSC does not approve an update or amendment to the GDP within [...***...] after such update or amendment is submitted to the JSC for approval:

(i) if the update or amendment is a proposal by a Party (the “**Proposing Party**”) to add a Potential Independent Study to the GDP, then (A) such proposal will not be a Committee Matter subject to resolution in accordance with Section 2.8 and (B) the Proposing Party may make an Independent Study Proposal pursuant to Section 4.3.2 to perform such Clinical Study at its own expense to the extent permitted under Section 4.3; and

(ii) otherwise, the approval of such update or amendment shall be a Committee Matter subject to resolution in accordance with Section 2.8 and the then-current GDP shall continue to apply until such Committee Matter is resolved.

(g) For reference, any Development Costs in excess of the Development Budget shall be dealt with in accordance with Section 8.4.3(b).

4.2 Conduct of Development Activities.

4.2.1 General. Each Party shall use Diligent Efforts to execute and to perform, or cause to be performed, the Development activities allocated to it in the GDP, and to cooperate with the other Party in carrying out the GDP, in accordance with the timetables in the GDP.

4.2.2 Allocation of Development Activities.

(a) As soon as practicable after the Effective Date, argenx shall transfer to Janssen, and Janssen shall assume, responsibility for the conduct of the Ongoing Phase 1/2 Clinical Study. At the same time, argenx shall transfer to Janssen the IND/CTA for the Ongoing Phase 1/2 Clinical Study in accordance with Section 5.1.2. argenx shall continue to conduct such Clinical Study until completion of such transfer. After such transfer, Janssen shall continue to conduct such Clinical Study until completion.

(b) The JDC shall allocate responsibility between the Parties for the conduct of other Clinical Studies and the various other Development activities included in the GDP, and shall set forth such allocation in the GDP. In allocating responsibilities between the Parties, the JDC shall take into consideration each Party’s expertise, capabilities, staffing and available resources to conduct such activities. Unless otherwise determined by the JDC, Janssen shall be allocated responsibility for conducting all Clinical Studies and all other Development activities in the GDP.

4.2.3 Standards of Conduct. Each Party and its Affiliates shall conduct all Development activities with respect to the Licensed Products in good scientific manner and in compliance with applicable Law, including laws regarding environmental, safety and industrial hygiene, Good Laboratory Practice, Good Clinical Practice, informed consent and Institutional

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

Review Board regulations, current standards for pharmacovigilance practice, and all applicable requirements relating to the protection of human subjects.

4.2.4 Subcontracting. Each Party (or its Affiliate) may subcontract the performance of any Development activities with respect to the Licensed Products undertaken in accordance with this Agreement to one or more Third Parties (each such Third Party, a “**Subcontractor**”), provided that any such Third Party must satisfy any subcontractor criteria established by the JDC. All subcontracted activities shall be conducted pursuant to a written agreement between the subcontracting Party and the Subcontractor (a “**Subcontract**”), which shall be consistent with the terms and conditions of this Agreement, shall contain confidentiality provisions no less restrictive than those set forth in Article X, and shall contain a certification that such Third Party and its officers, employees and agents have not been debarred, and are not subject to debarment, pursuant to Section 306 of the United States Federal Food, Drug, and Cosmetic Act, and are not the subject of a conviction described in such section. The subcontracting Party shall oversee the performance of its Subcontractors, and each Party shall have the right from time to time, but not more than [...***...], to audit the performance of the other Party’s Subcontractors. Notwithstanding the foregoing, the subcontracting Party (or Party whose Affiliate enters into a Subcontract) shall remain liable under this Agreement for the performance of all its obligations under this Agreement and shall be responsible for and liable for compliance by its Subcontractors with the applicable provisions of this Agreement.

4.2.5 Clinical Quality Agreement. Before commencing the first Development activity in the GDP following the Effective Date, the JDC shall form a Quality Working Group and the Parties shall negotiate in good faith and use reasonable efforts to enter into a clinical quality agreement. The clinical quality agreement shall set forth the standards, expectations, and responsibilities of the Parties with respect to managing clinical quality (including quality assurance (QA), quality control (QC), and quality risk management (QRM)) for the Parties’ Development activities with respect to the Licensed Products under this Agreement.

4.2.6 Safety Concerns.

(a) Notwithstanding anything to the contrary in this Agreement or the GDP, a Party shall not be obligated to commence or continue a Clinical Study of a Licensed Product if such Party reasonably determines that such Clinical Study would pose an unacceptable safety or tolerability risk for the study subjects. Such Party shall so notify the other Party of its determination and the Parties shall discuss the concerns in good faith to determine whether to terminate, suspend, modify or continue such Clinical Study.

(b) If a Party who is not sponsoring a Clinical Study of a Licensed Product believes in good faith that termination or suspension of such Clinical Study is warranted because of safety or tolerability risks to the study subjects, then such Party shall so notify the sponsoring Party and the Parties shall discuss the non-sponsoring Party’s concerns in good faith to determine whether to terminate, suspend, modify or continue such Clinical Study.

4.2.7 Development Reports. At each meeting of the JDC, each Party will report on the Development activities with respect to the Licensed Products that such Party and its Affiliates has performed or caused to be performed since the last meeting of the JDC, evaluate

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

the work performed in relation to the goals of the GDP and provide such other information as may be reasonably requested by the JDC with respect to such Development activities.

4.2.8 Day-to-Day Responsibility. Each Party shall be responsible for day-to-day implementation of the Development activities for which it is assigned responsibility under the GDP or this Agreement and shall have the right to make operational and administrative decisions with respect to how to implement such Development activities (e.g., with respect to a Clinical Study, the responsible Party shall have the right to select and engage clinical trial sites), provided that such decisions shall not conflict with the GDP or any decision of the JDC or JSC with respect to such Development activity. Each Party shall keep the other Party reasonably informed on the progress of its Development activities, as determined by the JDC.

4.3 Independent Studies.

4.3.1 Definition. A “**Potential Independent Study**” means a Clinical Study of a Licensed Product intended to generate data to obtain Marketing Approval of such Licensed Product for [...***...], subject to Section 4.3.6.

4.3.2 Independent Study Proposal. If the JSC does not approve an update or amendment to the GDP to add a Potential Independent Study and the Proposing Party desires to conduct such Clinical Study at its own expense, then the Proposing Party may provide the other Party with a detailed proposal for such Clinical Study (an “**Independent Study Proposal**”). The Independent Study Proposal shall include: (a) a description of the Development strategy for the applicable Indication; (b) a summary clinical trial protocol for the proposed Clinical Study; (c) a description of the scientific rationale for such Clinical Study and a demonstration of commercial viability and incremental return for the applicable Indication; (d) a description of the label expansion that the Proposing Party intends to seek based upon the data from such Clinical Study; and (e) a budget of the estimated Development Costs of such Clinical Study, broken down by Calendar Year.

4.3.3 Right to Object to Independent Study. The non-Proposing Party may, within [...***...] after receiving an Independent Study Proposal, object to the conduct of such Clinical Study if [...***...]. If the non-Proposing Party notifies the Proposing Party in writing of an objection to the proposed Clinical Study in accordance with this Section 4.3.3, the Proposing Party may not conduct the proposed Clinical Study.

4.3.4 Conduct of Independent Study. If the non-Proposing Party does not object to an Independent Study Proposal in accordance with Section 4.3.3, then the Proposing Party may conduct such Clinical Study at its sole cost and expense (an “**Independent Study**”) in accordance with the following terms and conditions:

(a) The Independent Study shall be conducted in accordance with the Independent Study Proposal.

(b) The Independent Study shall be conducted in accordance with all provisions of this Agreement that apply to the conduct of Clinical Studies in the GDP, including Sections 4.2.3, 4.2.4, 4.2.5, 4.2.6, 4.2.7, 4.2.8 and 4.4.

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

(c) If argenx conducts an Independent Study, then, notwithstanding Article V, argenx shall have the right to submit IND/CTAs and communicate with Regulatory Authorities with respect to the Independent Study and to prepare a Supplemental Application for a label expansion for the Licensed Product based on the efficacy data generated from such Independent Study (consistent with the proposed label expansion set forth in the Independent Study Proposal). Following review and approval of such Supplemental Application by Janssen, Janssen shall submit such supplement or variation to the FDA or EMA, as applicable, and use Diligent Efforts to obtain approval of such Supplemental Application.

(d) The Party conducting an Independent Study shall bear all costs of the Independent Study, and such costs shall not be included in the Development Costs shared by the Parties pursuant to Section 8.4.

4.3.5 Opt-In.

(a) Upon the occurrence of an Opt-In Event for an Independent Study, the non-Proposing Party shall pay the Proposing Party an amount equal to the Applicable Percentage of the Development Costs for the Independent Study that were actually incurred by the Proposing Party on or before the date of the Opt-In Event (but only to the extent that such Development Costs are within the budget included in the Independent Study Proposal) (the “**Opt-In Payment**”). If an Opt-In Payment is made with respect to an Independent Study that is a registration study, and the Proposing Party also conducted other non-registrational Independent Studies for the same Indication pursuant to Section 4.3.4, the Development Costs of such other studies shall be included in the calculation of the Opt-In Payment (but only to the extent that such Development Costs are within the budget included in the applicable Independent Study Proposal).

(b) “**Opt-In Event**” means, with respect to an Independent Study: (i) the non-Proposing Party notifies the Proposing Party in writing that it elects to share the costs of such Independent Study; or (ii) [...***...].

(c) “**Applicable Percentage**” means (a) with respect to Janssen, [...***...] and (b) with respect to argenx, [...***...].

(d) After the occurrence of an Opt-In Event for an Independent Study, the GDP shall be deemed to be amended to add such Independent Study, the Development Costs for such Independent Study incurred after the date of the Opt-In Event shall be shared in the same manner as the Development Costs of other Clinical Studies in the GDP, and this Section 4.3 shall no longer apply to such Independent Study.

4.3.6 Exceptions and Clarifications; Studies of Non-Licensed Compounds and Products.

(a) This Section 4.3 does not apply to, and cannot be used by a Party to conduct, a Clinical Study (i) of a dose or formulation of a Licensed Product that has not previously been studied by the Parties pursuant to the GDP, (ii) of a Licensed Compound that has not previously been studied by the Parties pursuant to the GDP, or (iii) that is a Medical Affairs Study.

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

(b) For clarity, each Party shall at all times be free to independently conduct a Clinical Study of any Anti-CD70 Antibody that is not a Licensed Compound or Licensed Product, and no such Clinical Study shall be governed by the terms and conditions of this Agreement so long as such Clinical Study does not involve a Licensed Product.

(c) During the period beginning on the Effective Date and ending [...***...] after the date that the first Licensed Product has received Marketing Approval in the U.S. and each of the Major European Countries, each Party shall notify the other Party in writing at least [...***...] before commencing the first Clinical Study of [...***...].

4.4 Clinical Studies of Combination Regimens.

4.4.1 Neither Party shall conduct a Clinical Study of a Combination Regimen except as a Clinical Study under the GDP or as an Independent Study pursuant to this Agreement, unless the Parties otherwise agree.

4.4.2 For clarity, each Party shall at all times be free to independently conduct a Clinical Study of any combination regimen that includes an Anti-CD70 Antibody that is not a Licensed Compound or Licensed Product and at least one other distinct drug or biological product that is not a Licensed Product, and no such Clinical Study shall be governed by the terms and conditions of this Agreement so long as such Clinical Study does not involve a Licensed Product.

4.5 Clinical Studies of Other Products. After a Licensed Product has received Marketing Approval in the U.S. and each of the Major European Countries (the “**Approval Date**”), each Party may use such Licensed Product in a Clinical Study of another product outside of this collaboration, if the purpose of such Clinical Study is to generate data about such other product (e.g., use of the Licensed Product as standard of care of the control arm of a study); provided, however, that neither Party shall use such Licensed Product in a Clinical Study of [...***...]. Neither Party shall be required to obtain the consent of the other Party to conduct such Clinical Study, subject to the proviso to the immediately preceding sentence. Upon request of the Party conducting such a Clinical Study, the Party that Manufactures such Licensed Product under this Agreement will provide clinical supplies of such Licensed Product for such Clinical Study at Cost of Goods.

4.6 Companion Diagnostics. If the JDC determines that it is necessary to Develop a companion diagnostic to support the Development and Commercialization of a Licensed Product, the Parties shall amend this Agreement to include the terms and conditions for the development, manufacturing and commercialization of such companion diagnostic.

4.7 Existing Research Collaboration. The Parties agree that argenx will have the right to [...***...], through completion of the existing work plan. Promptly following completion of such existing work plan and the availability of the results thereof, the JDC shall assess in good faith whether to extend the research collaboration with [...***...].

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

**ARTICLE V
REGULATORY**

5.1 Regulatory Matters.

5.1.1 Regulatory Responsibilities. Subject to Sections 5.1.2 and 5.1.4, Janssen shall have the sole right to prepare and submit all Regulatory Documentation (including Drug Approval Applications) and to obtain and maintain all Regulatory Licenses (including Marketing Approvals and pricing and reimbursement approvals) for Licensed Products in the U.S. and OUS Territory, and to conduct communications with Regulatory Authorities with respect to the Licensed Products in the U.S. and OUS Territory, except to the extent necessary for argenx to continue to perform Development activities with respect to the Licensed Compounds and the Licensed Products that argenx is undertaking as of the Execution Date. Janssen shall use Diligent Efforts to conduct such activities in accordance with the Registration Plan.

5.1.2 Transition of Existing Regulatory Documentation and Regulatory License.As soon as practicable after the Effective Date, argenx shall deliver to Janssen electronic copies (unless otherwise required by applicable Law) of all Regulatory Documentation relating to the Licensed Products in the U.S. and OUS Territory. Upon the completion of such transfer, argenx shall, and hereby does, assign to Janssen all such Regulatory Documentation and shall promptly (and in any case within [...***...]) take all steps reasonably necessary to effectuate the assignment of all IND/CTAs, Drug Approval Applications and Regulatory Licenses included in such Regulatory Documentation, including submitting to any applicable Regulatory Authority a letter or other necessary documentation (with copy to Janssen) notifying the Regulatory Authority of the assignment. In the event that any such IND/CTA, Drug Approval Application or Regulatory License cannot be transferred within such [...***...] period, argenx shall take all actions reasonably requested by Janssen with respect to the maintenance or transfer of such IND/CTA, Drug Approval Application or Regulatory License, and the costs thereof shall be shared by the Parties as Development Costs. Prior to any such transfer, the Parties shall enter into the Pharmacovigilance Agreement in accordance with Section 5.2 and an IND/CTA transfer agreement.

5.1.3 Ownership of Regulatory Documentation and Regulatory Licenses. Janssen shall own all Regulatory Documentation and Regulatory Licenses for the Licensed Products in the U.S. and the OUS Territory.

5.1.4 Regulatory Cooperation.

(a) Subject to applicable Law, argenx shall have the right to have one representative participate in all material meetings (including by telephone), conferences and discussions by Janssen or its Affiliate with Regulatory Authorities in the U.S. pertaining to Development or any Regulatory License of a Licensed Product. Janssen shall, to the extent feasible, provide argenx with reasonable advance notice of all such meetings and other contact and advance copies of all related documents and other relevant information relating to such meetings or other contact.

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

(b) Janssen shall provide argenx with advance drafts of any material documents or other material correspondence pertaining to Regulatory Documentation with respect to Licensed Products, including any proposed labeling, that Janssen plans to submit to any Regulatory Authority in the U.S. (or, upon request of the other Party, any other country). argenx may provide comments regarding such material documents and other material correspondence before their submission, which comments Janssen shall consider in good faith. Janssen shall provide argenx with copies of all material submissions it makes to, and all material correspondence (including written summaries of material oral correspondence) it receives from, a Regulatory Authority in the U.S. in accordance with this Section 5.1.4. Notices, copies of material submissions and material correspondence, and other materials to be given in advance as provided in this Section 5.1.4 shall be provided to argenx a reasonable time in advance in order to allow argenx a reasonable amount of time to review such notices, copies of submission and correspondence and materials before their submission to the applicable Regulatory Authority, and in any event at least [...***...] in advance, unless circumstances necessitate a shorter time period. Material correspondence and other material documents received from a Regulatory Authority in the U.S. must be provided to argenx as soon as practicable, and in any event within [...***...].

(c) Janssen shall keep argenx regularly informed through the JDC regarding material regulatory activities with respect to Licensed Products in the OUS Territory and, upon argenx's reasonable request, Janssen shall provide argenx with copies of material Regulatory Documentation with respect to Licensed Products in the [...***...].

5.2 Pharmacovigilance; Safety Database. Prior to transfer of the existing IND/CTA in accordance with Section 4.2.2, the Parties will enter into an agreement setting forth the Parties' pharmacovigilance obligations with respect to the Licensed Products (the "**Pharmacovigilance Agreement**"). The Pharmacovigilance Agreement shall define safety data exchange procedures concerning adverse events, including adverse drug reactions, with respect to any Licensed Products, sufficient to permit each Party and its Affiliates and subcontractors or sublicensees, as the case may be, to comply with applicable Law requirements pertaining to drug safety and pharmacovigilance, including, to the extent applicable, those obligations contained in Health Care Laws. Janssen shall establish the global safety database of adverse events and relevant pharmacovigilance information for the Licensed Products. argenx shall transfer all safety information in its possession relating to the Licensed Compound or Licensed Product to the global safety database within an agreed time period, providing Janssen with sufficient time to enter all the data and to obtain validation of the database. The Pharmacovigilance Agreement shall require each Party to handle all serious adverse events information and other safety data that comes into its possession pursuant to the activities performed under this Agreement in accordance with all applicable Laws. The Pharmacovigilance Agreement shall require Janssen, in the event that argenx reasonably deems it necessary, to promptly make available to argenx such information from Janssen's global safety database for the Licensed Compound or Licensed Product as may reasonably be required in order for argenx to comply with any pharmacovigilance reporting and other compliance obligations under applicable Law.

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

**ARTICLE VI
COMMERCIALIZATION**

6.1 Commercialization in the U.S.

6.1.1 General. The Parties shall Commercialize the Licensed Products in the U.S. in accordance with the U.S. Commercialization Plan and the terms of this Section 6.1, subject to the oversight of the USCC as set forth in this Section 6.1.

6.1.2 U.S. Commercialization Plan.

(a) The U.S. Commercialization Plan shall set forth the strategy for the Commercialization of the Licensed Products in the U.S., the key Commercialization activities to be performed to implement such strategy, the staffing requirements for each such Commercialization activity and a pricing and reimbursement strategy for the U.S. as set forth in Section 6.1.6. argenx acknowledges that Janssen's global commercialization strategy for the Commercialization of Licensed Product will inform the U.S. Commercialization Plan.

(b) The U.S. Commercialization Plan shall include the U.S. Commercialization Budget. The "**U.S. Commercialization Budget**" means the budget for Allowable Expenses to be incurred by the Parties in conducting Commercialization activities for the Licensed Products in the U.S. pursuant to the U.S. Commercialization Plan during a given Calendar Year and the [...***...] succeeding Calendar Years. The U.S. Commercialization Budget shall include budgeted amounts for Commercial FTE Costs and Out-of-Pocket Costs, broken down by [...***...], for Commercialization activities in the U.S. and a breakout of costs by functional area or category, as determined by the USCC in conjunction with the JFC. The [...***...] of the U.S. Commercialization Budget shall be binding on the Parties to the extent provided in the Financial Exhibit, and the [...***...] shall serve as non-binding guidance for the Parties. Each U.S. Commercialization Budget shall also include an annual amount for strategic commercial efforts that will be undertaken by Janssen and its Affiliates at the global team level that are intended to support pre-launch, launch and life cycle management activities with respect to the Licensed Products across regions and key functions, of which [...***...] shall be allocable to the U.S. (the "**Allocable Global Strategy Costs**"). If the JSC does not approve the budgeted amount for Allocable Global Strategy Costs for a Calendar Year prior to the start of such Calendar Year, then (i) if there is an Allocable Global Strategy Costs Benchmark Amount for such Calendar Year, the amount included in the U.S. Commercialization Budget for Allocable Global Strategy Costs for such Calendar Year shall equal [...***...] or (ii) otherwise, the amount included in the U.S. Commercialization Budget for Allocable Global Strategy Costs for such Calendar Year shall equal [...***...].

(c) If argenx exercises the U.S. Commercialization Option pursuant to Section 6.1.3, the following provisions shall apply regarding the preparation of the U.S. Commercialization Plan:

(i) Janssen and argenx shall collaborate to prepare and develop, the initial U.S. Commercialization Plan which shall be submitted to the USCC for review no later than [...***...] before the anticipated First Commercial Sale of the first

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

Licensed Product in the U.S. Each Party shall consider input provided by the other Party in good faith and seek to reach a consensus between the Parties on the contents of the U.S. Commercialization Plan. The USCC shall review, and submit to the JSC for approval, the initial U.S. Commercialization Plan no later than [...***...] before the anticipated First Commercial Sale of the first Licensed Product in the U.S.

(ii) Janssen and argenx shall collaborate to prepare and develop annual updates to the U.S. Commercialization Plan which shall be submitted to the USCC for review. Each Party shall consider input provided by the other Party in good faith and seek to reach a consensus between the Parties on the contents of any updates to the U.S. Commercialization Plan. The USCC shall submit each updated U.S. Commercialization Plan to the JSC for review and approval in time to permit the JSC's preliminary approval to occur by no later than [...***...] to which the proposed update relates. Upon the JSC's preliminary approval, such plan shall be submitted to each Party for its internal budgeting process with a target for final approval by the JSC no later than [...***...] to which the proposed update relates (or at a later date if agreed by the JSC). After final approval by the JSC, such U.S. Commercialization Plan shall take effect on the [...***...] to which such U.S. Commercialization Plan applies.

(d) If argenx does not exercise the U.S. Commercialization Option pursuant to Section 6.1.3, the following provisions shall apply regarding the preparation of the U.S. Commercialization Plan:

(i) Janssen will submit the initial U.S. Commercialization Plan to the USCC for review no later than [...***...] before the anticipated First Commercial Sale of the first Licensed Product in the U.S. Janssen shall consider input provided by argenx in good faith and take into account reasonable suggestions made by argenx. The USCC shall review, and submit to the JSC for approval, the initial U.S. Commercialization Plan no later than [...***...] before the anticipated First Commercial Sale of the first Licensed Product in the U.S.

(ii) Janssen shall prepare and develop annual updates to the U.S. Commercialization Plan which shall be submitted to the USCC for review. Janssen shall consider in good faith input provided and reasonable suggestions made by argenx. The USCC shall submit each updated U.S. Commercialization Plan to the JSC for review and approval in time to permit the JSC's preliminary approval to occur by no later than [...***...] to which the proposed update relates. Upon the JSC's preliminary approval, such plan shall be submitted to each Party for its internal budgeting process with a target for final approval by the JSC no later than [...***...] to which the proposed update relates (or at a later date if agreed by the JSC). After final approval by the JSC, such U.S. Commercialization Plan shall take effect on the [...***...] to which such U.S. Commercialization Plan applies.

(e) Either Party may submit a proposed update or amendment to the U.S. Commercialization Plan to the other Party from time to time. The USCC shall discuss such proposal at its next meeting and make a recommendation to the JSC as to whether to approve such update or amendment. The USCC may also independently develop proposed updates and

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

amendments to the U.S. Commercialization Plan, which the USCC shall submit to the JSC for review and approval.

6.1.3 U.S. Co-Commercialization Responsibilities.

(a) Each Party shall use Diligent Efforts to perform the Commercialization activities allocated to such Party in the U.S. Commercialization Plan; *provided, however*, that if argenx does not exercise its U.S. Commercialization Option, then argenx shall be relieved of its obligation to use Diligent Efforts under this Section.

(b) With respect to Commercialization of the Licensed Products in the U.S., argenx shall have the right to elect to perform: (x) up to [...***...] of the customer facing efforts (including clinical nurse educators, thought leader liaisons, medical science liaisons and field-based MD support, but excluding any customer facing efforts required to support activities Janssen has the exclusive responsibility to perform under Section 6.1.5); and (y) up to [...***...] of home office functions (including marketing, scientific communications (home office coordination role), health economics research (home office coordination role)). If argenx desires to exercise the U.S. Commercialization Option, it shall give notice in writing to Janssen at least [...***...] before the anticipated date of either of the following events: (i) first Marketing Approval of a Licensed Product in the U.S. or (ii) Marketing Approval of a Licensed Product in the U.S. for [...***...]. If argenx elects to exercise the U.S. Commercialization Option, the U.S. Commercialization Plan shall be prepared and updated in accordance with Section 6.1.2(c), and the responsibility to execute the U.S. Commercialization Plan shall be jointly shared by the Parties (excluding any activities that Janssen has the exclusive responsibility to perform under Section 6.1.5). The U.S. Commercialization Plan shall allocate responsibilities between the Parties based upon the election made by argenx. If requested by argenx, allocation of Commercialization activities to argenx may increase over time (up to the maximum levels of participation set forth above) and Janssen shall be responsible for conducting the activities set forth in the U.S. Collaboration Plan to the extent that they are not allocated to argenx. If argenx does not elect to exercise the U.S. Commercialization Option prior to the time period described in the second sentence of this Section 6.1.3(b), Janssen shall be responsible for conducting all of the activities set forth in the U.S. Commercialization Plan; *provided, however*, that argenx shall have the right to elect to exercise the U.S. Commercialization Option as it develops sufficient infrastructure and capabilities to conduct Commercialization activities in the U.S. by serving notice on Janssen at least [...***...] in advance of the date that argenx desires to commence such activities.

6.1.4 U.S. Commercialization Reports. At each meeting of the USCC, each Party will report on any Commercialization activities that such Party and its Affiliates have performed in the U.S. since the last USCC meeting. Each Party will provide an evaluation of the work it and its Affiliates have performed in relation to the goals of the U.S. Commercialization Plan and provide such other information as may be required by the U.S. Commercialization Plan or reasonably requested by the USCC with respect to such Commercialization activities.

6.1.5 Booking Sales in U.S. Janssen and its Affiliates shall book all sales of Licensed Products in the U.S. and shall be responsible for all aspects of distribution of the Licensed Products in the U.S. (including offering for sale, selling, importing, exporting,

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

inventory management and control, store, warehousing, transportation, all aspects of order processing, invoicing, collection of sales proceeds, booking of sales, preparation of sales records and reports, customer relations and services and handling of returns) and all pricing and reimbursement activities with respect to the Licensed Products in the U.S. (including obtaining pricing and reimbursement approvals, conducting reimbursement/access services, conducting health policy/advocacy activities, determining prices charged and discounts offered, and conducting price calculations and related reporting to governmental authorities). If argenx receives any orders for a Licensed Product in the U.S., it shall refer such orders to Janssen.

6.1.6 U.S. Pricing Matters. The USCC shall develop and approve a pricing and reimbursement strategy for the Licensed Products in the U.S. as part of the U.S. Commercialization Plan, [...***...]. Janssen shall otherwise be solely responsible for and have sole authority with respect to the prices charged, any discounts and rebates offered or provided, and any other sale and reimbursement terms and conditions for the Licensed Products in the U.S., which shall be consistent with the pricing and reimbursement strategy approved by the USCC. [...***...].

6.1.7 U.S. Recalls. Janssen shall decide, in its sole discretion, whether to conduct a recall of a Licensed Product in the U.S. and shall have sole discretion to determine the manner in which any such recall shall be conducted. Janssen shall notify argenx prior to commencing any recall and shall in good faith take into account any reasonable suggestions made by argenx in respect of such recall.

6.1.8 U.S. Medical Inquiries. Janssen shall handle all medical questions or inquiries from members of the medical profession in the U.S. regarding the Licensed Products. Janssen shall keep argenx reasonably informed through the USCC of any material medical question or inquiry from members of the medical profession in the U.S. regarding the Licensed Products.

6.1.9 U.S. Commercialization Subcontracting. Each Party (or its Affiliate) may subcontract the performance of any Commercialization activities in the U.S. with respect to the Licensed Products in accordance with Section 4.2.4, provided that the applicable Subcontractors satisfy any subcontractor criteria established by the USCC.

6.1.10 U.S. Commercialization Compliance Matters.

(a) argenx and Janssen shall each ensure that its and its Affiliates' sales representatives in the U.S. do not make any representation, statement, warranty or guaranty with respect to the Licensed Product that is not consistent with the applicable, current package insert of prescribing information or other documentation accompanying or describing a Licensed Product, including mutually approved limited warranty and disclaimers, if any. argenx and Janssen shall each ensure that its and its Affiliates' sales representatives in the U.S. do not make any statements, claims or undertakings to any person with whom they discuss or promote the Licensed Products that are not consistent with, nor provide or use any labeling, literature or other materials other than, those promotional materials currently approved for use in the U.S. under this Agreement. If at any time the use of specified promotional materials is no longer approved under this Agreement for the U.S., each Party shall as soon as practicable take action to remove

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

the promotional materials from use by its and its Affiliates' sales representatives and destroy such materials.

(b) argenx and Janssen shall each cause its and its Affiliates' sales representatives in the U.S. to comply with applicable Laws and guidelines related to the performance of its obligations under this Agreement, including Health Care Laws, Drug Regulation Laws and all applicable regulations thereunder, the AMA and PhRMA Guidelines, and all relevant regulations, authorizations and local laws regarding advertisement, sale and promotion of pharmaceutical products as well as any relevant code of practice.

(c) Each Party shall ensure that its sales representatives perform details of the Licensed Products in the U.S. in compliance with applicable Law, all of Janssen's reasonable instructions, the agreed quality and compliance standards, policies and guidelines relating to the Commercialization of the Licensed Products and any corporate integrity agreement between a Party and the HHS Office of Inspector General. Each Party shall establish and maintain a compliance program that satisfies the seven elements for an effective compliance program set forth in the HHS Office of Inspector General's Compliance Program Guidance for Pharmaceutical Manufacturers, including designation of a compliance officer and the conduct of effective training and education. argenx and Janssen shall each be responsible for tracking and reporting transfers of value initiated and controlled by its and its Affiliates' employees, contractors and agents pursuant to the requirements of the marketing reporting laws or research expense reporting laws of any Governmental Authority, including Section 6002 of PPACA, commonly referred to as the "Sunshine Act."

6.1.11 Day-to-Day Responsibility. Each Party shall be responsible for day-to-day implementation of the Commercialization activities in the U.S. for which it is assigned responsibility under the U.S. Commercialization Plan or this Agreement and shall have the right to make operational and administrative decisions with respect to how to implement such Commercialization activities (e.g., with respect to sales representatives, if a Party is responsible for providing [...***...] of the sales representatives in the U.S., such Party shall be responsible for hiring, training, deploying and managing such sales representatives but shall coordinate such efforts with the other Party), provided that such decisions shall not conflict with the U.S. Commercialization Plan or any decision of the USCC or JSC with respect to such Commercialization activity. Each Party shall keep the other Party reasonably informed on the progress of its Commercialization activities in the U.S., as determined by the USCC.

6.2 Commercialization in OUS Territory.

6.2.1 General. Janssen shall have the sole right and authority, at its sole cost and expense, to Commercialize the Licensed Products in the OUS Territory, including the specific rights and authority set forth in this Section 6.2.

6.2.2 Diligence. Janssen shall use Commercially Reasonable Efforts to Commercialize each Licensed Product in [...***...] (each, a "**Major Country**") following receipt of Commercialization Approval of such Licensed Product in the applicable country. Subject to the preceding provision of this Section 6.2.2, Janssen shall have the sole right and authority to make decisions regarding whether and when to launch a Licensed Product in a particular country

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

or region and the level of efforts to be expended in any particular country or region. Janssen shall promptly notify argenx upon making any determination not to pursue Commercialization of any Licensed Product in any Major Country, whereupon the JSC shall promptly convene a meeting to discuss such matter. If, following such discussion, argenx desires to Commercialize such Licensed Product in such Major Country, [...***...].

6.2.3 Compliance. Janssen shall conduct Commercialization of Licensed Products in the OUS Territory in accordance with the terms and conditions of this Agreement and in compliance with applicable Law.

6.2.4 Booking Sales in OUS Territory. Janssen and its Affiliates shall book all sales of Licensed Products in the OUS Territory and shall be responsible for warehousing and distributing the Licensed Products in the OUS Territory. If argenx receives any orders for a Licensed Product in the OUS Territory, it shall refer such orders to Janssen.

6.2.5 OUS Territory Pricing Matters. Janssen shall be solely responsible for and have sole authority with respect to the prices charged and discounts, rebates and other sale and reimbursement terms and conditions for the Licensed Products in the OUS Territory, provided that [...***...]. Janssen shall keep argenx reasonably informed through the JSC of such matters.

6.2.6 OUS Territory Recalls. Janssen shall decide, in its sole discretion, whether to conduct a recall of a Licensed Product in the OUS Territory and shall have sole discretion to determine the manner in which any such recall shall be conducted.

6.2.7 OUS Territory Medical Inquiries. Janssen shall handle all medical questions or inquiries from members of the medical profession in the OUS Territory regarding the Licensed Products.

ARTICLE VII MANUFACTURE AND SUPPLY

7.1 Manufacturing Responsibilities.

7.1.1 Existing Manufacturing Arrangements. Prior to the Effective Date, argenx appointed Lonza to undertake various CMC Development and Manufacturing activities in respect of the Lead Anti-CD70 Antibody pursuant to the Lonza Manufacturing Agreement and appointed Patheon to undertake the Manufacture of Licensed Product containing the Lead Anti-CD70 Antibody pursuant to the Patheon Manufacturing Agreement. As soon as reasonably practicable following the Effective Date, argenx shall use Diligent Efforts to assign the Lonza Manufacturing Agreement (and any ancillary agreement(s)) and the Patheon Manufacturing Agreement (and any ancillary agreement(s)) to Janssen.

7.1.2 Initial CMC Plan. As soon as reasonably practicable following the Effective Date, the JMC shall jointly prepare a plan for (a) undertaking the CMC Development activities related to the Lead Anti-CD70 Antibody and the Licensed Product containing the Lead Anti-CD70 Antibody, (b) the Manufacture of clinical supplies of the Lead Anti-CD70 Antibody and the Licensed Product containing the Lead Anti-CD70 Antibody, (c) CMC Development and Manufacturing for initial Commercialization of Licensed Product containing Lead Anti-CD70

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

Antibody Manufactured by Lonza at its [...***...] facility, and (d) CMC Development and Manufacturing for Commercialization of Licensed Product containing Lead Anti-CD70 Antibody Manufactured at a Lonza facility and/or at a facility belonging to Janssen or its Affiliates. An initial draft of such plan is set out in Exhibit F and this will form the basis of the more detailed plan (the “**CMC Plan**”). The CMC Plan shall include a plan and timeline for technology transfer of CMC Development and Manufacturing activities for the Lead Anti-CD70 Antibody and the Licensed Product containing the Lead Anti-CD70 Antibody to Janssen. The budget for all such technology transfer activities is included in the Development Budget.

7.1.3 JMC Governance. As contemplated under Section 2.5, the JMC shall oversee CMC Development and the establishment of Manufacturing sources and Licensed Product supply chains pursuant to the CMC Plan, subject to the provisions of this Article VII. Each Party shall use its Diligent Efforts to undertake and manage its responsibilities under the CMC Plan. The JMC shall propose and prepare updates and amendments to the CMC Plan from time to time. The JMC shall submit such updates and amendments to the JSC for review and approval. If the JSC approves an update or amendment to the CMC Plan (including any corresponding update or amendment to the Development Budget, if needed), the CMC Plan (and the Development Budget) shall be deemed to be amended accordingly on the date of such approval. No update or amendment to the CMC Plan shall become effective unless and until the JSC approves a corresponding update or amendment to the Development Budget, if needed.

7.1.4 Clinical Supplies. Janssen shall be solely responsible for the Manufacture of clinical supplies of Licensed Compounds and Licensed Products for any Development activities conducted pursuant to this Agreement; provided that argenx shall be responsible for continuing to obtain clinical supplies from Lonza and Patheon and providing such supplies to Janssen until the applicable Manufacturing Agreement is assigned to Janssen pursuant to Section 7.1.1. The costs of clinical supplies of Licensed Products for activities conducted pursuant to the GDP shall be [...***...] as Development Costs. The costs of clinical supplies of Licensed Products for Independent Studies conducted by argenx pursuant to Section 4.3.4 shall be met by [...***...].

(a) If required, until the applicable Manufacturing Agreement is assigned to Janssen pursuant to Section 7.1.1, and upon the reasonable request of Janssen, the Parties shall enter into a clinical supply agreement and related quality agreement with respect to clinical supplies of Licensed Products containing the Lead Anti-CD70 Antibody or Lead Anti-CD70 Antibody to be provided by argenx to Janssen.

(b) Following assignment of the applicable Manufacturing Agreement pursuant to Section 7.1.1, if requested by argenx in relation to any Independent Study to be carried out by argenx, the Parties shall enter into a clinical supply agreement and related quality agreement with respect to clinical supplies of Licensed Products to be provided by Janssen to argenx. Such agreements shall include customary audit provisions for argenx.

Notwithstanding the foregoing, if the JMC deems there to be a clinical supply shortfall, then the needs of the GDP shall take priority over the needs of any planned Independent Study.

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

7.1.5 Commercial Supplies. Janssen shall have the sole right and authority to Manufacture (or to have Manufactured) commercial supplies of Licensed Compounds and Licensed Products. The costs of commercial supplies of Licensed Compounds or Licensed Products for Commercialization in the U.S. shall be [...***...] as Allowable Expenses, and the costs of commercial supplies of Licensed Compounds or Licensed Products for Commercialization in the OUS Territory shall be borne by [...***...].

7.1.6 Conduct of Manufacturing Activities. Each Party shall perform CMC Development and Manufacturing activities in accordance with the terms and conditions of this Agreement, and in compliance with applicable Law, including those related to GMP and the protection of the environment and occupational health and safety. Neither Party nor any of their Affiliates shall Manufacture any Licensed Compounds or Licensed Products for any use or purpose other than the Development and Commercialization activities to be conducted by the Parties pursuant to this Agreement.

7.1.7 Manufacturing Site Audits.

(a) Until each of the Lonza Manufacturing Agreement and Patheon Manufacturing Agreement have been assigned to Janssen in accordance with Section 7.1.1 of this Agreement, argenx shall use Diligent Efforts to enable Janssen to conduct an audit of the sites where such activities are conducted (subject to the terms of such agreements) and argenx shall facilitate the accommodation of such request with Lonza or Patheon as the case may be. argenx may participate as an observer in any such audit upon reasonable request to Janssen. Following the completion of any such audit, Janssen will notify argenx of the results thereof. Janssen may request the remediation of deficiencies that are identified during such audit as not in compliance with GMP. In the case of any critical observation relating to the Licensed Compounds or Licensed Products that argenx, Lonza or Patheon, as the case may be, cannot or do not remediate in a timely manner, the Parties shall present the audit findings to the JMC and discuss whether to requisition an alternative Subcontractor for such activities.

(b) With effect from the date of assignment to Janssen of each of the Lonza Manufacturing Agreement and Patheon Manufacturing Agreement respectively in accordance with Section 7.1.1, Janssen shall provide argenx with reasonable notice of any audit of the sites where the CMC Development or Manufacturing activities are conducted by Lonza or Patheon as the case may be (subject to the terms of the relevant agreement) and argenx may request participation as an observer in any such audit, such request not to be unreasonably withheld by Janssen. Following the completion of any such audit, Janssen will notify argenx of the results thereof. argenx may request the remediation of deficiencies that are identified during such audit as not in compliance with GMP. In the case of any critical observation relating to the Licensed Compounds or Licensed Products that Janssen or, as the case may be, Lonza or Patheon, cannot or do not remediate in a timely manner, the Parties shall present the audit findings to the JMC and discuss whether to requisition an alternative Subcontractor for such activities.

7.1.8 Manufacturing Subcontracting. Each Party (or its Affiliate) may subcontract the performance of any of its CMC Development or Manufacturing activities with respect to the Licensed Compounds or Licensed Products in accordance with Section 4.2.4,

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

provided that the applicable Subcontractor(s) satisfy any subcontractor criteria established by the JMC.

7.2 Subcontractor Manufacturing. Until respectively each of the Manufacturing Agreements have been assigned to Janssen pursuant to Section 7.1.1, argenx shall update the provisions of such agreements as necessary (including for the avoidance of doubt, Schedule 2 of the Lonza Manufacturing Agreement and Part C of the Patheon Manufacturing Agreement) to provide for argenx's responsibilities under the CMC Plan, and if relevant, argenx's responsibilities set out in the Global Development Plan, subject to the following:

7.2.1 All costs incurred by argenx pursuant to each of the Manufacturing Agreements (including any updates) with respect to Licensed Compounds or Licensed Products after the Execution Date are Development Costs; and

7.2.2 Janssen acknowledges that argenx shall perform its obligations under this Agreement to develop the Manufacturing process, undertake any CMC Development activities and supply any Licensed Compound or Licensed Product through its Third Party Subcontractors, Lonza and Patheon, pursuant to the Lonza Manufacturing Agreement or Patheon Manufacturing Agreement, as applicable. argenx shall use Diligent Efforts to ensure that each of Lonza and Patheon complies with the applicable agreement. In the event that there is a claim against either Lonza or Patheon relating to the supply of any Licensed Compound or Licensed Product pursuant to the applicable agreement, then the Parties shall report the claim to the JMC in order to agree whether and how any claim should be made against such Subcontractor.

7.3 Transfer of Manufacturing. Pursuant to Section 2.11 of the Lonza Manufacturing Agreement, argenx has the right to request that Lonza undertakes technology transfer to argenx or its appointed manufacturer. On the request of Janssen or as required to comply with the CMC Plan, argenx shall make the written request as provided for in the Section 2.11 of the Lonza Manufacturing Agreement and shall use its Diligent Efforts to procure that Lonza complies with such request. Janssen agrees that, to the extent that Janssen, its Affiliate or nominee receives the benefit of such technology transfer, it shall, and shall procure that its Affiliate or nominee shall, comply with the requirements set out in Section 2.11 of the Lonza Manufacturing Agreement relating to the Transferee (as such term is defined in the Lonza Manufacturing Agreement), including but not limited to the requirement to [...***...]. The costs of such technology transfer pursuant to Section 2.11 of the Lonza Manufacturing Agreement shall be shared by the Parties in accordance with the Development Budget.

7.4 Manufacturing IP License. Janssen acknowledges that certain CMC-related and other intellectual property has been licensed to argenx pursuant to the Manufacturing License Agreement. Pursuant to the Manufacturing License Agreement, argenx is entitled to grant sub-licenses of and to transfer the Transfected Potelligent® CHOK1SV Cells (as defined in the Manufacturing License Agreement) to a Strategic Partner (as defined in the Manufacturing License Agreement), subject to certain obligations. Janssen acknowledges that the sublicense to Janssen of the rights that are granted to argenx in the Manufacturing License Agreement is expressly subject to and subordinate to the terms of the Manufacturing License Agreement, and Janssen hereby covenants that it shall:

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

ARTICLE VIII FINANCIAL PROVISIONS

8.1 Upfront Payment. In partial consideration for the licenses granted by argenx to Janssen in accordance with Section 3.1 of this Agreement, Janssen shall make a non-refundable, non-creditable payment of three hundred million U.S. dollars US\$300,000,000 to argenx within [...***...] after the Effective Date.

8.2 Development and Approval Milestone Payments.

8.2.1 Milestone Payments and Events. In partial consideration for the licenses granted by argenx to Janssen in accordance with Section 3.1 of this Agreement, Janssen shall make the non-refundable, non-creditable payments (each, a “**Milestone Payment**”) to argenx set forth in the table below not later than [...***...] after argenx delivers an invoice to Janssen upon the first occurrence of the corresponding milestone event set forth below (each, a “**Milestone Event**”). Janssen shall provide notice to argenx within [...***...] after occurrence of any of the Milestone Events (provided that if argenx is the sponsor of the Ongoing Phase 1/2 Clinical Study as of the achievement of the first Milestone Event, then argenx shall provide notice to Janssen within [...***...] after occurrence of such first Milestone Event):

	Milestone Event	Milestone Payment
	<i>Development Milestones</i>	
1.	[...***...]	[...***...]
2.	[...***...]	[...***...]
3.	[...***...]	[...***...]
4.	[...***...]	[...***...]
5.	[...***...]	[...***...]
6.	[...***...]	[...***...]
7.	[...***...]	[...***...]
8.	[...***...]	[...***...]
	<i>Regulatory Filing Milestones</i>	
9.	[...***...]	[...***...]
10.	[...***...]	[...***...]
11.	[...***...]	[...***...]
12.	[...***...]	[...***...]
13.	[...***...]	[...***...]
14.	[...***...]	[...***...]
15.	[...***...]	[...***...]
16.	[...***...]	[...***...]
17.	[...***...]	[...***...]
18.	[...***...]	[...***...]
19.	[...***...]	[...***...]

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

	Milestone Event	Milestone Payment
20.	[...***...]	[...***...]
21.	[...***...]	[...***...]
22.	[...***...]	[...***...]
23.	[...***...]	[...***...]
24.	[...***...]	[...***...]
25.	[...***...]	[...***...]
26.	[...***...]	[...***...]
27.	[...***...]	[...***...]
28.	[...***...]	[...***...]
29.	[...***...]	[...***...]
	Commercialization Approval Milestones	
30.	[...***...]	[...***...]
31.	[...***...]	[...***...]
32.	[...***...]	[...***...]
33.	[...***...]	[...***...]
34.	[...***...]	[...***...]
35.	[...***...]	[...***...]
36.	[...***...]	[...***...]
37.	[...***...]	[...***...]
38.	[...***...]	[...***...]
39.	[...***...]	[...***...]
40.	[...***...]	[...***...]
41.	[...***...]	[...***...]
42.	[...***...]	[...***...]
43.	[...***...]	[...***...]
44.	[...***...]	[...***...]
45.	[...***...]	[...***...]
46.	[...***...]	[...***...]
47.	[...***...]	[...***...]
48.	[...***...]	[...***...]
49.	[...***...]	[...***...]
50.	[...***...]	[...***...]

8.2.2 Definitions. For purposes of Section 8.2.1:

[...***...].

8.2.3 Rules Regarding Payment of Milestones.

(a) Each Milestone Payment shall be payable only once upon the first occurrence of the relevant Milestone Event by the first Licensed Product, even if the Milestone Event occurs with respect to more than one Licensed Product or multiple times with respect to the same Licensed Product.

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

- (b) For purposes of Milestone Event 1, [...***...].
- (c) With respect to Milestone Events 9-29, such Milestone Events shall occur upon [...***...].
- (d) With respect to Milestone Events 30-50, such Milestone Event shall not be deemed to occur unless [...***...].
- (e) For purposes of Milestone Event 33, [...***...].
- (f) No Milestone Events shall be deemed to occur, and no Milestone Payments shall become due, if the applicable Milestone Event is achieved with respect to an Independent Study, or based upon efficacy data from an Independent Study.
- (g) For the avoidance of doubt: [...***...].

8.3 Sales Milestone Payments. In partial consideration for the licenses granted by argenx to Janssen in accordance with Section 3.1 of this Agreement:

8.3.1 Janssen shall notify argenx in the applicable royalty report delivered pursuant to Section 8.6.4 the first time the aggregate Net Sales of Licensed Products in any Calendar Year by Janssen, its Affiliates and its sublicensees in the OUS Territory exceed the amounts set forth in the following table (each, a “**Sales Milestone Event**”); provided, however, that Net Sales of a particular Licensed Product in a particular country occurring after expiration of the Royalty Term for such Licensed Product in such country shall be disregarded in the calculation of Net Sales for purposes of this Section 8.3; and

8.3.2 Janssen shall pay to argenx the applicable milestone payments set forth in the table below (each, a “**Sales Milestone Payment**”) within [...***...] after receipt of an invoice from argenx with respect to achievement of each Sales Milestone Event. Each Sales Milestone Payment shall be non-refundable and non-creditable.

Sales Milestone Event	Sales Milestone Payment
[...***...]	[...***...]
[...***...]	[...***...]
[...***...]	[...***...]

Each Sales Milestone Payment shall be payable only once upon the first occurrence of the relevant Sales Milestone Event, even if the Sales Milestone Event occurs multiple times.

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

8.4 Shared Development Costs.

8.4.1 Cost Sharing. Development Costs incurred during the Term by the Parties and their Affiliates shall be borne [...] by Janssen and [...] by argenx. Development Costs will not be included in Allowable Expenses for purposes of calculating U.S. Collaboration Results, and any amounts included in Allowable Expenses will not be included in Development Costs.

8.4.2 Cost Reports.

(a) Development Costs shall initially be borne by the Party incurring the cost or expense, subject to reimbursement as provided in Section 8.4.3. Each Party shall calculate and maintain records of Development Costs incurred by it and its Affiliates in accordance with procedures to be established by the JFC in coordination with the JDC.

(b) The procedures for quarterly reporting of actual results, quarterly review and discussion of potential discrepancies, quarterly reconciliation, reasonable cost forecasting, and other finance and accounting matters related to Development Costs will be determined by the JFC (the “**Development Reconciliation Procedures**”). Such procedures will provide the ability to comply with financial reporting requirements of each Party.

(c) The Development Reconciliation Procedures shall provide that, within [...] after the end of each Calendar Quarter, each Party shall submit to the JFC and the JDC a report, in a format established by the JFC, of all Development Costs incurred by such Party and its Affiliates during such Calendar Quarter (each, a “**Cost Report**”). Within [...] following the receipt of each Cost Report, each Party shall have the right to request reasonable additional information (as determined by the JFC) related to the other Party’s and its Affiliates’ Development Costs during such Calendar Quarter in order to confirm that such other Party’s spending is in conformance with the approved Development Budget.

(d) The JFC shall establish reasonable procedures for the Parties to share estimated Development Costs for each Calendar Quarter before the end of such Calendar Quarter, to enable each Party to appropriately accrue its share of Development Costs for financial reporting purposes.

8.4.3 Reimbursement of Shared Development Costs.

(a) The Party (with its Affiliates) that incurs more than its share of the total actual Development Costs with respect to a Calendar Quarter shall be paid by the other Party an amount of cash sufficient to reconcile to its agreed percentage of actual Development Costs in such Calendar Quarter pursuant to Section 8.4.1. Notwithstanding the foregoing, on a Calendar Year-to-date basis, the Parties shall not share any Development Costs in excess of the amounts allocated for such Calendar Year-to-date period in the Development Budget, except as follows:

(i) Development Costs in excess of the Development Budget shall be included in the calculation of Development Costs to be shared by the Parties to the extent such excess Development Costs do not exceed [...] of the total

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

Development Costs allocated to be incurred by such Party and its Affiliates in the applicable Calendar Year-to-date period in accordance with the applicable Development Budget for such Calendar Year; and

(ii) the Parties shall share any and all Development Costs in excess of the Development Budget, as applicable, to the extent attributable to: (A) a change in applicable Law; (B) a Force Majeure Event; (C) a variation in actual patient enrollment from projected patient enrollment; (D) a change to a clinical trial protocol required or requested by any Governmental Authority; or (E) increases in the cost of raw materials.

(b) If any excess Development Costs are excluded from sharing by the Parties for a particular Calendar Year-to-date period pursuant to Section 8.4.3(a), such excess Development Costs shall be carried forward to the subsequent Calendar Quarters (provided that such Calendar Quarters fall within the same Calendar Year) and, to the extent the total Development Costs incurred by such Party and its Affiliates for the Calendar Year-to-date as of the end of such subsequent Calendar Quarter are less than [...***...] of the aggregate Development Costs allocated to such Party under the Development Budget for such Calendar Year-to-date period, such carried forward amounts shall be included in Development Costs to be shared by the Parties for such Calendar Year-to-date-period (i.e., so that the total Development Costs incurred by such Party and its Affiliates that are shared pursuant to this Section 8.4 during any Calendar Year do not exceed [...***...] of the Development Costs allocated to such Party under the Development Budget for such Calendar Year, unless otherwise approved by the JSC).

(c) The Development Reconciliation Procedures shall require the JFC to develop a written report setting out the calculation of any net amount owed by argenx to Janssen or by Janssen to argenx, as the case may be, as necessary to accomplish the sharing of Development Costs set forth in Section 8.4.1 and this Section 8.4.3, and to prepare such report promptly following delivery of the Cost Reports and in a reasonable time (to be defined in the Development Reconciliation Procedures) in advance of payment.

(d) The net amount payable to accomplish the sharing of Development Costs as provided under this Agreement shall be paid by Janssen or argenx, as the case may be, within [...***...] after the end of the applicable Calendar Quarter.

(e) In establishing the Development Reconciliation Procedures, the Finance Working Group shall work to coordinate and harmonize the Development Reconciliation Procedures with the U.S. Reconciliation Procedures to permit for reconciliation, and associated payments, with respect to Development Costs and U.S. Collaboration Results within [...***...] after the end of the applicable Calendar Quarter.

8.5 U.S. Territory Royalties.

8.5.1 U.S. Royalties. In partial consideration for the licenses granted by argenx to Janssen in accordance with Section 3.1 of this Agreement, Janssen shall pay to argenx royalties in an amount that will divide the U.S. Collaboration Results 50-50 between Janssen and argenx. The U.S. Collaboration Results shall be calculated as set forth in the Financial Exhibit,

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

and, without limiting the generality of the foregoing, the Allowable Expenses in such calculation shall be subject to the limitations set forth in section (1) of the Financial Exhibit. The reconciliation process shall occur on a quarterly basis in accordance with Section 8.5.2(b).

8.5.2 Quarterly Reconciliation and Payments.

(a) Procedures for quarterly reporting of actual results and review and discussion of potential discrepancies, quarterly reconciliation, reasonable forecasting, and other finance and accounting matters, to the extent not set forth in the Financial Exhibit, will be established by the JFC (the “**U.S. Reconciliation Procedures**”). Such procedures will take into account the ability of each Party to comply with its own financial reporting requirements.

(b) The U.S. Reconciliation Procedures shall provide that within [...***...] after the end of each Calendar Quarter, each Party shall submit to the JFC a report, in such reasonable detail and format as is established by the JFC, of all Net Sales and Allowable Expenses and other amounts necessary to calculate U.S. Collaboration Results, the royalty due by Janssen to argenx in accordance with Section 8.5.1, the amount of Allowable Expenses to be invoiced by argenx to any of its Affiliates in accordance with Section 8.5.2(d) and any royalty rebate due by argenx to Janssen in accordance with Section 8.5.2(d). Within [...***...] following the receipt of such report, each Party shall have the right to request reasonable additional information (as determined by the JFC) necessary to permit calculation and reconciliation of the U.S. Collaboration Results for the applicable Calendar Quarter, and to confirm that Allowable Expenses are in conformance with the approved U.S. Commercialization Budget.

(c) The U.S. Reconciliation Procedures shall provide for the JFC to develop a written report setting forth the calculation of U.S. Collaboration Results for the applicable Calendar Quarter, royalties owed by Janssen to argenx, Allowable Expenses to be invoiced by argenx or by any of its Affiliates, and the calculation of any negative U.S. Collaboration Results, and to prepare such report promptly following delivery of the reports from the Parties as described above in this Section and in a reasonable time (to be defined in the U.S. Reconciliation Procedures) in advance of applicable payments in accordance with Sections 8.5.1 and 8.5.2 for the applicable Calendar Quarter.

(d) In the event of negative U.S. Collaboration Results for a particular Calendar Quarter, argenx shall pay to Janssen a royalty rebate in an amount that will divide the negative U.S. Collaboration Results 50-50 resulting from the Net Sales, Other Income and the Allowable Expenses (all as defined in the Financial Exhibit) between Janssen and argenx. This reconciliation process shall occur on a quarterly basis in accordance with Section 8.5.2(b) and the Financial Exhibit. Any Allowable Expenses, as defined in the Financial Exhibit, incurred by argenx or any of its Affiliates, shall be invoiced by argenx or any of its Affiliates, depending on the case, to Janssen or its designated Affiliate for an amount equal to the aggregate of the amount of the Allowable Expenses and a profit margin. The profit margin will be determined by argenx or any of its Affiliates, depending on the case, at its discretion in accordance with its transfer pricing policy. Any such amount charged by argenx or any of its Affiliates shall be deducted from the royalty to be paid by Janssen or its designated Affiliate to argenx in accordance with Section 8.5.1 or shall be added to the royalty rebate to be paid by argenx to Janssen in accordance with this Section. Any such amount charged by argenx or any of its Affiliates,

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

excluding the profit margin, will remain to be considered an Allowable Expense for determining the U.S. Collaboration Results.

(e) Payments in accordance with Sections 8.5.1 and 8.5.2 shall be paid by the relevant Party within [...***...] after the end of each Calendar Quarter.

8.6 OUS Territory Royalties.

8.6.1 Royalty Rates. In partial consideration of the licenses granted by argenx to Janssen in accordance with Section 3.1 of this Agreement, Janssen shall pay to argenx royalties on the aggregate Net Sales of Licensed Products by Janssen, its Affiliates and sublicensees in the OUS Territory during each Calendar Year at the rates set forth in the table below. For clarity, Net Sales of all Licensed Products that contain a given Licensed Compound shall be aggregated for purposes of calculation of royalties pursuant to this Section 8.6; *provided, however*, that Net Sales of a particular Licensed Product in a particular country occurring after expiration of the Royalty Term for such Licensed Product in such country shall be disregarded in the calculation of royalties pursuant to this Section 8.6.

Annual Aggregate Net Sales of Licensed Products in the OUS Territory	Royalty Rate
For that portion of annual Net Sales of Licensed Products in the OUS Territory in such Calendar Year less than [...***...]	[...***...]%
For that portion of annual Net Sales of Licensed Products in the OUS Territory in such Calendar Year greater than or equal to [...***...] and less than [...***...]	[...***...]%
For that portion of annual Net Sales of Licensed Products in the OUS Territory in such Calendar Year greater than or equal to [...***...] and less than [...***...]	[...***...]%
For that portion of annual Net Sales of Licensed Products in the OUS Territory in such Calendar Year greater than or equal to [...***...] and less than [...***...]	[...***...]%
For that portion of annual Net Sales of Licensed Products in the OUS Territory in such Calendar Year greater than or equal to [...***...]	[...***...]%

By way of example, if annual Net Sales of Licensed Products in the OUS Territory during such Calendar Year were [...***...], the royalties due with respect to such Licensed Product would equal the sum of [...***...].

8.6.2 Royalty Reductions.

(a) Subject to Section 8.6.2(c), in the event that Janssen (or its Affiliate or Sublicensee, as applicable) is required to obtain one or more licenses under issued

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

patents of any Third Party (other than a Sublicensee) reasonably necessary for the manufacture, use or sale of a Licensed Product in a country in the OUS Territory (each, a “**OUS Third Party License**”), Janssen shall have the right to deduct [...] of the royalties actually paid to such Third Party(ies) under such OUS Third Party License(s) by Janssen (or by such Affiliate or Sublicensee, as applicable) with respect to sales of such Licensed Product in such country in the OUS Territory in a Calendar Quarter from the royalty payments payable by Janssen to argenx with respect to Net Sales of such Licensed Product in such country in such Calendar Quarter; provided, however, that [...***...].

(b) Subject to Section 8.6.2(c), on a country-by-country and Licensed Product-by-Licensed Product basis, the royalties due to argenx pursuant to Section 8.6.1 shall be reduced during the Royalty Term for a Licensed Product in a country to [...] of the amount otherwise payable from and after the later of (i) the date that there is no Valid Claim of (i) an argenx Patent Right or Joint Collaboration Patent Right in such country that Covers the composition of matter or any method of use of such Licensed Product or (ii) a Specified Manufacturing Patent Right in such country that Covers any method of manufacture of such Licensed Product or (ii) if any Regulatory Exclusivity is granted with respect to such Licensed Product in such country, the date on which all such Regulatory Exclusivity expires.

(c) Notwithstanding the foregoing, in no event shall the total deductions under Sections 8.6.2(a) and 8.6.2(b) reduce the royalties payable to argenx under Section 8.6.1 with respect to a given Licensed Product in a given country in any Calendar Quarter by more than [...] of the amount that would otherwise be payable if such deductions were not made; provided, however, that to the extent [...***...].

8.6.3 Royalty Term Expiration. Upon the expiration of the Royalty Term with respect to a Licensed Product in a country in the OUS Territory, argenx hereby grants to Janssen a perpetual, irrevocable, non-exclusive, fully-paid and royalty-free right and license, with the right to grant sublicenses, under the argenx Intellectual Property to use, Develop, have Developed, make, have made, Manufacture, sell, offer for sale, have sold, import, Commercialize and otherwise Exploit such Licensed Product in the Field in such country. For clarity, after the Royalty Term expires with respect to a Licensed Product in a country, the calculation of annual Net Sales of such Licensed Product in the OUS Territory shall exclude sales of such Licensed Product in such country.

8.6.4 Royalty Reports and Payments. Commencing with the First Commercial Sale of a Licensed Product by Janssen or its Affiliates or sublicensees in the OUS Territory, Janssen shall (a) within [...] after the end of each Calendar Quarter, deliver a preliminary written report to argenx stating, by Licensed Product, the estimated aggregate Net Sales in U.S. Dollars of Licensed Products sold in the OUS Territory during such Calendar Quarter by Janssen and its Affiliates and sublicensees, and (b) within [...] after the end of each Calendar Quarter, deliver a final written report to argenx stating, by Licensed Product and by region (which regions shall be [...***...]), the aggregate Net Sales in U.S. Dollars of Licensed Products sold in the OUS Territory during such Calendar Quarter by Janssen and its Affiliates and sublicensees. The final report shall also show (x) the calculation of the royalty payments due to argenx on such Net Sales (including aggregate gross amounts invoiced for such Licensed Product in such region during the reporting period), (y) the amount of taxes, if any, withheld to

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

comply with applicable Laws, and (z) the exchange rates used in calculating the payments due argenx. Simultaneously with the delivery of each such final report, Janssen shall pay to argenx the total royalties, if any, due to argenx for the period of such report. If no royalties or Sales Milestone Payments are due, Janssen shall so report. All preliminary and final reports delivered by Janssen under this Section shall be Confidential Information of Janssen, save that, to the extent argenx is obliged to share information contained in such preliminary and final reports with any counterparty to a Royalty-Bearing Agreement, it may disclose such reports to such counterparty, subject to the applicable confidentiality provisions of such Royalty-Bearing Agreement.

8.6.5 Royalty Conditions. All royalties due to argenx pursuant to Section 8.6.1 are subject to the following conditions: (a) only one royalty shall be due with respect to the same unit of Licensed Product; (b) no royalties shall be due upon the sale or other transfer among Janssen or its Affiliates, but in such cases the royalty shall be due and calculated upon Janssen's or its Affiliate's Net Sales to the first independent Third Party, and Distributors of Janssen selling Licensed Product will not, for this purpose, be deemed to be sublicensees of Janssen and shall instead be considered as independent Third Parties; and (c) no royalties shall be due upon free samples, donations, patient assistance, test marketing programs or other similar programs or studies.

8.7 Third Party Patent Rights.

8.7.1 If, during the Term, a Party determines, in its reasonable judgment, that it is necessary to obtain rights under any Patent Rights Controlled by a Third Party in order to Exploit a Licensed Compound or Licensed Product in accordance with this Agreement, such Party shall promptly notify the other Party. The Parties shall then discuss whether to obtain rights under such Patent Rights. Upon request of either Party, the Parties shall seek the advice of mutually agreed joint patent counsel and reasonably take into account such counsel's opinion. In the event that the Parties do not agree, then Janssen shall have final decision-making authority.

8.7.2 If the Parties determine, or the Parties do not agree and Janssen determines, that it is necessary to obtain a license under any Patent Rights Controlled by a Third Party to Exploit a Licensed Compound or Licensed Product in accordance with this Agreement, Janssen shall have the right to enter into a license agreement with the applicable Third Party to obtain a license under such Patent Rights from the relevant Third Party to Exploit a Licensed Compound or Licensed Product (a "**New Third Party License**"), which New Third Party License shall be sublicenseable to argenx to the extent necessary to grant argenx the licenses set forth in Section 3.2 or Section 13.6.2.

8.7.3 Milestone payments and royalties actually paid under a New Third Party License shall be borne as follows:

(a) such milestone payments and royalties shall be included as Development Costs, to the extent such payments are specifically attributable and allocable to Development of Licensed Compounds and Licensed Products pursuant to the GDP;

(b) such milestone payments and royalties shall be included as Allowable Expenses, to the extent specifically attributable and allocable to Commercialization of Licensed Compounds and Licensed Products in the U.S.; and

(c) such milestone payments and royalties shall be borne solely by Janssen (and not included as Development Costs or Allowable Expenses), to the extent specifically attributable and allocable to Commercialization of Licensed Compounds and Licensed Products in the OUS Territory, subject to Section 8.6.2(a).

Except as expressly set forth above in this Section 8.7.3, any and all payments to any Third Party with respect to the license or acquisition by Janssen or any of its Affiliates of Patent Rights or other intellectual property of any Third Party shall be borne solely by Janssen and not included as Development Costs or Allowable Expenses.

8.8 Existing Third Party Agreement Payments. Payments under the Existing Third Party Agreements incurred after the Execution Date (a) that are attributable and allocable to Commercialization of Licensed Compounds and Licensed Products in the OUS Territory undertaken in accordance with this Agreement shall be the sole responsibility of argenx and shall not be included as Development Costs or Allowable Expenses, (b) that are attributable and allocable to Development of Licensed Compounds and Licensed Products undertaken under the GDP in accordance with this Agreement shall be included as Development Costs and (c) that are attributable and allocable to Commercialization of Licensed Compounds and Licensed Products in the U.S. undertaken in accordance with this Agreement shall be included as Allowable Expenses except that, if in order to implement the CMC Plan, argenx is required to pay any royalties under the Lonza Manufacturing Agreement that exceed the royalties payable by argenx under the Lonza Manufacturing Agreement as of the Execution Date, such additional royalties shall be [...***...]. The JFC shall determine the manner in which Janssen will reimburse argenx for its [...***...] share of such additional royalties.

8.9 Audits.

8.9.1 Each Party shall keep, and cause its Affiliates and sublicensees to keep, complete and accurate records of the items underlying Development Costs, Allowable Expenses, Other Income, Net Sales, and the other elements required to prepare the reports or calculate payments required by Sections 8.4, 8.5 and 8.6 and the U.S. Reconciliation Procedures, and any other payments under this Agreement. Such records must be retained for a period of [...***...] following the relevant reporting period. Each Party will have the right at its own expense to have an independent, certified public accountant, selected by such Party and reasonably acceptable to the other Party, review any such records of the other Party and its Affiliates in the location(s) where such records are maintained by the other Party or its Affiliates upon [...***...] prior written notice and during normal business hours and under obligations of confidence, for the sole purpose of verifying the basis and accuracy of payments made under Sections 8.4, 8.5 and 8.6, and any other payments due under this Agreement, within the prior [...***...] period. Audits may not be conducted by a Party under this Section more than [...***...], and an audit of the records relating to a particular Calendar Year may be conducted not more than once. To the extent that any Royalty-Bearing Agreement obligates argenx to maintain records for a longer period, or provides any Royalty-Bearing Agreement counterparty with the right to conduct audits for a

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

longer period after the Term or with respect to records extending further in the past, than set forth in this Section 8.9.1, then the terms of such Royalty-Bearing Agreement shall take precedence over the terms of this Section 8.9.1, provided that any records of Janssen that are subject to audit pursuant to any Royalty-Bearing Agreement shall be subject to the applicable confidentiality provisions of such Royalty-Bearing Agreement.

8.9.2 The report of the independent certified public accountant shall be shared with the audited Party before distribution to the auditing Party so that the audited Party can provide the independent public accountant with justifying remarks for inclusion in the report before sharing the conclusions of such independent public audit with the auditing Party. The final audit report will be shared with the auditing and audited Party at the same time and shall specify whether the amounts paid to the auditing Party during the audited period were correct or, if incorrect, the amount of any underpayment or overpayment. The audit report shall only contain the information relevant to support the statement as to whether the amounts due under this Agreement were calculated and paid accurately and shall not include any confidential (or additional information that is ordinarily not included in the reports to the auditing Party) disclosed to the auditor during the course of the audit. Where argenx is the auditing Party, argenx may disclose such conclusions of the independent public audit to all Royalty-Bearing Agreement counterparties, to the extent required under the relevant Royalty-Bearing Agreement, provided that such conclusions shall be subject to the applicable confidentiality provisions of such Royalty-Bearing Agreement.

8.9.3 If the review of such records reveals that the other Party has failed to accurately report information pursuant to Section 8.4, 8.5 or 8.6, or make any payment (or portion thereof) required under this Agreement, then the other Party shall pay, within [...***...] after receipt of the final audit report by the audited Party, to the auditing Party any underpaid amounts due under Section 8.4, 8.5 or 8.6, or otherwise due under this Agreement, together with interest calculated in the manner provided in Section 8.12. If any such discrepancies are an underpayment of amounts due under this Agreement greater than [...***...] of the amounts actually due for any Calendar Year, the other Party shall pay all reasonable costs incurred in conducting such review. If any such discrepancies are an overpayment of amounts due under this Agreement greater than [...***...] of the amounts actually due for any Calendar Year, the other Party shall pay all reasonable costs incurred in conducting such review. If the audited Party disagrees with the findings of the audit report, the Parties will first seek to resolve the matter between themselves, and in the event they fail to reach agreement, the dispute resolution provisions set forth in Article XV shall apply.

8.10 Tax Matters.

8.10.1 Each Party will make all payments to each other under this Agreement without deduction or withholding for Taxes except to the extent that any such deduction or withholding is required by Law in effect at the time of payment.

8.10.2 Any Tax required to be withheld on amounts payable under this Agreement will promptly be paid by the Party making the payment (the “**Payor**”) on behalf of the Party receiving the payment (the “**Payee**”) to the appropriate Governmental Authority, and Payor will furnish Payee with proof of payment of such Tax. Any such Tax, to the extent

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

withheld and paid to the appropriate Governmental Authority, shall be treated for all purposes of this Agreement as having been paid to the Payee. Any such Tax required to be withheld will be an expense of and borne by Payee.

8.10.3 The Parties will cooperate with respect to all documentation required by any taxing authority or reasonably requested by either Party to secure a reduction in the rate of applicable withholding Taxes. If the withholding tax rate is reduced according to the provisions of an applicable double tax treaty or regulations applicable thereto, no deduction or withholding shall be made (or a reduced amount shall be deducted or withheld), in each case as applicable, only if the Payor is timely furnished with necessary documents or certification by the Payee issued by the tax authority certifying that the payment is exempt from tax or subject to a reduced tax rate or the Payee otherwise satisfies the requirements to obtain the treaty benefit in question.

8.10.4 If Payor had a duty to withhold Taxes in connection with any payment it made to Payee under this Agreement but Payor failed to withhold, and such Taxes were assessed against and paid by Payor, then Payee will indemnify and hold harmless Payor from and against such Taxes, except to the extent such Taxes resulted from Payor's negligent failure to withhold; provided, however, that Payor shall only be responsible for such Taxes to the extent such Taxes do not exceed the amount of Tax that Payor would have withheld if it had received from Payee the documentation necessary to secure any available reduction in the rate of applicable Taxes. If Payor makes a claim under this Section 8.10.4, it will comply with the obligations imposed by Section 8.10.1 as if Payor had withheld Taxes from a payment to Payee.

8.10.5 [...***...]. All Tax Returns reflecting any such amounts shall be filed in a manner consistent with the foregoing.

8.10.6 "Tax" or "Taxes" means any present or future taxes, levies, imposts, duties, charges, withholdings, assessments or fees imposed in the nature of a tax (including penalties and additions to tax and interest thereon). "Tax Return" shall mean any return, report, declaration or similar document filed or required to be filed with any Governmental Authority relating to Taxes.

8.11 Currency Exchange.

8.11.1 Currency of Payments. All payments under this Agreement shall be paid in U.S. Dollars by wire transfer to an account designated by the receiving Party (which account the receiving Party may update from time to time in writing).

8.11.2 Currency Conversion. If any amounts that are relevant to the determination of amounts to be paid under this Agreement or any calculations to be performed under this Agreement are received or paid initially reported in a currency other than U.S. Dollars, then such amounts shall be converted to their U.S. Dollar equivalent as follows:

(a) Janssen will notify argenx in writing of Johnson & Johnson's Currency Hedge Rate for a given Calendar Year in advance of such Calendar Year, within [...***...] after the Currency Hedge Rate(s) are available [...***...].

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

(b) Then: (i) the Currency Hedge Rate(s) as provided in the notice to argenx will remain constant throughout the applicable Calendar Year; and (ii) Janssen shall use such Currency Hedge Rate(s) to convert non-U.S. Dollar amounts to U.S. Dollars for the purpose of calculating U.S. Collaboration Results or royalties and the achievement of Sales Milestone Events for, and Development Costs incurred during, each Calendar Quarter in the applicable Calendar Year.

8.12 Late Payments. If either Janssen or argenx shall fail to make a timely payment pursuant to Section 8.2, 8.3, 8.4, 8.5, 8.6 or any other provision of this Agreement, any such payment that is not paid on or before the date such payment is due under this Agreement shall bear interest at a rate per annum equal to [...***...] or a comparable reference interbank rate per currency or the maximum rate allowable by applicable Law, whichever is lower.

ARTICLE IX

INTELLECTUAL PROPERTY OWNERSHIP, PROTECTION AND RELATED MATTERS

As applicable to any argenx Patent Rights that are licensed to argenx pursuant to any Existing Third Party Agreement, the provisions of this Article IX shall be subject to the terms and conditions of such Existing Third Party Agreement.

9.1 Reporting of Collaboration Inventions; Ownership and Disclosure.

9.1.1 Reporting. Each Party shall designate a patent attorney or agent as its contact to coordinate with the other Party the filing, prosecution and maintenance of Patent Rights as provided in this Article IX (the “**Patent Representative**”). Each Party shall promptly report to the other Party’s Patent Representative any material Collaboration Invention.

9.1.2 Ownership. Each Party shall solely own any Collaboration Know-How that is an invention (a “**Collaboration Invention**”) that is invented solely by an employee, agent or consultant of such Party or any of its Affiliates (a “**Sole Collaboration Invention**”), and any Patent Rights Covering its Sole Collaboration Inventions. The Parties shall jointly own any Collaboration Invention for which the inventors include at least one employee, agent or consultant of argenx or any of its Affiliates and at least one employee, agent or consultant of Janssen or any of its Affiliates (a “**Joint Collaboration Invention**”), and any Patent Rights Covering a Joint Collaboration Invention (the “**Joint Collaboration Patent Rights**”). Inventorship shall be determined in accordance with U.S. patent laws. Any dispute regarding inventorship shall be subject to the dispute resolution procedure set out in Section 14.

9.1.3 Assignment. Each Party hereby assigns, and shall cause its Affiliates and their respective employees, agents and consultants to assign, to the other Party, an undivided one-half (1/2) ownership interest in and to the Joint Collaboration Inventions to effectuate the ownership set forth in Section 9.1.1.

9.1.4 Disclosure. Each Party shall promptly disclose to the other Party each Collaboration Invention invented by an employee, agent or consultant of such Party or any of its Affiliates. With respect to any Collaboration Invention disclosed by argenx, argenx shall promptly disclose to Janssen any invention disclosures, or other similar documents, submitted to

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

it by its employees, agents or consultants describing such Collaboration Invention, and all Know-How relating to such Collaboration Invention to the extent necessary for the preparation, filing and maintenance of Patent Rights Covering such Collaboration Invention pursuant to Section 9.2. With respect to any Collaboration Invention disclosed by Janssen, Janssen shall promptly disclose to argenx any invention disclosures, or other similar documents, submitted to it by its employees, agents or consultants describing such Collaboration Invention, and all Know-How relating to such Collaboration Invention to the extent necessary for the preparation, filing and maintenance of Patent Rights Covering such Collaboration Invention pursuant to Section 9.2. Any invention disclosure, or other similar document, relating to any Collaboration Invention disclosed by one Party to the other Party pursuant to this Section 9.1.4 shall be the Confidential Information of the Party providing such information, except that any invention disclosure or other similar document relating to any Joint Collaboration Invention shall be the joint Confidential Information of both Parties.

9.1.5 Right to Practice Joint Collaboration Intellectual Property. Except to the extent either Party is restricted by the express terms of this Agreement, with respect to Joint Collaboration Intellectual Property, each Party shall have the right to practice and exploit such Joint Collaboration Intellectual Property with full rights to license its interest therein in the Territory and without the duty of accounting to or any duty to seek consent from the other Party, and upon the reasonable request of either Party, the other Party shall execute documents that evidence and confirm the requesting Party's right to engage in such activities. Each Party shall promptly notify the other Party following the grant by it of any license under the Joint Collaboration Intellectual Property to any Affiliate or Third Party.

9.1.6 Inventor Remuneration. Each Party shall be solely responsible for providing to its workers and agents, all wages, compensations, awards, remunerations and benefits that are required under Law (in any and all relevant jurisdictions), including all inventor award and remuneration. Other than the compensation specifically and expressly stated in this Agreement, neither Party and its workers and agents will receive from the other Party or its Affiliates any further payment related to employee or agents regarding the other Party's rights and the exercise thereof in intellectual property arising from this Agreement regardless of what action the concerned Party elects to take regarding such intellectual property, including the filing of patent applications, granting of patents, and commercialization of patented inventions.

9.2 Prosecution and Maintenance of Patent Rights.

9.2.1 Each Party shall use reasonable efforts to handle all communications between the Parties under this Section 9.2 through their Patent Representatives and keep such communications in strict confidence to protect their attorney-client privileged status.

9.2.2 argenx shall have the first right to prepare, file, prosecute and maintain the argenx Patent Rights that are Sole Collaboration Inventions on a worldwide basis, using outside counsel selected by argenx and acceptable to Janssen. argenx shall provide Janssen with a reasonable opportunity to review and comment on its efforts to prepare, file, prosecute and maintain argenx Patent Rights, including by providing Janssen with a copy of material communications from any patent authority regarding any argenx Patent Right, and by providing drafts of any material filings or responses to be made in advance of submitting such filings or

responses. argenx shall consider Janssen's comments regarding such communications and drafts in good faith. If argenx determines, in its sole discretion, to abandon or not maintain any argenx Patent Right in any country, then argenx shall provide Janssen with written notice of such determination within a period of time sufficiently in advance to enable Janssen to determine whether it will assume responsibility for such argenx Patent Right (which notice shall be given no later than [...***...] prior to any final deadline for any pending action or response that may be due with respect to such argenx Patent Right with the applicable patent authority). If Janssen provides written notice to argenx that it will assume responsibility for such argenx Patent Right, argenx shall transfer such responsibility to Janssen and shall execute any documents necessary to complete such transfer. Upon completion of such transfer, Janssen shall have the right to prepare, file, prosecute and maintain such Patent Right at its sole expense (which shall not be shared by the Parties as Allowable Expenses) and such Patent Right shall no longer be included in the argenx Patent Rights.

9.2.3 Janssen shall have the sole right and authority to prepare, file, prosecute and maintain the Janssen Patent Rights that Cover Sole Collaboration Inventions and the Joint Collaboration Patent Rights on a worldwide basis. Janssen shall keep argenx reasonably informed regarding the filing, prosecution and maintenance of such Janssen Patent Rights and the Joint Collaboration Patent Rights.

9.2.4 The Out-of-Pocket Costs incurred by argenx or Janssen or their Affiliates in preparing, filing, prosecuting and maintaining the argenx Patent Rights, the Janssen Patent Rights or Joint Collaboration Patent Rights shall be borne by the Party incurring such expense.

9.2.5 Each Party shall provide the other Party with all reasonable assistance and cooperation in preparing, filing, prosecuting and maintaining Patent Rights pursuant to this Section 9.2, including providing any necessary powers of attorney and executing any other required documents or instruments, as well as further actions as set forth below. Such assistance and cooperation shall include making a Party's inventors and other scientific advisors reasonably available to assist the other Party's efforts to prepare, file, prosecute and maintain Patent Rights pursuant to this Section 9.2.

9.2.6 All communications between the Parties relating to the preparation, filing, prosecution or maintenance of Patent Rights pursuant to this Section 9.2, including copies of any draft or final documents or any communications received from or sent to patent offices or patenting authorities with respect to such Patents, shall be considered Confidential Information of the Party Controlling the relevant Patent and subject to the confidentiality provisions of Article X.

9.2.7 Each Party shall take all reasonable actions requested by the other Party responsible for preparing, filing, prosecuting or maintaining Patent Rights pursuant to this Section 9.2 to perfect or separately document the other Party's ownership interest rights in such Patent Right as provided for in this Agreement, including by causing its and its applicable Affiliates' employees, agents and consultants to execute appropriate assignment documents. The requesting Party shall not be required to pay any remuneration to the other Party or its Affiliates, or any of their employees, agents or consultants, for the execution of any assignments or other papers pursuant to this Section. Each Party shall be solely responsible for any compensation due

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

to its and its Affiliates' employees, agents and consultants for (i) the assignment of their respective rights to any Collaboration Inventions and associated Patent Rights pursuant to this Agreement or (ii) the Exploitation of any such Collaboration Inventions or associated Patent Rights by any Party or its Affiliates pursuant to this Agreement, including any required by operation of applicable Law.

9.3 Patent Term Extensions. The JSC shall discuss and agree the strategy for applying for the extension of the term of any argenx Patent Right, Joint Collaboration Patent Right or Janssen Patent Right, such as under the Hatch-Waxman Act, the Supplementary Certificate of Protection of the Member States of the European Union and other similar measures in any other country. If the JSC is unable to agree on such strategy, the matter shall be referred for resolution by the Executive Officers in accordance with Section 15.2. If the Executive Officers are unable to resolve the matter, Janssen shall have the final decision making authority regarding such strategy. Janssen shall apply for and use its reasonable efforts to obtain such an extension, and argenx hereby grants permission to Janssen to do so (and argenx agrees to cooperate with Janssen or its sublicensee, as applicable, in the exercise of such authorization and shall execute such documents and take such additional action as Janssen may reasonably request in connection therewith). Janssen and argenx agree to cooperate with one another in obtaining any patent extension hereunder as directed by the JSC.

9.4 Patent Certifications and Notice. The JSC shall discuss and agree the strategy with respect to certifications, notices and patent enforcement procedures under the Hatch-Waxman Act and the BPCIA. If the JSC is unable to agree on such strategy, the matter shall be referred for resolution by the Executive Officers in accordance with Section 15.2. If the Executive Officers are unable to resolve the matter, Janssen shall have the final decision making authority regarding such strategy. argenx shall cooperate, as reasonably requested by Janssen, in connection with the implementation of the strategy which is developed in accordance with this Section 9.4. argenx hereby authorizes Janssen to: (a) provide in any Drug Approval Application or in connection with the BPCIA, a list of patents which includes argenx Patent Rights and Joint Collaboration Patent Rights that relate to the Licensed Products and such other information as Janssen believes is appropriate; (b) except as otherwise provided in this Agreement, exercise any rights that may be exercisable by Janssen as patent owner under the Hatch-Waxman Act or the BPCIA; and (c) exercise any rights that may be exercisable by Janssen as reference product sponsor under the BPCIA, including, (i) providing a list of patents that relate to the Licensed Product, including argenx Patent Rights and Joint Collaboration Patent Rights, (ii) engaging in the patent resolution provisions of the BPCIA, and (iii) determining which patents will be the subject of immediate patent infringement action under Section 351(l)(6) of the BPCIA, provided that with respect to Janssen's exercise of rights under the BPCIA consistent with this Section 9.4, Janssen shall consult with a representative of argenx designated by argenx in writing and qualified to receive confidential information pursuant to Section 365(l) of the BPCIA with respect to Janssen's exercise of any rights exercisable as reference product sponsor including providing such representative with timely copies of material correspondence relating to such matters, providing such representative the opportunity, reasonably in advance of any related Janssen action, to comment thereon and to consult with and consider in good faith the requests and suggestions of argenx with respect to such matters.

9.5 Infringement of Patent Rights by Third Parties.

9.5.1 Notification. Each Party shall promptly notify the other Party in writing of any existing, alleged or threatened infringement of any argenx Patent Right, Joint Collaboration Patent Right or Janssen Patent Right of which it becomes aware, and shall provide copies of all material information in such Party's possession or control demonstrating such infringement.

9.5.2 Infringement of argenx Patent Rights or Joint Collaboration Patent Rights.

(a) Janssen, subject to Section 9.5.2(b) through 9.5.2(g), shall have the first right, but not the obligation, to bring an appropriate suit or other action against any Third Party engaged in any existing, alleged or threatened infringement of any argenx Patent Rights or Joint Collaboration Patent Rights with respect to any infringement or misappropriation that involves the Exploitation of an Anti-CD70 Antibody.

(b) Janssen shall notify argenx of its election to take any action in accordance with Section 9.5.2(a) within the earlier of: (i) [...***...] after the first notice under Section 9.5.2(a); or (ii) [...***...] before any time limit set forth in applicable Law or regulation, including the time limits set forth under the BPCIA. Notwithstanding the foregoing sentence, Janssen shall not initiate any such suit or take such other action with respect to any argenx Patent Right or Joint Collaboration Patent Right without first consulting with argenx and giving good faith consideration to any reasonable objection from argenx regarding Janssen's proposed course of action. argenx shall cooperate in the prosecution of any suit under this Section 9.5.2 as may be reasonably requested by Janssen subject to reimbursement of argenx's reasonable costs and expenses. If Janssen elects not to initiate a lawsuit or take other reasonable action with respect to an infringement described in Section 9.5.2(a), argenx shall have the right, but not the obligation, to initiate such suit or take such other action, after providing [...***...] notice to Janssen and giving good faith consideration to Janssen's reason(s) for not initiating a suit or taking other action.

(c) If one Party elects to bring suit or take action under Section 9.5.2(b) against an infringement, then the other Party shall have the right, prior to commencement of the suit or action, to join any such suit or action at its own cost and expense.

(d) Each Party shall provide to the Party enforcing any such rights under Section 9.5.2(b) reasonable assistance in such enforcement, at such enforcing Party's request and expense, including joining such action as a party plaintiff if required by applicable Law to pursue such action. The enforcing Party shall keep the other Party regularly informed of the status and progress of such enforcement efforts, shall reasonably consider the other Party's comments on any such efforts, and shall consult the other Party in any important aspects of such enforcement, including determination of material litigation strategy and filing of important papers to the competent court.

(e) Each Party shall bear all of its own internal costs incurred in connection with its activities under this Section 9.5.2. In the event that the Parties are joined in suit or action against the infringement or the non-enforcing Party elects to join such suit or action

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

and, in either case, elects to be represented by the same outside counsel as the enforcing Party, then the enforcing Party shall be responsible for all expenses arising from such outside counsel, provided that the enforcing Party consents to such joint representation by outside counsel, such consent not to be unreasonably withheld, delayed or conditioned.

(f) The Party not bringing an action with respect to infringement under this Section 9.5.2 shall be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but such Party shall at all times cooperate fully with the Party bringing such action.

(g) Neither Party shall settle any claim, suit or action that it brought under this Section 9.5.2 involving argenx Patent Rights or Joint Collaboration Patent Rights without the prior written consent of the other Party, such consent not to be unreasonably withheld, delayed or conditioned.

9.5.3 Infringement of Janssen Patent Rights. For any and all infringement of any Janssen Patent Right, Janssen shall have the sole and exclusive right, but not the obligation, to bring, at Janssen's expense and in its sole control, an appropriate suit or other action against any person or entity engaged in such infringement of the Janssen Patent Right.

9.5.4 Allocation of Proceeds. If either Party recovers monetary damages from any Third Party in a suit or action brought under Section 9.5.2(b) or any royalties, milestones or other payments from a license agreement with a Third Party related to any alleged infringement related to a Licensed Product, whether such damages or royalties result from the infringement of argenx Patent Rights, Joint Collaboration Patent Rights or Janssen Patent Rights, such recovery ("**Infringement Recovery**") shall be allocated first to the reimbursement of any expenses incurred by each of the Parties in such litigation, action or license negotiations, and any remaining amounts shall be allocated as follows:

(a) with respect to suits or actions brought by Janssen resulting in an Infringement Recovery relating to a Licensed Product in the U.S., [...***...] to Janssen and [...***...] to argenx;

(b) with respect to suits or actions brought by Janssen resulting in an Infringement Recovery relating to a Licensed Product in the OUS Territory, then [...***...]; and

(c) with respect to suits or actions brought by argenx, the Infringement Recovery shall be retained by argenx.

9.6 Infringement of Third Party Rights.

9.6.1 Notification. If any Licensed Product used or sold by either Party, its Affiliates or Sublicensees becomes the subject of a Third Party's claim or assertion of infringement of a Patent Right granted by a jurisdiction, the Party first having notice of the claim or assertion shall promptly notify the other Party.

9.6.2 Defense. Janssen shall have the first right, but not the obligation, to defend any such Third Party claim or assertion of infringement of a Patent Right as described in

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

Section 8.6.1, at Janssen's expense. If Janssen does not commence actions to defend such claim within [...***...] after it receives notice thereof (or within [...***...] after it should have given notice thereof to argenx as required by Section 8.6.1), then, to the extent allowed by applicable Law, argenx shall have the right, but not the obligation, to control the defense of such claim by counsel of its choice, at argenx's expense. The non-defending Party shall reasonably cooperate with the Party conducting the defense of the claim or assertion, including if required to conduct such defense, furnishing a power of attorney.

9.6.3 Settlement; Licenses. Neither Party shall enter into any settlement of any claim described in this Section 9.6 that detrimentally affects the other Party's material rights or interests without the other Party's prior written consent, such consent not to be unreasonably withheld, delayed or conditioned. Each Party shall have the right to decline to defend or to tender defense of any claim described in this Section 9.6 upon reasonable notice to the other Party, including if the other Party fails to agree to a settlement that the declining Party proposes. If it is determined by any court of competent jurisdiction that the Development, Manufacture, Commercialization or other Exploitation of a Licensed Product pursuant to this Agreement infringes any Patent Right, copyright, trademark, data exclusivity right or trade secret right of any Third Party, then: (i) Janssen shall use Diligent Efforts to procure a license on reasonable terms from such Third Party authorizing the Parties to continue to conduct such activities; or (ii) the Parties shall modify such activities so as to render the activities non-infringing. Any payments or expenses pursuant to a license or settlement under this Section 9.6 shall be governed by the provisions of Section 8.7 hereof.

9.7 Patent Challenges.

9.7.1 Third Party Patent Rights. If either Party desires to bring an opposition, action for declaratory judgment, nullity action, interference, declaration for non-infringement, reexamination or other attack upon the validity, title or enforceability of a Patent Right owned or controlled by a Third Party and having one or more claims that Cover a Licensed Product, or the use, sale, offer for sale or importation of a Licensed Product (except insofar as such action is a counterclaim to or defense of, or accompanies a defense of, a Third Party's claim or assertion of infringement under Section 9.6, in which case the provisions of Section 9.6 shall govern), such Party shall so notify the other Party and the Parties shall promptly confer to determine whether to bring such action or the manner in which to settle such action. Janssen shall have the exclusive right, but not the obligation, to bring, at its own expense and in its sole control, such action. If Janssen does not bring such an action within [...***...] of notification thereof pursuant to this Section 9.7.1 (or earlier, if required by the nature of the proceeding), then argenx shall have the right, but not the obligation, to bring such action, at argenx's own expense. The Party not bringing an action under this Section 9.7.1 shall be entitled to separate representation in such proceeding by counsel of its own choice and at its own expense, and shall cooperate fully with the Party bringing such action. Any awards or amounts received in bringing any such action shall be first allocated to reimburse the initiating Party's expenses in such action, and any remaining amounts shall be allocated between the Parties as provided in Section 9.5.4.

9.7.2 Parties' Patent Rights. If any argenx Patent Right or Joint Collaboration Patent Right becomes the subject of any proceeding commenced by a Third Party in connection with an opposition, reexamination request, action for declaratory judgment, nullity action,

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

interference or other attack upon the validity, title or enforceability thereof (a “**Third Party Patent Challenge**”) (except insofar as such action is a counterclaim to or defense of, or accompanies a defense of, an action for infringement against a Third Party pursuant to Section 9.6, in which case the provisions of Section 9.6 shall govern), then the Party responsible for filing, preparing, prosecuting and maintaining such Patent Right as set forth in Section 9.2 shall control such defense at its own expense. The controlling Party shall permit the non-controlling Party to participate in the proceeding to the extent permissible under applicable Law, and to be represented by its own counsel in such proceeding, at the non-controlling Party’s expense. If either Party decides that it does not wish to defend against such action, then the other Party shall have a backup right to assume defense of such Third Party action at its own expense. Any awards or amounts received in defending any such Third Party action shall be allocated between the Parties as provided in Section 9.5.4. Janssen shall have the sole discretion whether to defend and shall solely control any defense of a Janssen Patent Right which is the subject of a Third Party Patent Challenge.

9.8 Trademarks.

9.8.1 Product Trademarks. Janssen will develop proposed names for Product Trademarks with appropriate subcontractors and will determine the ability to use the proposed Product Trademarks through legal searches. The costs of the development and searching/clearance process of the proposed Product Trademarks shall be included as Allowable Expenses. Janssen shall select all Product Trademarks, having considered any comments from argenx. Janssen will own all right, title and interest in and to the Product Trademarks. Neither Party will, and will ensure that its Affiliates do not: (i) challenge any Product Trademark or the registration thereof in any country (other than based upon a trademark filed or used by argenx or Janssen prior to knowledge of the Product Trademark); (ii) file, register or maintain any registrations for any trademarks or trade names that are confusingly similar to any Product Trademark (other than for a Product), in any country without the express prior written consent of the other Party; or (iii) authorize or assist any Third Party to do the foregoing. Janssen shall also be responsible for registering and maintaining all Product Domain Names and Websites and shall own all rights, title and interest in such Product Domain Names and Websites. Janssen will provide updates to the JSC as reasonably requested by argenx on the activities undertaken by Janssen and its Affiliates pursuant to this Section 9.8.1.

9.8.2 Prosecution and Maintenance. Janssen shall be responsible for prosecution and maintenance of all Product Trademarks pertaining to the Product and for registering and maintaining all Product Domain Names and Websites. If Janssen determines, in its sole discretion, to abandon or not maintain any Product Trademark in any country, then Janssen shall provide argenx with written notice of such determination within a period of time sufficiently in advance to enable argenx to determine whether it will assume responsibility for such Product Trademark (which notice shall be given no later than [...***...] prior to any final deadline for any pending action or response that may be due with respect to such Product Trademark with the applicable trademark authority). If argenx provides written notice to Janssen that it will assume responsibility for such Product Trademark, Janssen shall transfer such responsibility to argenx and shall execute any documents necessary to complete such transfer. The costs of prosecution and maintenance of Product Trademarks pertaining to the

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

Product and registration and maintenance of Product Domain Names and Websites in the U.S. only shall be included as Allowable Expenses.

9.8.3 Coordination Regarding Product Trademarks. The JSC shall discuss and agree on an overall strategy pertaining to the Product Trademarks and related marks and activities. If the JSC is unable to agree on such strategy, the matter may be referred for resolution by the Executive Officers in accordance with Section 2.8.1(d). If the Executive Officers are unable to resolve the matter, Janssen shall have the final decision making authority regarding such strategy. Janssen will provide updates to the JSC as reasonably requested by argenx regarding filing and material issues pertaining to Product Trademarks.

9.8.4 Required Use and Compliance.

(a) Each Party may only use the other Party's Housemarks and the Product Trademarks solely to carry out their respective obligations under this Agreement.

(b) Each Party agrees that it and its Affiliates will: (i) ensure that each use of the Product Trademarks and the other Party's Housemarks by such Party is accompanied by an acknowledgement that the Product Trademarks and/or Housemarks are owned by the other Party (i.e. the use by one Party of the other Party's Housemark shall indicate that such Housemark is used under license); (ii) not use the Product Trademarks or the other Party's Housemarks in a way that might materially prejudice their distinctiveness or validity or the goodwill of the other Party therein and includes the trademark registration symbol ® or TM as appropriate; and (iii) not use any trademarks or trade names so resembling any of the Product Trademarks or the other Party's Housemarks as to be likely to cause confusion or deception; and (iv) use the other Party's Housemarks in accordance with that Party's reasonable quality standards as notified in writing from time to time.

9.8.5 Housemark Licenses.

(a) *To Janssen.* argenx hereby grants to Janssen a non-exclusive, royalty-free license to use the argenx Housemarks solely as set forth in the promotional materials for the Licensed Products and other materials provided to it by argenx, and solely to Develop, Manufacture and Commercialize Licensed Products in accordance with this Agreement.

(b) *To argenx.* Janssen hereby grants to argenx a non-exclusive, royalty-free license to use the Janssen Housemarks solely as set forth in the promotional materials for the Licensed Products and other materials provided to it by Janssen, and solely to Develop, Manufacture and Commercialize Licensed Products in accordance with this Agreement.

9.8.6 Respect of Trademarks. Janssen will not have, assert or acquire any right, title or interest in or to any argenx Housemarks or the goodwill pertaining thereto, and argenx will not have, assert or acquire any right, title or interest in or to any Janssen Housemarks or the goodwill pertaining thereto, in each case by means of entering into or performing under this Agreement, except in each case for the limited licenses explicitly provided in this Agreement. All use by a Party of the Housemarks of the other Party shall inure to the benefit of such other Party.

9.8.7 Trademark Infringement.

(a) Each Party will monitor the Product Trademarks in the U.S. and Janssen will monitor the Product Trademarks in the OUS Territory against infringing uses relating to the Product. Each Party will promptly notify the other Party of any infringement or threatened infringement of any of the Product Trademarks of which it becomes aware. Each Party may use Third Party watch services, as necessary, to monitor filings for similar Third Party trademarks. Except to the extent that argenx has assumed responsibility for a Product Trademark in accordance with Section 9.8.2, Janssen shall defend the Product Trademarks in the U.S. and OUS Territory against oppositions, nullity or other legal actions filed by Third Parties and shall promptly undertake to oppose, nullify or take other appropriate action, where reasonable, against similar or identical Third Party trademarks filed for products or services related to those claimed by the Product Trademarks. Janssen will determine (after consultation with argenx and taking into account any reasonable suggestions made by argenx) what action, if any, to take in response to any such opposition, infringement or threatened infringement of any Product Trademark in accordance with this Section 9.8.7 and shall keep argenx informed as reasonably requested by argenx on the activities undertaken by it pursuant to this Section 9.8.7(a).

(b) Janssen shall be primarily responsible for protecting and maintaining the Product Trademarks, including all enforcement and defense thereof. Janssen will consult with argenx and take into account any reasonable suggestions made by argenx concerning what action to take to protect and maintain the Product Trademark and shall keep argenx informed as reasonably requested by argenx on the activities undertaken by it pursuant to this Section 9.8.7(b). argenx may, at its own expense, participate in any litigation relating to the enforcement or defense of any Product Trademark in a subordinate role and Janssen shall consider input on strategy and tactics offered by argenx. In the event Janssen fails to initiate a suit or take other commercially reasonable action to enforce or defend any Product Trademark within [...***...] after becoming aware of the basis for such suit or actions, then argenx may, in its discretion, provide Janssen with notice of its intent to initiate a suit or take other commercially reasonable action with respect to the enforcement and defense of the Product Trademark. If argenx provides such notice and Janssen fails to initiate a suit or take such other commercially reasonable action within [...***...] after receipt of such notice from argenx, then argenx shall have the right to initiate a suit or take other commercially reasonable actions that it believes are reasonably required to enforce and defend the Product Trademark. The non-enforcing Party may participate in any such action and be represented in any such action by its own counsel and at its own expense and the enforcing Party shall consider the input on strategy and tactics offered by the non-enforcing Party. The non-enforcing Party, shall at the enforcing Party's expense, provide all assistance reasonably requested by the enforcing Party in connection with the maintenance, enforcement and defense of the Product Trademarks.

9.8.8 Recording of License. If argenx considers it advisable to record argenx as a licensee or "registered user" of any of the Product Trademarks under local law, Janssen shall do all such acts and sign or have signed all such documents as are reasonably proper and necessary to secure such recordation and for any changes thereof in the future. In such event, argenx is responsible for recording this Agreement or a document reflecting this Agreement's contents with any applicable Governmental Authority and for all associated recordation fees and related costs and expenses. Upon termination of argenx's right to use a Product Trademark,

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

Janssen may at any time thereafter apply for cancellation of the record of argenx as a licensee upon written notice to argenx, and argenx consents to such cancellation.

9.8.9 Product Copyright Ownership. The Party that creates, or hires a third party to create on its behalf, a copyright work with respect to a Licensed Product will own all right, title, and interest in and to all such Copyrights.

ARTICLE X CONFIDENTIALITY AND PUBLICITY

10.1 Non-Disclosure and Non-Use.

10.1.1 During the Term and for a period of [...***...] thereafter, the Party (the “**Receiving Party**”) receiving or otherwise in possession of Confidential Information of the other Party (the “**Disclosing Party**”) shall: (a) maintain in confidence such Confidential Information using not less than the efforts such Receiving Party uses to maintain in confidence its own confidential or proprietary information of similar kind and value (but no less than reasonable efforts); (b) not disclose such Confidential Information to any Third Party without the prior written consent of the Disclosing Party, except for disclosures expressly permitted in Sections 10.3 and 10.4; and (c) not use such Confidential Information for any purpose except those permitted by this Agreement or the Investment Agreement or internal management and operations directly related to this Agreement (it being understood that this Article X shall not create or imply any rights or licenses not expressly granted under this Agreement).

10.1.2 “Confidential Information” shall mean all non-public or proprietary information disclosed orally, visually, in writing or other form by or on behalf of a Party (or an Affiliate or representative of such Party) to the other Party (or to an Affiliate or representative of such Party) pursuant to or in connection with this Agreement, whether prior to, on or after the Execution Date. All Data and Know-How generated by either Party in the performance of Development or U.S. Commercialization activities under this Agreement shall be deemed to be the Confidential Information of both Parties, regardless of whether such Data or Know-How is disclosed by one Party to the other Party. The term “Confidential Information” shall also include all notes, analyses, compilations, studies, interpretations, memoranda, reports or other documents (regardless of the form thereof) prepared by the Receiving Party (or by any Person to whom the Receiving Party has disclosed the Confidential Information pursuant to Section 10.3.1(f)) which contain, reflect, or are based upon, in whole or in part, any Confidential Information furnished to the Receiving Party.

10.2 Exceptions. The obligations in Section 10.1 shall not apply to the extent of any portion of the Confidential Information that the Receiving Party can show by competent written evidence:

(a) is publicly disclosed by the Disclosing Party, either before or after it is disclosed to the Receiving Party under this Agreement;

(b) was known to the Receiving Party or any of its Affiliates, without any obligation to the Disclosing Party to keep it confidential or any restriction on its use, before disclosure to the Receiving Party or any of its Affiliates by the Disclosing Party;

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

(c) is subsequently disclosed to the Receiving Party or any of its Affiliates on a non-confidential basis by a Third Party that, to the Receiving Party's knowledge after due inquiry, is not bound by a duty of confidentiality to the Disclosing Party or restriction on its use;

(d) is now, or hereafter becomes, through no act or failure to act on the part of the Receiving Party or any of its Affiliates in violation of this Agreement, generally known or available, either before or after it is disclosed to the Receiving Party by the Disclosing Party; or

(e) is independently discovered or developed by or on behalf of the Receiving Party or any of its Affiliates without the use of or reference to the Confidential Information of the Disclosing Party.

10.3 Authorized Disclosure. The Receiving Party may disclose Confidential Information of the Disclosing Party only to the extent such disclosure is reasonably necessary in the following instances, or to the extent permissible under the other applicable provisions of this Agreement or the Investment Agreement:

(a) filing, prosecuting, maintaining, enforcing or defending Patent Rights as permitted by this Agreement;

(b) as reasonably required in generating Regulatory Documentation and filing for and obtaining Regulatory Licenses as permitted by this Agreement;

(c) prosecuting or defending litigation, including responding to a subpoena in a Third Party litigation;

(d) subject to Section 10.4, complying with applicable Law (including regulations promulgated by securities exchanges) or court or administrative orders, including as a result of any actions taken by a Party not in violation of this Agreement or the Investment Agreement;

(e) complying with any obligation under this Agreement or the Investment Agreement;
or

(f) to its Affiliates and existing or prospective (sub)licensees, subcontractors, consultants, agents and advisors to the extent reasonably necessary for the Receiving Party to exercise its rights or fulfill its obligations under this Agreement or the Investment Agreement, each of whom before disclosure must be bound under a written agreement containing confidentiality provisions that are consistent with those set forth in this Agreement, provided that the Receiving Party shall remain responsible for any violation of such confidentiality provisions by any Person who receives Confidential Information pursuant to this Section 10.3.1(f).

If and whenever any Confidential Information is disclosed in accordance with this Section 10.3, such disclosure shall not cause any such information to cease to be Confidential Information for purposes of this Agreement, except to the extent that such disclosure results in a public

disclosure of such information (other than by breach of this Agreement). Notwithstanding the foregoing, in the event a Party intends to make a disclosure of the other Party's Confidential Information pursuant to Section 10.3.1(c) or Section 10.3.1(d), it will, except where impracticable or not legally permitted, give [...***...] advance notice (or, if [...***...] notice is not possible under the circumstances, reasonable advance notice) to the other Party of such disclosure and use not less than the same efforts to secure confidential treatment of such information as it would to protect its own confidential information from disclosure (but no less than reasonable efforts).

10.4 Confidential Terms. This Agreement and all of the respective terms of this Agreement shall be treated as Confidential Information of each Party. In addition to the disclosures permitted under Section 10.3, either Party may disclose the terms of this Agreement and other information relating to this Agreement or the transactions contemplated by this Agreement to the extent required, in the reasonable opinion of such Party's counsel, to comply with the rules and regulations promulgated by the United States Securities and Exchange Commission or the Nasdaq Stock Market or similar security regulatory authorities or stock market in other countries, including as a result of any actions taken by a Party not in violation of this Agreement. If a Party intends to disclose this Agreement or any of its terms or other such information in accordance with this Section 10.4, such Party will, except where impracticable or not legally permitted, give reasonable advance notice to the other Party of such disclosure and seek confidential treatment of portions of this Agreement or such terms or information, as may be reasonably requested by the other Party in a timely manner.

10.5 Publicity.

10.5.1 Initial Press Release. Each Party may, but is not obligated to, make a public announcement of the execution of this Agreement in the forms attached as Exhibits G and H to this Agreement, which shall be issued at a time to be mutually agreed by the Parties no later than [...***...] after the Execution Date.

10.5.2 Further Publicity. Except as required to comply with applicable Law or as permitted by Section 10.3, 10.4 or 10.5.1, if either Party intends to issue any press release or make other public statement disclosing any information relating to this Agreement, it shall give the other Party a reasonable opportunity to review and comment and shall consider any such comments in good faith. In addition, such Party shall not issue such press release or public statement without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed. If a Party intends to issue such a press release or other public statement as required to comply with applicable Law, such Party will, except where impracticable or not legally permitted, give reasonable advance notice to the other Party of such disclosure. Notwithstanding the foregoing, once information relating this Agreement has been publicly disclosed as permitted under this Agreement, neither Party shall be required to obtain the other Party's consent or provide notice of its further public disclosure, provided that such information remains accurate and not misleading in all material respects at the time of such further public disclosure.

10.6 Prior Non-Disclosure Agreement. As of the Execution Date, the terms of this Article X shall supersede that certain [...***...]. Any information disclosed pursuant to such

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

agreement that was deemed “Confidential Information” under such agreement shall be deemed Confidential Information under this Agreement.

10.7 Equitable Relief. Given the nature of the Confidential Information and the competitive damage that may result to a Party upon unauthorized disclosure, use or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages may not be a sufficient remedy for any breach of this Article X. In addition to all other remedies, a Party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this Article X.

10.8 Publications.

10.8.1 Global Publication Strategy. The JDC shall develop, and the JSC shall approve, a global publication strategy for the Development and Commercialization activities related to the Licensed Compounds and Licensed Products in the Field (the “**Global Publication Strategy**”). The publication and presentation of the results of Development carried out on the Licensed Compounds and Licensed Products in the Field shall be governed by the Global Publication Strategy, and the Parties shall conduct such publication activities in accordance with the Global Publication Strategy. In the event that the JSC does not reach consensus on a Global Publication Strategy, Section 2.8.1(b) shall not apply and, instead, either Party may refer such matter to the Executive Officers for resolution. If the Executive Officers do not reach consensus on such matter within [...***...] after such matter is referred to the Executive Officers, [...***...] shall have final decision-making authority.

10.8.2 Approval of Publications. Before publishing or presenting the results of any Development activities related to the Licensed Compounds or Licensed Products, each Party (the “**Publishing Party**”) shall provide to the other Party (the “**Reviewing Party**”) a copy of any proposed abstracts, manuscripts or summaries of presentations that such Publishing Party intends to publish or present (“**Proposed Publications**”). Each Party shall designate a Person or Persons who shall be responsible for reviewing (or having reviewed) all Proposed Publications submitted by the other Party. No later than [...***...] after receipt of any Proposed Publications (and no later than [...***...] in the case of an abstract or presentation summary) unless such Proposed Publication would disclose the Confidential Information of any counterparty to an Existing Academic Agreement, in which case such notice period shall be extended as required in order for argenx to comply, in full, with any publication provisions of such Existing Academic Agreements. A Reviewing Party’s designated Person shall notify the Publishing Party in writing whether the Reviewing Party has an objection to the Proposed Publications because the Reviewing Party, or any Existing Academic Agreement counterparty, reasonably believes it needs to seek patent protection. If a Reviewing Party notifies a Publishing Party of such an objection, the Publishing Party shall reasonably cooperate with the Reviewing Party to address such concern and shall delay publication in order to enable the preparation and filing of a patent application on any patentable subject matter described in the manuscript for [...***...], or such other longer period, as may be specified in the relevant Existing Academic Agreement; provided, however, that such delay shall not prejudice a Party’s timely prosecution and maintenance of its intellectual property rights under this Agreement. The Publishing Party shall reasonably consider any other suggestions of the Reviewing Party that are provided in a timely manner and, after doing so, may proceed with the Proposed Publication. With respect to any proposed

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

abstracts, manuscripts or summaries of presentations that investigators or other Third Parties propose to publish or present, such materials shall be subject to review under this Section. If it is determined by a counterparty to an Existing Academic Agreement that any proposed publication would involve the disclosure of its confidential information, the Publishing Party shall comply with any request to remove such confidential information from the proposed publication to avoid such disclosure. The Publishing Party shall appropriately acknowledge the contributions of the other Party and of any counterparties to the Existing Academic Agreements, and their employees, as may be proposed by the Reviewing Party. Notwithstanding the foregoing, argenx may publish the manuscript previously disclosed to Janssen.

ARTICLE XI

REPRESENTATIONS AND WARRANTIES; CERTAIN COVENANTS

11.1 Representations of Authority. argenx and Janssen each represents and warrants to the other Party that, as of the Execution Date, it has full right, power and authority to enter into this Agreement and to perform its respective obligations under this Agreement and that it has the right to grant to the other the licenses and sublicenses granted pursuant to this Agreement.

11.2 Consents. argenx and Janssen each represents and warrants to the other Party that, except for any Regulatory Licenses, pricing or reimbursement approvals, manufacturing approvals or similar approvals necessary for the Exploitation of the Licensed Compounds and Licensed Products, all necessary consents, approvals and authorizations of all government authorities and other persons required to be obtained by it as of the Execution Date in connection with the execution, delivery and performance of this Agreement (as contemplated as of the Execution Date) have been obtained by the Execution Date, except for those that would not, individually or in the aggregate, be reasonably expected to have a material adverse effect on the Exploitation of the Licensed Compounds and Licensed Products.

11.3 No Conflict. argenx and Janssen each represents and warrants to the other Party that, notwithstanding anything to the contrary in this Agreement, the execution and delivery of this Agreement by such Party, the performance of such Party's obligations under this Agreement (as contemplated as of the Execution Date) and the licenses and sublicenses to be granted by such Party pursuant to this Agreement (i) do not conflict with or violate with such Party's organizational documents or any requirement of Laws existing as of the Execution Date and applicable to such Party and (ii) do not conflict with, violate, breach or constitute a default under any contractual obligations of such Party or any of its Affiliates existing as of the Execution Date, except, in each case, for those conflicts, violations, breaches or defaults that would not, individually or in the aggregate, be reasonably expected to have a material adverse effect on the Exploitation of the Licensed Compounds and Licensed Products.

11.4 Enforceability. argenx and Janssen each represents and warrants to the other Party that, as of the Execution Date, this Agreement is a legal and valid obligation binding upon it and is enforceable against it in accordance with its terms, except as such enforcement may be limited by bankruptcy, insolvency, fraudulent conveyance, reorganization, moratorium and other laws affecting the rights of creditors generally and general equitable principles (whether considered in a proceeding in equity or at law).

11.6 Transparency Regulations. Each Party acknowledges that certain Laws and regulations (including regulations imposed on members of the European Federation of Pharmaceutical Industries and Associations (EFPIA)) require pharmaceutical, medical device and other companies to disclose information on compensation, gifts or other remuneration provided to physicians and other health care professionals. Each Party is in compliance and will continue to comply with such Laws and regulations to the extent they are applicable. Each Party acknowledges that the other Party may provide information about remuneration provided under this Agreement, as required by Law or regulation, and each party agrees to track, maintain and provide such information to the other Party as needed for it to comply with its legal obligations. Once reported, such information may be publicly accessible. Notwithstanding any other provision in this Agreement, each Party acknowledges that the other Party reserves the right to post on a website accessible to the public certain information regarding funding under this Agreement required by Law or regulation, including the identity of the recipient, the monetary value of the funding, the purposes of such funding, and other information as such Party determines is appropriate.

11.7 Additional Representations and Warranties of argenx. argenx represents and warrants to Janssen that, as of the Execution Date:

11.7.1 Except for the Existing Third Party Agreements, neither argenx nor any of its Affiliates is party to any license agreement with a Third Party in effect on the Execution Date pursuant to which argenx (or their respective Affiliates) is obligated to pay any amount to such Third Party for the practice of any intellectual property rights with respect to argenx's (or their respective Affiliates') Exploitation of the Licensed Product pursuant to the Agreement.

11.7.2 The Existing Third Party Agreements constitute all agreements pursuant to which argenx has licensed rights with respect to the Licensed Products, the Lead Anti-CD70 Antibody and the argenx Intellectual Property licensed to Janssen hereunder. argenx has provided Janssen with a copy of each Existing Third Party Agreement as well as all other material agreements related to Licensed Products (including with respect to the Lead Anti-CD70 Antibody) existing as of the Execution Date and argenx has not received any written notice that it is not in compliance with the terms of any such agreement.

11.7.3 argenx, together with its Affiliates, are the sole and exclusive owners of, or otherwise Control, the argenx Intellectual Property. argenx has all rights necessary to grant the licenses under the argenx Intellectual Property that it grants to Janssen in this Agreement.

11.7.4 argenx has not previously (i) licensed, assigned, transferred, or otherwise conveyed any right, title or interest in, to or under the argenx Patent Rights, or (ii) otherwise granted any rights, in each case to any Third Party in any way that would legally conflict with the licenses and rights granted to Janssen under this Agreement.

11.7.5 The argenx Patent Rights are free and clear of any liens, charges and encumbrances that would conflict with the license grants to Janssen hereunder.

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

11.7.6 To the best of argenx's knowledge, neither argenx nor any of its Affiliates or their respective current or former employees has misappropriated any of (i) the Know-How necessary or used by argenx for the Exploitations of the Licensed Products by argenx as of the Execution Date, or (ii) the argenx Know-How, in each case from any Third Party, and argenx is not aware of any claim by a Third Party that such misappropriation has occurred.

11.7.7 argenx has not received any written notice of any existing or threatened actions, suits or other proceedings pending against it with respect to the argenx Intellectual Property (other than patent office actions or the actions of any Regulatory Authority) that have not already been disclosed to Janssen.

11.7.8 Except as already disclosed, argenx has not received written notice from a Third Party claiming that a patent owned by such Third Party would be infringed by the manufacture, use, sale, offer for sale or import of the Licensed Product in the U.S. or OUS Territory, and no Third Party has threatened in writing to make any such claim.

11.7.9 The argenx Patent Rights listed in Schedule 1.10 represent all Patent Rights that argenx or any of its Affiliates owns or Controls that Cover or disclose any invention necessary or used by argenx for the Exploitation of the Licensed Product utilized therein as of the Execution Date. The argenx Patent Rights that are existing as of the Execution Date are listed in Schedule 1.10. argenx: (i) is not aware of any claim made against it asserting the invalidity, misuse, unregistrability, unenforceability or non-infringement of any of listed argenx Patent Rights other than patent office actions or the actions of any Regulatory Authority and, (ii) is not aware of any claim made against it challenging argenx's Control of listed Argenx Patent Rights or making any adverse claim of ownership of the rights of argenx to listed argenx Patent Rights.

11.7.10 argenx has prepared, maintained and retained all Regulatory Documentation and Regulatory Licenses for the Licensed Compounds and Licensed Products in accordance in all material respects with all applicable Law and regulatory standards, including as applicable GCP and GLP. argenx has not, to its knowledge, made any false and misleading statements in connection with submitting or obtaining such Regulatory Documentation and Regulatory Licenses.

11.7.11 argenx has conducted, and has used reasonable efforts to cause its contractors and consultants to conduct, the Development and Manufacture of the Licensed Compounds and Licensed Products (including all clinical studies) in accordance in all material respects with applicable Law, professional scientific standards, accepted ethical standards, including as applicable GCP and GLP, and applicable experimental protocols, procedures and controls.

11.7.12 Except as disclosed in writing to Janssen by argenx prior to the Execution Date, no adverse event involving human subjects reported to argenx has occurred in connection with any clinical study or other use of the Licensed Products.

11.7.13 argenx has made available to Janssen all material information in argenx's or its Affiliate's control relating to the Development and Manufacture of the Licensed

Compounds and Licensed Products as conducted by or on behalf of argenx prior to the Execution Date, including complete and correct copies of the following: adverse event reports; clinical study reports and material study data (subject to the last sentence of this Section 11.7.13); and Regulatory Authority inspection reports, notices of adverse findings, warning letters, regulatory filings and other material correspondence with Regulatory Authorities. For clarity, argenx makes no representation or warranty to Janssen as to the completeness or correctness of any raw data made available to Janssen relating to the Development or Manufacture of Licensed Compounds or Licensed Products.

11.7.14 there is no claim, action, suit, arbitration, inquiry, audit or investigation by or before any Governmental Authority pending or, to the knowledge of argenx, threatened against argenx or involving any of the Licensed Compounds or Licensed Products. There is no award, stay, writ, judgement, injunction, decree or similar order of any Governmental Authority outstanding, or to argenx's knowledge pending, involving argenx or any of the Licensed Compounds or Licensed Products. With respect to each clinical trial of any Licensed Product conducted by or on behalf of argenx, argenx has secured all legally- and ethically-required patient consents for the collection, use, processing and disclosure of such patients' data and biological specimens.

11.7.15 All personal data and biological specimens collected from or disclosed by human subjects in clinical trials of the Licensed Products has been collected, used, processed and disclosed in compliance with applicable Laws.

11.7.16 Neither argenx nor any of its Affiliates is or has been a party to any agreement with a Governmental Authority pursuant to which such Governmental Authority provided or may provide funding for the Development of any Licensed Compound or Licensed Product.

11.8 Additional Representations and Warranties of Janssen.

11.8.1 [...***...].

11.8.2 Janssen represents, warrants and covenants to argenx that all Licensed Products Manufactured by or on behalf of Janssen or any of its Affiliates for use in any Clinical Study or for commercial distribution in the U.S. or the OUS Territory (a) will have been manufactured in all material respects in accordance with applicable Law and will have been manufactured in compliance with GMP (or, in the case of Licensed Products manufactured for use in any Clinical Study, in compliance with GMP as applicable to investigational new drugs), (b) in the case of Licensed Products manufactured by Janssen or any of its Affiliates (and not by any Third Party on behalf of Janssen or any of its Affiliates), will have been manufactured in all material respects in accordance with Janssen's quality standards, and (c) as of the date such Licensed Product is released by or on behalf of such Janssen or any of its Affiliates for use in any Clinical Study or for commercial distribution, will conform to the applicable specifications for such Licensed Product then in effect.

11.9 Existing Third Party Agreements. With respect to each of the Existing Third Party Agreements, argenx shall:

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

11.9.1 use Diligent Efforts to maintain in full force and effect such agreement (in accordance with its terms) and keep Janssen fully informed of any material development pertaining thereto for so long as such Third Party rights are sublicensed to Janssen in accordance with Section 3.1;

11.9.2 not take any action to terminate, modify, amend, waive any right, to the extent incompatible with the rights sublicensed to Janssen in accordance with Section 3.1;

11.9.3 not fail to enforce any right, knowingly breach or otherwise take any other action with respect to any such Existing Third Party Agreement that would reasonably be expected to materially impact the rights granted to Janssen under this Agreement, without the consent of Janssen;

11.9.4 not assign such Existing Third Party Agreement, or any of its rights thereunder, without the consent of Janssen;

11.9.5 comply in all material respects with the terms of such Existing Third Party Agreement;

11.9.6 make all payments that become due under such Existing Third Party Agreement in accordance with the terms of such Existing Third Party Agreement;

11.9.7 if argenx or any of its Affiliates receives written notice from the applicable Third Party claiming that argenx or any of its Affiliates has breached or defaulted under, or is in breach of or default under, its obligations under such Existing Third Party Agreement, provide a copy thereof to Janssen promptly after receipt and, following consultation with Janssen, consider Janssen's input in good faith and take such actions as may be reasonably necessary to cure any breach or default; and

11.9.8 take all actions reasonably requested by Janssen to provide Janssen with the rights and/or benefits available to argenx or Janssen as a sublicensee under the applicable Existing Third Party Agreement with respect to the argenx Licensed Patents licensed to argenx thereunder, including enforcing any rights granted to argenx under the applicable Existing Third Party Agreement with respect to such argenx Patent Rights.

11.10 No Warranties. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, TO THE OTHER PARTY, AND EACH PARTY HEREBY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT WITH RESPECT TO THE LICENSED COMPOUNDS AND PRODUCTS. EACH PARTY HEREBY DISCLAIMS ANY REPRESENTATION OR WARRANTY THAT THE EXPLOITATION OF THE LICENSED COMPOUNDS AND LICENSED PRODUCTS PURSUANT TO THIS AGREEMENT WILL BE SUCCESSFUL OR THAT ANY PARTICULAR SALES LEVEL WITH RESPECT TO THE LICENSED PRODUCTS WILL BE ACHIEVED.

11.11 No Debarment or Exclusion. Each Party represents and warrants that, as of the Execution Date, neither it nor any of its Affiliates, nor any of their officers, employees or agents has been debarred or is subject to debarment as authorized by Section 306 of the United States Federal Food, Drug, and Cosmetic Act or has been excluded or is subject to exclusion from participation in Government Health Care Programs under 42 U.S.C. § 1320a-7, and neither Party nor any of its Affiliates will use in any capacity, in connection with the Exploitation of the Licensed Compounds or Licensed Products in the Field, any Person who has been debarred pursuant to Section 306 of the United States Federal Food, Drug, and Cosmetic Act, who is the subject of a conviction described in such section, who has been excluded from participation in Government Health Care Programs under 42 U.S.C. § 1320a-7 or who has been convicted of any crime or engaged in any conduct for which such Person could be excluded from participation in Government Health Care Programs under 42 U.S.C. § 1320a-7. Each Party agrees to inform the other Party in writing immediately if it, any of its officers, employees or agents, or any Person who is performing services under this Agreement is debarred, is the subject of a conviction described in Section 306 of the United States Federal Food, Drug, and Cosmetic Act, is excluded from participation in Government Health Care Programs under 42 U.S.C. § 1320a-7 or is convicted of any crime for which such Person could be excluded from participation in Government Health Care Programs under 42 U.S.C. § 1320a-7, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of such Party's knowledge, is threatened, relating to the debarment, exclusion or conviction of such Party or any Person used in any capacity by such Party or any of its Affiliates in connection with the Exploitation of the Licensed Compounds or Licensed Products.

11.12 Compliance with Anti-Corruption Laws.

11.12.1 Notwithstanding anything to the contrary in the Agreement, each Party hereby agrees that:

(a) it shall not, in the performance of this Agreement, perform any actions that are prohibited by local and other anti-corruption laws (including the provisions of the U.S. Foreign Corrupt Practices Act, collectively "**Anti-Corruption Laws**") that may be applicable to one or both Parties to this Agreement;

(b) it shall not, in the performance of this Agreement, directly or indirectly, make any payment, or offer or transfer anything of value, or agree or promise to make any payment or offer or transfer anything of value, to a government official or government employee, to any political party or any candidate for political office or to any other Third Party related to the transaction with the purpose of influencing decisions related to either Party and/or its business in a manner that would violate Anti-Corruption Laws;

(c) argenx shall designate an individual within its organization to receive training from Janssen on Anti-Corruption Laws as well as applicable rules on interactions with health care professionals, as mutually agreed to by the Parties. Such designated individual shall then provide such training on Anti-Corruption Laws, using applicable training materials to be provided by Janssen, on at least an annual basis to all persons employed by argenx who perform any activities under this Agreement and interact with government officials or health care professionals in the normal course of their responsibilities. Upon the Parties'

mutual agreement, such training may also be provided directly by Janssen to such employees of argenx. argenx and Janssen shall each use reasonable efforts to provide such training or training materials to any contractors or subcontractors of such Party engaged to perform activities under this Agreement where such contracted or subcontracted activities include responsibility for, directly or indirectly, interacting with Public Officials. argenx may fulfill its obligation under the preceding sentence by requesting appropriate materials from Janssen and forwarding such materials, if any, received from Janssen to the applicable contractor or subcontractor. In the event that argenx is not able to obtain a contractor or subcontractor's agreement to receive such training or materials, argenx will use reasonable efforts to facilitate an introduction of Janssen to such contractor or subcontractor and not object to reasonable efforts of Janssen to provide such training or materials to the applicable contractor or subcontractor. Any training and materials provided by Janssen does not relieve argenx of any obligations it has independent of the Agreement and argenx shall not rely on Janssen's training and materials for any such obligations;

(d) it shall, on [...***...] basis upon request by the other Party, verify in writing that to the best of such Party's knowledge, there have been no violations of Anti-Corruption Laws by such Party or persons employed by or subcontractors used by such Party in the performance of the Agreement, or will provide details of any exception to the foregoing; and

(e) it shall maintain records (financial and otherwise) and supporting documentation related to the subject matter of the Agreement in order to document or verify compliance with the provisions of this Section 11.12, and upon request of the other Party, up to [...***...] and upon reasonable advance notice, shall provide a Third Party auditor mutually acceptable to the Parties with access to such records for purposes of verifying compliance with the provisions of this Section 11.12. Acceptance of a proposed Third Party auditor may not be unreasonably withheld by either Party. It is expressly agreed that the costs related to the Third Party auditor will be fully paid by the Party requesting the audit, and that any auditing activities may not unduly interfere with the normal business operations of Party subject to such auditing activities. The audited Party may require the Third Party auditor to enter into a reasonable confidentiality agreement in connection with such an audit.

11.12.2 argenx hereby represents and warrants to Janssen that, to its knowledge as of the Execution Date, neither argenx nor any of its Subsidiaries nor any of their Affiliates, directors, officers, employees, distributors, agents, representatives, sales intermediaries or other Third Parties acting on behalf of argenx or any of its subsidiaries or any of their Affiliates:

(a) has taken any action in violation of any applicable Anti-Corruption Law; or

(b) has corruptly, offered, paid, given, promised to pay or give, or authorized the payment or gift of anything of value, directly or indirectly, to any Public Official (as defined in Section 11.12.3 below), for the purposes of:

(i) influencing any act or decision of any Public Official in his official capacity;

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

lawful duty;

(ii) inducing such Public Official to do or omit to do any act in violation of his

(iii) securing any improper advantage; or

(iv) inducing such Public Official to use his or her influence with a government, governmental entity, or commercial enterprise owned or controlled by any government (including state-owned or controlled veterinary or medical facilities) in obtaining or retaining any business whatsoever.

11.12.3 argenx hereby represents and warrants to Janssen that, as of the Execution Date, none of the officers, directors, employees of argenx or of any of its subsidiaries acting on behalf of argenx or any of its subsidiaries, in each case that are employed or reside outside the United States, are themselves Public Officials.

11.12.4 For purposes of this Section 11.12, “**Public Official**” means:

(a) any officer, employee or representative of any regional, federal, state, provincial, county or municipal government or government department, agency or other division;

(b) any officer, employee or representative of any commercial enterprise that is owned or controlled by a government, including any state-owned or controlled veterinary or medical facility;

(c) any officer, employee or representative of any public international organization, such as the African Union, the International Monetary Fund, the United Nations or the World Bank; and

(d) any person acting in an official capacity for any government or government entity, enterprise or organization identified above.

11.13 Insurance. Beginning at the time any Licensed Product is being distributed, sold or Commercialized, each Party will secure and maintain in full force and effect adequate insurance coverage against its liabilities under this Agreement including commercial general liability and product liability insurance in an amount not less than [...***...] per occurrence and annual aggregate. Such insurance shall be maintained beyond the expiration or termination of this Agreement for a period of five years thereafter. Before the initiation of any Clinical Study, the Party responsible for the applicable Clinical Study shall secure and maintain in full force and effect clinical trial insurance in compliance with applicable Law in those territories where Clinical Studies are conducted. Upon written request, each Party shall provide the other with a certificate of insurance evidencing the required coverage. Notwithstanding the foregoing, either Party’s failure to maintain adequate insurance shall not relieve the other Party of its obligations set forth in this Agreement.

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

**ARTICLE XII
INDEMNIFICATION**

12.1 General Indemnification by argenx. argenx shall indemnify and hold harmless Janssen, its Affiliates and their respective directors, officers, employees and agents (collectively, the “**Janssen Indemnified Parties**”), from, against and in respect of any and all Actions, damages, losses, liabilities, costs (including costs of investigation, defense), fines, penalties, Government Orders, taxes, expenses or amounts paid in settlement (in each case, including reasonable attorneys’ and experts fees and expenses), resulting from a claim or Action of a Third Party or Governmental Authority (collectively, “**Losses**”), incurred or suffered by the Janssen Indemnified Parties or any of them as a result of, arising out of or relating to: [...***...]; except, in each case, to the extent caused by and attributable to the negligence, intentional misconduct or violation of Law of or by Janssen or any of the other Janssen Indemnified Parties, or any breach or violation of any covenant or agreement in or pursuant to this Agreement by Janssen or any of the other Janssen Indemnified Parties. For clarity, Losses shall not include any losses or damages sustained by any Janssen Indemnified Party as a result of the actions described in clauses (i), (ii) or (iii) of the immediately preceding sentence, except to the extent that such losses or damages are paid by a Janssen Indemnified Party to a Third Party or Governmental Authority as a result of a claim or Action of a Third Party or Governmental Authority.

12.2 General Indemnification by Janssen. Janssen shall indemnify and hold harmless argenx, its Affiliates and their respective directors, officers, employees and agents (collectively, the “**argenx Indemnified Parties**”), from, against and in respect of any and all Losses incurred or suffered by the argenx Indemnified Parties or any of them as a result of, arising out of or relating to: [...***...]; except, in each case, to the extent caused by and attributable to the negligence, intentional misconduct or violation of Law of or by argenx or any of the other argenx Indemnified Parties, or any breach or violation of any covenant or agreement in or pursuant to this Agreement by argenx or any of the other argenx Indemnified Parties. For clarity, Losses shall not include any losses or damages sustained by any argenx Indemnified Party as a result of the actions described in clauses (i) or (ii) of the immediately preceding sentence, except to the extent that such losses or damages are paid by an argenx Indemnified Party to a Third Party or Governmental Authority as a result of a claim or Action of a Third Party or Governmental Authority.

12.3 Claims for General Indemnification.

12.3.1 Notice. A Person entitled to indemnification under Section 12.1 or 12.2 (an “**Indemnified Party**”) shall give prompt written notification to the Party from whom indemnification is sought (the “**Indemnifying Party**”) of the commencement of any claim or Action of a Third Party or Governmental Authority for which indemnification may be sought under Section 12.1 or 12.2 (each, a “**Claim**”) or, if earlier, upon the assertion of any such Claim by a Third Party; provided, however, failure to give notice or delay in giving notice by an Indemnified Party of a Claim as provided in this Section 12.3.1 shall not relieve the Indemnifying Party of its indemnification obligation under Section 12.1 or 12.2, except and only to the extent that such Indemnifying Party is actually, materially prejudiced as a result of such failure or delay. Each Claim notice shall identify the Third Party or Governmental Authority making such Claim, describe in reasonable detail the basis for such Claim (the “**Claim Basis**”),

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

and specify the amount or the estimated amount of Losses actually incurred or paid by the Indemnified Party as a result of the Claim Basis, to the extent then ascertainable (the “**Claim Amount**”).

12.3.2 Defense. Within [...***...] after delivery of a notice of any Claim in accordance with Section 12.3.1, the Indemnifying Party may, upon written notice thereof to the Indemnified Party, assume control of, and have sole power to direct, the defense of such Claim with counsel reasonably satisfactory to the Indemnified Party. If the Indemnifying Party does not assume control of such defense, the Indemnified Party shall control such defense. The Party not controlling such defense may participate therein at its own expense.

12.3.3 Cooperation. The Party controlling the defense of any Claim shall keep the other Party advised of the status of such Claim and the defense thereof and shall reasonably consider recommendations made by the other Party with respect thereto. The other Party shall cooperate fully with the Party controlling such defense and its Affiliates and agents in defense of the Claim.

12.3.4 Settlement. The Indemnified Party shall not agree to any settlement of such Claim without the prior written consent of the Indemnifying Party, which shall not be unreasonably withheld. The Indemnifying Party shall not agree to any settlement of such Claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party from all liability with respect thereto or that imposes any liability or obligation on the Indemnified Party for which the Indemnified Party is not indemnified under this Agreement without the prior written consent of the Indemnified Party, which shall not be unreasonably withheld.

12.4 Product Liability Claims.

12.4.1 “Product Liability Costs” means amounts paid to Third Parties (including damages and amounts paid in settlement to Third Parties and reasonable attorneys’ and experts fees and expenses), and internal costs incurred, by the Parties and their Affiliates that are associated with Third Party Products Liability Actions resulting from the Exploitation of the Licensed Products pursuant to this Agreement.

12.4.2 “Shared Product Liability Costs” means all Product Liability Costs other than (a) such portion (if any) of Product Liability Costs that are Losses entitled to indemnification under Section 12.1 or Section 12.2, or (b) such portion (if any) of Product Liability Costs that relate to Commercialization of the Licensed Products in the OUS Territory.

12.4.3 All Shared Product Liability Costs shall be borne [...***...] by Janssen and [...***...] by argenx. Product Liability Costs that are Losses entitled to indemnification under Section 12.1 or Section 12.2 shall be borne by the [...***...]. Product Liability Costs that relate to Commercialization of the Licensed Products in the OUS Territory shall be borne by [...***...].

12.4.4 Each of the Parties shall promptly notify the other in the event that any Third Party asserts or files any products liability claim or other Action relating to alleged defects in the Licensed Product (whether design defects, manufacturing defects or defects in sales or marketing) (“**Third Party Products Liability Action**”) against such Party; provided, however,

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

failure to give or delay in giving such notice shall not relieve either Party of its obligations under this Section 12.4, except to the extent the other Party is actually, materially prejudiced as a result of such failure or delay. To the extent such Third Party Products Liability Action relates to Commercialization of Licensed Compounds or Licensed Products in the OUS Territory, Janssen shall have the sole right to defend and settle such Third Party Products Liability Action. With respect to any other Third Party Products Liability Action (a “**Shared Third Party Products Liability Action**”), Janssen shall have the first right to defend and settle such Shared Third Party Products Liability Action. In the event that Janssen does not assume the defense of such Shared Third Party Products Liability Action within [...***...] following delivery and receipt of notice described in the immediately preceding sentence, argenx may notify Janssen of argenx’s desire to take the lead role in the defense of such Shared Third Party Products Liability Action. If, within [...***...] after argenx notifies Janssen of such desire, Janssen does not assume defense of such Shared Third Party Products Liability Action, then argenx may take the lead role in the defense of such Shared Third Party Products Liability Action. Each Party agrees to cooperate and to provide reasonable assistance to the other Party with respect to any Third Party Products Liability Action.

12.4.5 The Party assuming the defense of any Shared Third Party Products Liability Action under this Section 12.4 (the “**Controlling Party**”) shall consult with the other Party on all material aspects of the defense, including settlement, of such Shared Third Party Products Liability Action, and the Parties shall cooperate fully with each other in connection therewith. The non-defending Party shall also have the right to participate in the defense of any Shared Third Party Products Liability Action utilizing attorneys of its choice, at its own expense. In furtherance of the Parties’ cooperation, the Controlling Party will consult with the other Party regarding strategic decisions, including the retention of counsel and defense of each Shared Third Party Products Liability Action. The Controlling Party will otherwise keep the other Party fully informed of the status and progress of the defense and any settlement discussions concerning the Shared Third Party Products Liability Action. Any settlement of a Shared Third Party Products Liability Action that would admit liability on the part of any Party or its Affiliates, or that would involve any relief other than the payment of money damages within a budget previously agreed to by the Parties, shall be subject to the prior written approval of both Parties, such approval not to be unreasonably withheld or delayed. All damages and expenses (including reasonable attorney’s fees of the Controlling Party) incurred in connection with the defense of a Third Party Products Liability Action shall be allocated between Janssen and argenx in accordance with Section 12.4.2.

12.4.6 Shared Product Liability Costs shall initially be borne by the Party incurring the cost or expense, subject to [...***...] reimbursement (or such other reimbursement schedule as the JFC may approve) pursuant to procedures to be established by the JFC. Each Party shall calculate and maintain records of Shared Product Liability Costs incurred by it and its Affiliates in accordance with procedures to be established by the JFC promptly following commencement of any Shared Third Party Products Liability Action.

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

ARTICLE XIII
TERM AND TERMINATION

13.1 Term. Unless terminated earlier in accordance with this Article XIII or Section 14.1, this Agreement shall remain in force for the period commencing on the Execution Date and ending, on a country-by-country basis, upon the expiration (whether by the terms of this Agreement or by operation of Law) of all payment obligations in such country under Section 8.5 (with respect to the U.S., which for clarity shall survive so long as any Licensed Product is being sold in the U.S.) and Section 8.6 (with respect to a country in the OUS Territory) of this Agreement (the “**Term**”). The provisions of Article I (Definitions), Article X (Confidentiality and Publicity), Article XI (Representations and Warranties; Certain Covenants), Article XIV (HSR Compliance), Article XV (Dispute Resolution), Article XVI (Miscellaneous) and Section 13.2 (Termination for Material Breach) shall become effective on the Execution Date; the other provisions of this Agreement shall not become effective until the Effective Date.

13.2 Termination for Material Breach. Upon any material breach of this Agreement by a Party (the “**Breaching Party**”), the other Party (the “**Non-Breaching Party**”) may terminate this Agreement by providing [...***...] written notice to the Breaching Party, which notice shall reasonably describe the alleged breach which is the basis of such termination clearly state the Non-Breaching Party’s intent to terminate this Agreement if the alleged breach is not cured within the applicable cure period. The termination shall become effective at the end of the notice period unless the Breaching Party cures such breach during such notice period, provided that the Non-Breaching Party may, by notice to the Breaching Party, designate a later date for such termination in order to facilitate an orderly transition of activities relating to the Licensed Product. Notwithstanding the foregoing, if such breach (other than a payment breach), by its nature, is curable, but is not reasonably curable within the applicable cure period, then such cure period shall be extended if the Breaching Party provides a written plan for curing such breach to the Non-Breaching Party and uses Diligent Efforts to cure such breach in accordance with such written plan, provided that no such extension shall exceed [...***...] without the consent of the Non-Breaching Party.

13.3 Termination by Janssen Without Cause. Janssen may, upon [...***...] prior written notice to argenx, terminate this Agreement in its entirety.

13.4 Provisions for Insolvency.

13.4.1 A Party may terminate this Agreement in its entirety, or release the other Party from all or certain of its obligations under this Agreement, upon providing written notice to the other Party on or after the time that such other Party makes a general assignment for the benefit of creditors, files a voluntary petition in bankruptcy, consents to an order for relief in connection with an involuntary petition in bankruptcy filed against such Party (or an involuntary petition in bankruptcy filed against such Party remains un-dismissed or un-stayed for a period of more than [...***...]), petitions for or acquiesces in the appointment of any receiver, trustee or similar officer to liquidate or conserve its business or any substantial part of its assets, commences under the laws of any jurisdiction any proceeding involving its insolvency, bankruptcy, reorganization, adjustment of debt, dissolution, liquidation or any other similar

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

proceeding for the release of financially distressed debtors, or becomes a party to any proceeding or action of the type described above (each, an “**Insolvency Event**”).

13.4.2 All rights and licenses now or hereafter granted by argenx to Janssen under or pursuant to this Agreement, including, for the avoidance of doubt, the licenses granted to Janssen pursuant to Sections 3.1 and 3.4, are, for all purposes of Section 365(n) of Title 11 of the United States Code, as amended (such Title 11, the “**Bankruptcy Code**”), licenses of rights to “intellectual property” as defined in the Bankruptcy Code. Upon the occurrence of any Insolvency Event with respect to Licensor, argenx agrees that Janssen, as licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code. Without limiting the generality of the foregoing, argenx and Janssen intend and agree that any sale of argenx’s assets under Section 363 of the Bankruptcy Code shall be subject to Janssen’s rights under Section 365(n), that Janssen cannot be compelled to accept a money satisfaction of its interests in the intellectual property licensed pursuant to this Agreement, and that any such sale therefore may not be made to a purchaser “free and clear” of Janssen’s rights under this Agreement and Section 365(n) without the express, contemporaneous consent of Janssen. Further, each Party agrees and acknowledges that all payments by Janssen to argenx hereunder, other than the upfront payment pursuant to Section 8.1, U.S. Collaboration Results pursuant to Section 8.5, royalty payments pursuant to Section 8.6, and the Sales Milestone Payments pursuant to Section 8.3, do not constitute royalties within the meaning of Section 365(n) of the Bankruptcy Code or relate to licenses of intellectual property hereunder. Argenx shall, during the Term, create and maintain current copies or, if not amenable to copying, detailed descriptions or other appropriate embodiments, to the extent feasible, of all such intellectual property. argenx and Janssen acknowledge and agree that “embodiments” of intellectual property within the meaning of Section 365(n) include laboratory notebooks, cell lines, product samples and inventory, research studies and data, Regulatory Documentation and Regulatory Licenses. If (i) a case under the Bankruptcy Code is commenced by or against argenx, (ii) this Agreement is rejected as provided in the Bankruptcy Code, and (iii) Janssen elects to retain its rights hereunder as provided in Section 365(n) of the Bankruptcy Code, argenx (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee) shall:

(a) provide to Janssen all such intellectual property (including all embodiments thereof) held by argenx and such successors and assigns, or otherwise available to them, immediately upon Janssen’s written request. Whenever argenx or any of its successors or assigns provides to Janssen any of the intellectual property licensed hereunder (or any embodiment thereof) pursuant to this Section 13.4.1, Janssen shall have the right to perform argenx’s obligations hereunder with respect to such intellectual property, but neither such provision nor such performance by Janssen shall release argenx from liability resulting from rejection of the license or the failure to perform such obligations; and

(b) not interfere with Janssen’s rights under this Agreement, or any agreement supplemental hereto, to such intellectual property (including such embodiments), including any right to obtain such intellectual property (or such embodiments) from another entity, to the extent provided in Section 365(n) of the Bankruptcy Code.

13.4.3 All rights, powers and remedies of Janssen provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including the Bankruptcy Code) in the event of the commencement of a case under the Bankruptcy Code with respect to argenx. The Parties agree that they intend the following rights to extend to the maximum extent permitted by law, and to be enforceable under Bankruptcy Code Section 365(n):

(a) the right of access to any intellectual property (including all embodiments thereof) of argenx, or any Third Party with whom argenx contracts to perform an obligation of argenx under this Agreement, and, in the case of the Third Party, which is necessary for the manufacture, use, sale, import or export of Licensed Products; and

(b) the right to contract directly with any Third Party to complete the contracted work.

13.5 [...***...].

13.6 Effects of Termination or Expiration.

13.6.1 For argenx's Material Breach or Insolvency. In the event of termination of this Agreement by Janssen under Section 13.2 (Termination for Material Breach) or 13.4 (Provisions for Insolvency), then, upon the effective date of such termination:

(a) all licenses and other rights granted to either Party pursuant to this Agreement shall terminate (save for those (i) expressly stated to survive termination of this Agreement pursuant to Section 13.6.7, or (ii) to the extent necessary to enable either Party to perform any of its obligations that survive termination);

(b) Janssen shall wind down all of its Development and Commercialization activities as quickly as reasonably practicable, subject to compliance with ethical and legal requirements, and the Parties shall continue to share the reasonable costs of such activities in accordance with the terms of this Agreement until such wind down is complete; and

(c) each Party shall use Diligent Efforts to return or destroy, at the Disclosing Party's election, all Confidential Information of the other Party (provided that the Receiving Party may keep one copy of such Confidential Information subject to an ongoing obligation of confidentiality for archival purposes only). This obligation to return or destroy Confidential Information does not extend to automatically generated computer back-up or archival copies generated in the ordinary course of information system's procedures, provided that except as expressly set out herein, the Receiving Party shall not access nor make any use of such copies.

13.6.2 For Janssen's Material Breach or Insolvency or Termination Without Cause. In the event of termination of this Agreement by argenx under Section 13.2 (Termination for Material Breach) or 13.4 (Provisions for Insolvency), or by Janssen under Section 13.3 (Termination by Janssen without Cause), then the following provisions of this Section 13.6.2

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

shall apply upon the effective date of such termination (or upon the date expressly set forth in such provision).

(a) All licenses and other rights granted to either Party pursuant to this Agreement shall terminate (save for those (i) expressly stated to survive termination of this Agreement pursuant to Section 13.6.7; (ii) which are granted pursuant to this Section 13.6.2; or (iii) to the extent necessary to enable either Party to perform any of its obligations that survive termination).

(b) As soon as practicable, Janssen will assign or otherwise transfer to argenx all Regulatory Documentation, Regulatory Licenses and Drug Approval Applications specific to any Licensed Compound or Licensed Product Controlled by Janssen or any of its Affiliates or Sublicensees (which, for clarity, shall exclude any Regulatory Documentation, Regulatory License or Drug Approval Application for any compound or product that is neither a Licensed Compound nor a Licensed Product). Janssen shall, and shall procure that its Affiliates and Sublicensees shall, take such actions and execute such instruments, assignments and documents as may be reasonably requested by argenx to effect the transfer of rights under such Regulatory Documentation, Regulatory Filings and Drug Approval Applications to argenx. If applicable Law prevents or delays the transfer of ownership of any such Regulatory Documentation, Regulatory Filings or Drug Approval Applications to argenx, Janssen shall grant, and does hereby grant, to argenx an exclusive and irrevocable right of access and reference to such Regulatory Documentation, Regulatory Filings and Drug Approval Applications for the Licensed Compound and Licensed Products, and shall cooperate with argenx to make the benefits of such Regulatory Documentation, Regulatory Filings and Drug Approval Applications available to argenx or its designee(s) with effect from the effective date of such termination.

(c) Janssen hereby grants argenx (effective upon the effective date of such termination) a right of reference to any DMF or master files within the possession and Control of Janssen or its Affiliates, to the extent such DMF or master files relate to such Licensed Compound or Licensed Product.

(d) Following receipt of written request from argenx, Janssen shall deliver to argenx all safety data contained in the global safety database for Licensed Products and promptly transfer control of and responsibility for maintaining the global safety database for Licensed Products to argenx.

(e) Janssen hereby grants to argenx a perpetual, worldwide, exclusive, fully paid-up, irrevocable license with a right to sublicense (in multiple tiers) under the Janssen Intellectual Property and Janssen's interest in Joint Intellectual Property to the extent necessary or useful for argenx to Develop, have Developed and use; to make, have made and otherwise Manufacture; and to sell, have sold, offer for sale, import and otherwise Commercialize the Licensed Compounds and Licensed Products in the Field; provided, however, that: (i) if any such Janssen Intellectual Property was in-licensed or acquired from a Third Party and is subject to payment or other obligations to such Third Party, Janssen shall promptly disclose such obligations to argenx in writing and such Janssen Intellectual Property shall be subject to the license granted in this clause (e) only to the extent argenx agrees in writing to be bound by such obligations and reimburse all amounts owed to such Third Party as a result of argenx's exercise

of such license with respect to such Janssen Intellectual Property; and (ii) the Janssen Intellectual Property licensed to argenx pursuant to this clause (e) shall not include any proprietary manufacturing, formulation or drug delivery technology of Janssen that was not actually used by or on behalf of Janssen in the Manufacture of Licensed Compounds or Licensed Products.

(f) If Janssen is, as of the effective date of termination of this Agreement, party to any Subcontracts or Sublicenses that pertain solely to the Licensed Compounds or Licensed Products, then Janssen will assign to argenx any such Subcontracts or Sublicenses requested by argenx, to the extent it has the right under such contract(s) to do so (and will use reasonable efforts to obtain any required consents). If Janssen is not able to assign any such Subcontracts or Sublicenses, at argenx's request, or in the event that any Subcontract pertains both to the Licensed Compounds or Licensed Products and to any other product of Janssen, Janssen shall use Diligent Efforts to facilitate negotiations between argenx and any of Janssen's Subcontractors or Sublicensees that at the effective date of termination are performing any Development, Manufacturing or Commercialization activities with respect to any Licensed Compound or Licensed Product, subject to argenx's agreement to any associated reasonable costs.

(g) Janssen shall transfer to argenx, at argenx's request, any remaining inventory of Licensed Compounds and Licensed Products, and components thereof and raw materials used by or on behalf of Janssen in the Manufacture of Licensed Compounds or Licensed Products (collectively, "**Inventory**"), that, in each case, is in Janssen's possession as of the effective date of termination at a price equal to [...***...]; provided, however, that to the extent any Inventory in Janssen's possession as of the effective date of termination is necessary for Janssen to perform its Licensed Product supply obligations under Section 13.6.2(h) and/or its Commercialization Wind-Down Period obligations under 13.6.2(i) (if any) after the effective date of termination, then Janssen's Inventory transfer obligations under the preceding provisions of this Section 13.6.2(g) shall apply to any Inventory that is in Janssen's possession as of the date Janssen's obligations under Section 13.6.2(h) and/or Section 13.6.2(i) (as applicable) expire or terminate (or, if earlier, as of the date that Janssen no longer requires such Inventory for the performance of such obligations). Within [...***...] after the effective date of termination (or within [...***...] after such later date described in the preceding proviso, if applicable), Janssen shall notify argenx (i) of the quantity(ies) and type(s) of the remaining Inventory and [...***...] and (ii) whether any Licensed Products in such Inventory will need to be relabeled or repackaged to remove any Janssen Housemarks, and argenx shall have [...***...] after receipt of such notice in which to notify Janssen of the quantity(ies) and type(s) of the remaining Inventory that argenx wishes to acquire. If argenx does not so notify Janssen within the applicable period specified above, or notifies Janssen within the applicable period specified above that argenx elects to purchase less than all of the remaining Inventory, then (i) in the case of Inventory remaining in Janssen's possession as of the effective date of termination, Janssen shall be entitled to elect to continue to sell such Inventory for up to [...***...] after the effective date of termination, or to destroy such inventory, and (ii) in the case of Inventory remaining in Janssen's possession as of the date Janssen's obligations under Section 13.6.2(h) and/or Section 13.6.2(i) (as applicable) expire or terminate (or, if earlier, as of the date that Janssen no longer requires such Inventory for the performance of such obligations), Janssen shall destroy such Inventory. Licensed Products Commercialized by Janssen pursuant to this Section 13.6.2(g) (x) in the OUS Territory, shall be subject to payment of royalties pursuant to Section 8.6, and (y) in the U.S., shall be subject to

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

payment of royalties (including any applicable royalty rebates) pursuant to Section 8.5; provided, however, that the royalty rebates shall in no event require argenx to make a payment to Janssen.

(h) Janssen shall, at argenx's request, use Diligent Efforts to facilitate an orderly and prompt transition of any Manufacturing of Licensed Compounds and Licensed Products then being conducted by Janssen and any of its Affiliates or Third Party subcontractors to argenx or its designee. At argenx's request, while such Manufacturing activities are transitioned, Janssen shall supply argenx or its designee with Licensed Products at a price equivalent to [...***...], provided that Janssen shall not be obligated to continue to supply such Licensed Products after the date argenx is able to establish an alternative manufacturing source of Licensed Compound and Licensed Product sufficient to meet its needs (whether through assignment or entering into an agreement with one or more Third Parties pursuant to Section 13.6.2(f), or through establishment of its own Manufacturing facility), but in any event Janssen shall not be obligated to continue to supply such Licensed Products any longer than [...***...] following the effective date of termination of this Agreement.

(i) If the First Commercial Sale of a Licensed Product has occurred in a country prior to the effective date of termination of this Agreement, then, if requested by argenx, Janssen shall continue to Commercialize such Licensed Product in such country in accordance with the terms and conditions of this Agreement, for a period requested by argenx not to exceed [...***...] from the effective date of termination of this Agreement (the "**Commercialization Wind-Down Period**"), provided that argenx may terminate such activities during the Commercialization Wind-Down Period upon [...***...] notice to Janssen. Any Licensed Products Commercialized by Janssen during the Commercialization Wind-Down Period (x) in the OUS Territory, shall be subject to payment of royalties pursuant to Section 8.6, and (y) in the U.S., shall be subject to payment of royalties (including any applicable royalty rebates) pursuant to Section 8.5; provided, however, that the royalty rebates shall in no event require argenx to make a payment to Janssen.

(j) To the extent permitted by applicable Law, Janssen shall transfer to argenx promotional materials, sales training materials, Commercialization plans and customer contact information in Janssen's possession that are solely related to Commercialization of the Licensed Products (subject to the transition plan agreed to by the Parties pursuant to Section 13.6.3 with respect to OUS Territory plans and information).

(k) If, at the date of notice of termination, any Clinical Study are on-going (i.e. first patient dosed prior to the date of notice of termination) with respect to a Licensed Product pursuant to the GDP which are under Janssen's control or for which Janssen is the sponsor, then argenx shall notify Janssen in writing within [...***...] after the notice of termination to confirm whether argenx elects to have Janssen:

(i) complete such Clinical Study on behalf of argenx (unless material safety concerns regarding continuation of such Clinical Study have been identified), in which case, the Parties will negotiate in good faith a separate agreement setting forth the Parties' responsibilities and obligations with respect to such study. If the Parties fail to reach agreement within [...***...] after argenx makes such election, Janssen may wind down such Clinical Study in accordance with Section 13.6.2(k)(ii) below;

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

(ii) wind down such Clinical Study as soon as practicable, subject to compliance with ethical and legal requirements; or

(iii) transfer responsibility for and control of such Clinical Study to argenx as soon as practicable. Janssen shall use Diligent Efforts to effect such transfer, and argenx shall use Diligent Efforts to assume, such Clinical Study as promptly as practicable after the effective date of termination.

The costs of any such study shall be shared by the Parties pursuant to this Agreement until the effective date of termination, beyond which (1) costs of any study that argenx elects to have completed by Janssen shall be borne [...***...], (2) costs which are incurred in the winding down of any study shall be shared by the Parties in accordance with Section 8.4 of this Agreement and (3) costs of any study that argenx elects to have transferred to argenx shall be borne [...***...]. If argenx fails to notify Janssen which option (i) to (iii) it chooses within the prescribed time period set out in this Section 13.6.2(k), then Janssen may proceed on the basis that any Clinical Study should be wound down in accordance with Section 13.6.2(k)(ii).

(l) To the extent any Independent Study has been initiated by Janssen (i.e., first patient dosed) prior to the date of notice of termination, Janssen shall wind down such study as soon as practicable, subject to compliance with ethical and legal requirements, and shall bear any costs incurred in the winding down of such study.

(m) Following the date of notice of termination, Janssen shall have no obligation to initiate any Clinical Study of a Licensed Product or to commence any other new Development activities. If argenx elects to initiate any Clinical Study of a Licensed Product or to commence any other new Development activities after the date of notice of termination, then the costs of such activity shall be borne [...***...] and shall not be shared by the Parties pursuant to Section 8.4.

(n) Janssen shall cause to be assigned to argenx all worldwide rights in and to any Product Trademarks and Product Domain Names and Websites.

13.6.3 Transition Plan. As soon as practicable following receipt of notice of termination pursuant to this Article XIII, the Parties shall meet to discuss a transition plan which will set out in detail the steps and process to be followed on termination to achieve an efficient and orderly handover of Development, Manufacturing and Commercialization activities with respect to Licensed Products and to undertake the activities as set out in this Article XIII. Such transition plan will include, at Janssen's election, either a transfer of the existing OUS Territory Commercialization plans and customer contact information or a process by which the Parties will work together in good faith to develop new OUS Territory Commercialization plans and customer contact information for argenx. Except as expressly provided otherwise in this Article XIII, any costs incurred by the Parties between the date of notice of termination and the effective date of termination to conduct activities pursuant to this Article XIII shall be shared in accordance with this Agreement, as applicable, and thereafter each Party shall bear its own costs.

13.6.4 Expiration. If this Agreement expires in accordance with Section 13.1, the licenses and other rights granted by one Party to the other Party with respect to the Licensed

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

Products in the Field shall survive on a fully-paid, royalty-free, non-exclusive, irrevocable and perpetual basis.

13.6.5 Accrued Obligations. Expiration or termination of this Agreement for any reason shall not release either Party from any obligation or liability which, at the time of such expiration or termination, has already accrued to the other Party or which is attributable to a period before such expiration or termination.

13.6.6 Non-Exclusive Remedy. Notwithstanding anything herein to the contrary, expiration or termination of this Agreement by a Party shall be without prejudice to other remedies such Party may have at law or equity.

13.6.7 Survival. Except as expressly set forth in Section 14.1, in the event of any expiration or termination of this Agreement, the Sections and Articles set forth below, as well as any other Sections, Articles or defined terms referred to in such Sections or Articles or necessary to give them effect, shall survive:

Section 3.4 (Cross-License to Collaboration Know-How)

Section 8.4 (Shared Development Costs) – with respect to Development Costs incurred prior to the effective date of termination and, to the extent shared pursuant to Section 13.6.2(k), Development Costs incurred after the effective date of termination

Section 8.5 (U.S. Territory Royalties) – with respect to U.S. Collaboration Results prior to the effective date of termination or, to the extent provided in Section 13.6.2(g) or 13.6.2(i), U.S. Collaboration Results after the effective date of termination

Section 8.6 (OUS Territory Royalties) - with respect Net Sales of Licensed Products in the OUS Territory prior to the effective date of termination or, to the extent provided in Section 13.6.2(g) or 13.6.2(i), Net Sales of Licensed Product in the OUS Territory after the effective date of termination

Section 8.9 (Audits)

Section 8.10 (Tax Matters)

Section 8.11 (Currency Exchange)

Section 8.12 (Late Payments)

Section 9.1 (Reporting of Collaboration Inventions; Ownership and Disclosure)

Section 9.8.9 (Product Copyright Ownership)

Section 10.1 (Non-Disclosure and Non-Use)

Section 10.2 (Exceptions)

Section 10.3 (Authorized Disclosure)

Section 10.4 (Confidential Terms)

Section 10.6 (Prior Non-Disclosure Agreement)

Section 10.7 (Equitable Relief)

Section 11.8.2 (Additional Representations and Warranties of Janssen) – with respect to Licensed Compound or Licensed Product Commercialized by Janssen pursuant to Section 13.6.2(g) or 13.6.2(i) or Manufactured by or on behalf of Janssen pursuant to Section 13.6.2(h)

Section 11.10 (No Warranties)

Section 11.13 (Insurance)

Article XII (Indemnification)

Section 13.6 (Effects of Termination or Expiration)

Article XV (Dispute Resolution)

Section 16.1 (Assignment; Successors)

Section 16.3 (Parent Obligation)

Section 16.4 (Choice of Law)

Section 16.5 (Notices)

Section 16.6 (Severability)

Section 16.7 (Captions)

Section 16.8 (Further Actions) – with respect to the surviving rights and obligations of the Parties under this Agreement

Section 16.9 (Amendment; No Waiver)

Section 16.10 (Integration)

Section 16.11 (Independent Contractors; No Agency)

Section 16.12 (Submission to Jurisdiction)

Section 16.14 (No Consequential or Punitive Damages)

Section 16.17 (Construction)

Furthermore, any other provisions required to interpret the Parties' rights and obligations under this Agreement shall survive to the extent required. Except as otherwise provided in this Article XIII, all rights and obligations of the Parties under this Agreement, including any licenses and sublicenses granted under this Agreement, shall terminate upon expiration or termination of this Agreement for any reason.

ARTICLE XIV HSR COMPLIANCE

14.1 HSR Act Compliance. Notwithstanding anything to the contrary in this Agreement, this Agreement is binding upon the Parties as of the Execution Date to the extent permitted by the HSR Act. As used herein, the **"HSR Clearance Date"** means such time as: (a) the Parties shall have complied with all applicable requirements of the HSR Act; (b) the applicable waiting period under the HSR Act shall have expired or been terminated early; (c) no judicial or administrative proceeding opposing consummation of all or any part of this

Agreement or the Investment Agreement shall be pending; (d) no injunction (whether temporary, preliminary or permanent) prohibiting consummation of the transactions contemplated by this Agreement or the Investment Agreement (collectively, the “**Transactions**”) shall be in effect; and (e) no requirements or conditions shall have been formally requested or imposed by the DOJ or FTC in connection therewith that are not reasonably and mutually satisfactory to the Parties (collectively, the “**HSR Conditions**”). In the event that the HSR Clearance Date has not occurred by March 31, 2019, then either Party may terminate this Agreement upon notice, in which case, all provisions of this Agreement shall terminate and be of no force or effect whatsoever, except only that any liability of either Party for failing to comply with this Section 14.1 shall survive.

14.2 HSR Filing. Both Parties shall promptly file following the Execution Date (and in any event, within [...***...] after the Execution Date) their respective pre-merger notification and report forms (“**HSR Forms**”) with the United States Federal Trade Commission (“**FTC**”) and the United States Department of Justice (“**DOJ**”) pursuant to the HSR Act in connection with the Transactions to the extent applicable. Neither Party shall request early termination of the initial HSR Act waiting period in their respective HSR Form.

14.3 Cooperation.

14.3.1 The Parties shall use all reasonable efforts to promptly obtain the HSR Conditions for the consummation of the Transactions to the extent applicable and shall keep each other apprised of the status of any communications with, and any inquiries or requests for additional information from, the FTC and the DOJ and shall comply promptly with any such inquiry or request. The Parties shall instruct their respective counsel to coordinate and cooperate with each other and use commercially reasonable efforts to facilitate and expedite the identification and resolution of any such issues and, consequently, the expiration of the applicable HSR Act waiting period. In the context of this Section 14.3, all reasonable efforts and cooperation include counsel’s undertaking: (i) to reasonably keep each other informed of communications received from and submitted to personnel of the FTC, the DOJ or any other antitrust authority; and (ii) to confer with each other regarding appropriate contacts with and response to personnel of the FTC, the DOJ or any other antitrust authority and consider in good faith the views of the other Party, including all reasonable additions, deletions or changes suggested by the other Party; provided, however, Janssen shall have the principal responsibility for devising and implementing the strategy for obtaining the HSR Conditions and shall lead and direct all submissions to, meetings and communications with the FTC, the DOJ or any other party in connection with antitrust matters. Janssen shall be responsible for the applicable HSR Act filings fees in connection with the Investment Agreement and this Agreement to the extent applicable, and each Party shall be responsible for the costs and expenses of its own legal and other advice in relation to the HSR Forms submitted pursuant to the HSR Act therewith.

14.3.2 Janssen shall use its reasonable best efforts to take such actions as may be required under the HSR Act or other antitrust laws in order to satisfy the conditions set forth in this Section 14. Notwithstanding anything to the contrary in this Agreement, the terms “commercially reasonable efforts” or “reasonable best efforts” do not require that either Party (i) offer, negotiate, commit to or effect, by consent decree, hold separate order, trust or otherwise, the sale, divestiture, license or other disposition of any capital stock, assets, rights, products or

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

businesses of such Party or its Affiliates, (ii) agree to any restrictions on the activities of such Party or its Affiliates, or (iii) pay any material amount or take any other action to prevent, effect the dissolution of, vacate, or lift any decree, order, judgment, injunction, temporary restraining order, or other order in any suit or proceeding that would otherwise have the effect of preventing or delaying any of the Transactions.

ARTICLE XV DISPUTE RESOLUTION

15.1 Exclusive Dispute Resolution Mechanism. The Parties agree that the procedures set forth in this Article XV shall be the exclusive mechanism for resolving (i) any dispute that arises out of or in relation to or in connection with this Agreement, excluding any Committee Matter (which shall be subject to resolution under Section 2.8.1, 2.8.2 or 2.8.3, as applicable); and (ii) any issue relating to the interpretation, application, enforcement, termination or validity of this Agreement (any dispute or issue described in clause (i) or (ii), a “**Dispute**”). For clarity, a dispute regarding any of the following shall constitute a Dispute: (a) whether a matter is a Committee Matter; or (b) whether an exercise of final decision-making authority is made in accordance with Section 2.8.2, 8.7.1, 9.3, 9.4, 9.8.3 or 10.8.1, as applicable. Any Dispute shall be resolved in accordance with this Article XV.

15.2 Resolution by Executive Officers. In the event of any Dispute, the Parties shall first attempt in good faith to resolve such Dispute by negotiation and consultation between themselves. To initiate a negotiation, a Party shall give the other Party written notice of any Dispute not resolved in the normal course of business. In the event that such Dispute is not resolved within [...***...] after such notice is received (unless otherwise agreed by the Parties), either Party shall, by written notice to the other Party, refer the Dispute to the Executive Officers for attempted resolution by good faith negotiation within [...***...] after such notice is received (unless otherwise agreed by the Parties).

15.3 Arbitration.

15.3.1 Arbitration. Except as otherwise provided in this Agreement, any Dispute that has been referred to the Executive Officers for resolution in accordance with Section 15.2 and has not been resolved within the time specified in Section 15.2, shall be finally resolved by arbitration administered by the International Centre for Dispute Resolution (“**ICDR**”) in accordance with its International Arbitration Rules, except where those rules conflict with these provisions, in which case these provisions control. The language of the arbitration shall be English and the seat, or legal place of arbitration, shall be New York City, New York. All aspects of the arbitration shall be treated as confidential.

15.3.2 Panel. The number of arbitrators shall be three unless the aggregate damages sought by the claimant are stated to be less than [...***...], and the aggregate damages sought by the respondent/counterclaimant are stated to be less than [...***...], and neither side seeks equitable relief, in which case there shall be a single arbitrator. In the event there are three arbitrators, each Party shall appoint a person to serve as an arbitrator within [...***...] after the respondent submits its answer and counterclaims. The two party-appointed arbitrators shall then appoint the presiding arbitrator within [...***...] after the second party-appointed arbitrator’s

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

appointment. In the event there is one arbitrator, that arbitrator shall be appointed by the Parties by mutual agreement within [...***...] after the respondent submits its answer and any counterclaims. If any arbitrators are not selected within these time periods, the ICDR shall, at the written request of any Party, complete the appointments that have not been made. Each arbitrator shall be a lawyer with at least fifteen (15) years' experience with a law firm or corporate law department of over twenty five (25) lawyers or who was a judge of a court of general jurisdiction.

15.3.3 Timing. The Parties agree to cooperate (i) to meet with the arbitrator(s) within [...***...] of appointment; and (ii) to agree at that meeting or before upon procedures for discovery and as to the conduct of the hearing which will result in the hearing being concluded within no more than [...***...] after the first meeting with the arbitrator(s) and in the award being rendered within [...***...] of the conclusion of the hearings, or of any post-hearing briefing, which briefing will be completed by both sides within [...***...] after the conclusion of the hearings. In any event, the Parties shall endeavor in good faith to complete any arbitration under this Section 15.3 within [...***...] following the appointment of the arbitrator(s).

15.3.4 Discovery. In the event the Parties cannot agree upon procedures for discovery and conduct of the hearing meeting the schedule set forth in Section 15.3.3, then the arbitrator(s) shall set dates for the hearing, any post-hearing briefing, and the issuance of the award in accordance with the Section 15.3.3 schedule as closely as practical. The arbitrator(s) shall provide for discovery according to those time limits, giving recognition to the understanding of the Parties that they contemplate reasonable discovery, including document demands and depositions, but that such discovery will be limited so that the schedule set forth in Section 15.3.3 may be met without undue burden. The arbitrator(s) shall determine what discovery will be permitted, consistent with the goal of limiting the cost and time which the Parties must expend for discovery, provided that the arbitrator(s) shall permit such discovery as the arbitrator(s) deem necessary to permit an equitable resolution of the dispute, which may in the arbitrator(s)' discretion include requests for admission or interrogatories. Any written evidence originally in a language other than English shall be submitted in English translation accompanied by a copy of the document in its original language. If the document is lengthy and relevant only in part, it is sufficient to translate only relevant parts, provided that the arbitrator(s) may require a fuller or a complete translation at the request of any party or on its own initiative. The arbitrator(s) shall have power to exclude evidence on grounds of hearsay, prejudice beyond its probative value, redundancy, or irrelevance and no award shall be overturned by reason of any ruling on evidence. The hearings shall be transcribed and the transcript made available to the Parties.

15.3.5 Motions; Independent Expert. The arbitrator(s) are expressly empowered to decide dispositive motions in advance of any hearing, including motions to dismiss and motions for summary judgment, and shall endeavor to decide such motions as would a Federal District Judge sitting in the jurisdiction whose substantive law governs as set forth in Section 15.3.6. The arbitrator(s) may engage an independent expert with experience in the subject matter of the dispute to advise the arbitrator(s), but final decision-making authority shall remain in the arbitrator(s).

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

15.3.6 Decision of the Arbitrator(s). The arbitrator(s) shall decide the issues presented in accordance with the substantive law of New York and may not apply principles such as “amiable compositeur” or “natural justice and equity.” The arbitrator(s) shall render a written opinion stating the reasons upon which the award is based. No punitive or exemplary damages may be granted by the arbitrator(s). The Parties agree that the decision of the arbitrator(s) shall be the sole, exclusive and binding remedy between them regarding any and all disputes, controversies, claims and counterclaims presented to the arbitrator(s). The existence and content of the arbitral proceedings and any rulings or award shall be kept confidential and not be made public by either Party without the joint written consent of the Parties, except to the extent either Party is required to disclose such information by applicable Laws (or applicable rules of a public stock exchange) or disclosure is required to enforce an award, or to pursue an action in aid of arbitration or for injunctive relief. Notwithstanding anything to the contrary in this Agreement, either Party may disclose matters relating to the arbitration or the arbitral proceedings to its Affiliates, and its and its Affiliates’ advisors, to the extent reasonably necessary for the preparation or presentation of a claim or defense in such arbitration, each of whom before such disclosure must be bound under a written agreement containing confidentiality provisions that are consistent with those set forth in this Agreement. The costs of such arbitration, including administrative and arbitrator(s)’ fees, and the fees of any expert retained by the arbitrator(s), shall be shared [...***...]. The Parties hereby opt out of the provision of the ICDR Rules empowering the tribunal to allocate the costs of the arbitration between the Parties.

15.3.7 Courts. Any award of the arbitrator(s) may be entered in any court of competent jurisdiction for a judicial recognition of the decision and applicable orders of enforcement, and each Party may apply to any court of competent jurisdiction for appropriate temporary injunctive relief to avoid irreparable harm, maintain the status quo, or preserve the subject matter of the arbitration, in each case pending resolution of any arbitration proceeding. Without limiting the foregoing, the Parties consent to the jurisdiction of the Federal District Court for the district at the place of arbitration for the enforcement of these provisions and the entry of judgment on any award rendered under this Agreement.

15.3.8 EACH PARTY HERETO WAIVES ITS RIGHT TO TRIAL BY JURY OF ANY ISSUE WITHIN THE SCOPE OF THE AGREEMENT TO ARBITRATE AS SET FORTH IN SECTION 15.3.1.

ARTICLE XVI MISCELLANEOUS

16.1 Assignment; Successors. Neither Party may assign this Agreement or any of its rights or obligations under this Agreement without the written consent of the other Party; provided, however, that either Party may assign this Agreement in its entirety without such consent (but with notice to the other Party following such assignment), to: (a) an Affiliate, as long as the assignee remains an Affiliate of the assigning Party, provided that the assigning Party shall remain responsible for the performance of, and primarily liable under, this Agreement notwithstanding such assignment; or (b) a Third Party that acquires all or substantially all of the business or consolidated assets of such Party (whether by merger, reorganization, acquisition, sale or otherwise); provided, in each case ((a) or (b)), that if such assignment would cause

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

adverse tax consequences to the non-assigning Party (or such Party's Affiliates), as reasonably demonstrated by the non-assigning Party to the assigning Party, the Parties agree to cooperate reasonably to enable such assignment in a manner reasonably satisfactory to the non-assigning Party, including, if appropriate, indemnification by the assigning Party, [...***...]. No assignment of this Agreement shall be valid and effective unless and until the assignee agrees in writing to be bound by the terms and conditions of this Agreement. The terms and conditions of this Agreement shall be binding on and inure to the benefit of the successors and permitted assigns of the Parties. Any assignment of this Agreement not in accordance with this Section 16.1 shall be null and void.

16.2 argenx or Parent Change of Control.

[...***...].

16.3 Parent Obligation.

16.3.1 Parent irrevocably and unconditionally:

(a) guarantees to Janssen the full, prompt and complete performance by argenx of all of argenx's obligations under this Agreement;

(b) undertakes with Janssen that if argenx does not pay any amount or perform any obligation when due under or in connection with this Agreement, Parent shall pay that amount or perform or procure the performance of that obligation as if Parent were the principal obligor; and

(c) undertakes to indemnify and keep indemnified Janssen against any cost, loss or liability suffered by Janssen as a consequence of a breach by argenx of any obligation guaranteed by Parent and the amount of the cost, loss or liability shall be equal to the amount that Janssen would otherwise have been entitled to recover from argenx.

16.3.2 The guarantee contained in this Section 16.3 shall apply in respect of all obligations of argenx under this Agreement.

16.3.3 The obligations of Parent shall not be affected by any termination or variation of this Agreement or any amendment, novation, supplement or extension of this Agreement.

16.4 Choice of Law. This Agreement shall be governed by and interpreted under, and any court action in accordance with Section 16.12 shall apply, the laws of the State of New York excluding: (i) its conflicts of laws principles; (ii) the United Nations Conventions on Contracts for the International Sale of Goods; (iii) the 1974 Convention on the Limitation Period in the International Sale of Goods (the "**1974 Convention**"); and (iv) the Protocol amending the 1974 Convention, done at Vienna April 11, 1980. Notwithstanding anything to the contrary herein, the interpretation and construction of any Patent Rights shall be governed in accordance with the laws of the jurisdiction in which such Patent Rights were filed or granted, as the case may be.

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

16.5 Notices. All notices, requests, demands, waivers and other communications required or permitted to be given under this Agreement shall be in writing and deemed given if delivered personally or sent by overnight courier to the Parties hereto, in each case with a copy sent via electronic mail (if an electronic mail address of the party to whom the relevant communication is being made has been designated pursuant hereto and remains a working electronic mail address), at the following addresses (or at such other addresses as shall be specified by like notice):

If to argenx:

argenx BVBA
Industriepark Zwijnaarde 7
9052 Zwijnaarde
Attention: CEO and General Counsel

If to Janssen:

Cilag GmbH International
Gubelstrasse 34
6300 Zug
Switzerland
Attention: Chairperson of Managing Officers

With copies to:

Johnson & Johnson Law Department
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
Attention: General Counsel, Pharmaceuticals

All such notices, requests, demands, waivers and other communications shall be deemed to have been received, if by personal delivery or overnight courier, on the day delivered or, if by facsimile, on the next Business Day following the day on which such facsimile was sent; provided, in each case that a copy is also sent by electronic mail in accordance with the first sentence of this Section 16.5.

16.6 Severability. The provisions of this Agreement shall be deemed severable and the invalidity or unenforceability of any provision shall not affect the validity or enforceability of the other provisions hereof. If any provision of this Agreement, or the application of such provision to any Person or any circumstance, is invalid or unenforceable, (a) a suitable and equitable provision shall be substituted therefor in order to carry out, so far as may be valid and enforceable, the intent and purpose of such invalid or unenforceable provision and (b) the remainder of this Agreement and the application of such provision to other Persons or circumstances shall not be affected by such invalidity or unenforceability, nor shall such

invalidity or unenforceability affect the validity or enforceability of such provision, or the application of such provision, in any other jurisdiction.

16.7 Captions. All captions herein are for convenience only and shall not be interpreted as having any substantive meaning.

16.8 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments and to do all such other acts as may be necessary or appropriate to carry out the purposes and intent of this Agreement.

16.9 Amendment; No Waiver. No waiver, modification or amendment of any provision of this Agreement will be valid or effective unless made in writing and signed by a duly authorized officer of each Party (or, to the extent applicable, Parent). The failure of either Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement will not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition.

16.10 Integration. This Agreement constitutes the entire agreement between the Parties hereto with respect to the subject matter of this Agreement and supersedes all previous agreements, whether written or oral. Notwithstanding the authority granted to the Committees and any Working Groups under this Agreement, this Agreement may be amended only in writing signed by properly authorized representatives of each of argenx and Janssen. In the event of a conflict between the GDP or the U.S. Commercialization Plan, on the one hand, and this Agreement, on the other hand, the terms of this Agreement shall govern.

16.11 Independent Contractors; No Agency. Neither Party shall have any responsibility for the hiring, firing or compensation of the other Party's employees or for any employee benefits. No employee or representative of a Party, including the argenx sales representatives, shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's written approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, Janssen's legal relationship under this Agreement to argenx, and argenx's legal relationship under this Agreement to Janssen, shall be that of independent contractor and shall not constitute a partnership, joint venture or agency, and no Party shall take a position, or cause or permit any of its Affiliates, to take any position inconsistent with this Section 16.11 (including in the filing of tax returns and in the course of any audit, review or litigation) unless otherwise required by a determination of a relevant tax authority.

16.12 Submission to Jurisdiction. Each Party (i) submits to the jurisdiction of the state and federal courts sitting in New York, New York, with respect to actions or proceedings arising out of or relating to this Agreement in which a Party brings an action in aid of arbitration, (ii) agrees that all claims in respect of such action or proceeding may be heard and determined in any such court and (iii) agrees not to bring any action or proceeding arising out of or relating to this Agreement in any other court, other than an action or proceeding seeking injunctive relief or brought to enforce an arbitration ruling issued pursuant to Section 15.3. Each Party waives any defense of inconvenient forum to the maintenance of any action or proceeding so brought. Each

Party may make service on the other Party by sending or delivering a copy of the process to the Party to be served at the address and in the manner provided for the giving of notices in Section 16.4. Nothing in this Section 16.9, however, shall affect the right of any Party to serve legal process in any other manner permitted by Law.

16.13 Execution in Counterparts; Facsimile Signatures. This Agreement may be executed in counterparts, each of which counterparts, when so executed and delivered, shall be deemed to be an original, and all of which counterparts, taken together, shall constitute one and the same instrument even if both Parties have not executed the same counterpart. Signatures provided by facsimile transmission or by email of a .pdf attachment shall be deemed to be original signatures.

16.14 No Consequential or Punitive Damages.

16.14.1 NEITHER PARTY HERETO NOR ANY OF ITS AFFILIATES WILL BE LIABLE FOR INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, EXEMPLARY, PUNITIVE OR MULTIPLE DAMAGES ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS UNDER THIS AGREEMENT, OR FOR ANY LOSS OR INJURY TO A PARTY'S OR ITS AFFILIATES' PROFITS, BUSINESS OR GOODWILL ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES.

16.14.2 [...***...].

16.15 Performance by Affiliates. To the extent that this Agreement imposes obligations on Affiliates of a Party, such Party agrees to cause its Affiliates to perform such obligations. Each Party may use one or more of its Affiliates to perform its obligations and duties under this Agreement, provided that such Party provides prompt written notice to the other Party (subject to Section 3.3) and, further provided that such Party shall remain liable under this Agreement for the prompt payment and performance of all of its obligations under this Agreement.

16.16 Force Majeure. A Party shall not be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement, except for the payment of any amounts under this Agreement, when such failure or delay is caused by or results from causes beyond the reasonable control of such Party, including fires, floods, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorism, insurrections, riots, civil commotion, acts of God or acts, omissions or delays in acting by any Governmental Authority (each, a **"Force Majeure Event"**).

16.17 Construction. References to Sections include subsections, which are part of the related Section. Except as otherwise explicitly specified to the contrary, (i) references to a Section, Article, Exhibit or Schedule means a Section or Article of, or a Schedule or Exhibit to this Agreement and all subsections thereof, unless another agreement is specified; (ii) references to a particular statute or regulation include all rules and regulations thereunder and any successor statute, rules or regulations then in effect, in each case, including the then-current amendments thereto; (iii) words in the singular or plural form include the plural and singular form,

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

respectively; (iv) unless the context requires a different interpretation, the word “or” has the inclusive meaning that is typically associated with the phrase “and/or”; (v) terms “including,” “include(s),” “such as,” and “for example” as used in this Agreement mean including the generality of any description preceding such term and will be deemed to be followed by “without limitation”; (vi) whenever this Agreement refers to a number of days, such number will refer to calendar days unless Business Days are specified; (vii) when a time period set forth in this Agreement ends on a day that is not a Business Day, the last day of such time period shall be the next Business Day; (viii) references to a particular Person include such Person’s successors and assigns to the extent not prohibited by this Agreement; (ix) all words used in this Agreement will be construed to be of such gender or number as the circumstances require; (x) the words “hereof,” “herein,” “hereby” and derivative or similar words refer to this Agreement (including any Exhibits), and (xi) neither Party or its Affiliates shall be deemed to be acting “on behalf of” the other Party under this Agreement, except to the extent expressly otherwise provided.

[Remainder of this page intentionally blank.]

IN WITNESS WHEREOF, each Party has caused this Agreement to be duly executed by its authorized representative under seal, in duplicate on the dates written herein below.

ARGENX BVBA

By: /s/ Tim Van Hauwermeiren
Name: Tim Van Hauwermeiren
Title: CEO

By: /s/ Peter Verhaeghe
Name: Peter Verhaeghe
Title: Chairman of the Board

**ARGENX SE
(solely for purposes of Sections 16.2 and 0)**

By: /s/ Tim Van Hauwermeiren
Name: Tim Van Hauwermeiren
Title: CEO

By: /s/ Peter Verhaeghe
Name: Peter Verhaeghe
Title: Chairman of the Board

CILAG GMBH INTERNATIONAL

By: /s/ Ludo Ooms
Name: Ludo Ooms
Title: Managing Officer

By: /s/ Andrea Ostinelli
Name: Andrea Ostinelli
Title: Managing Officer

LIST OF EXHIBITS AND SCHEDULES

EXHIBIT	TITLE
A	Johnson & Johnson Universal Calendar
B	Initial GDP
C	Existing Third Party Agreements
D	Financial Exhibit
E	Cost of Goods
F	CMC Plan
G	argenx Press Release
H	Janssen Press Release

SCHEDULE	TITLE
1.10	argenx Patent Rights
1.80	Lead Anti-CD70 Antibody
1.118	Specified Manufacturing Patent Rights

EXHIBIT A

UNIVERSAL CALENDAR

[...***...]

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

EXHIBIT B

GLOBAL DEVELOPMENT PLAN

[...***... (two pages omitted)]

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

EXHIBIT C

EXISTING THIRD PARTY AGREEMENTS

[...***...]

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

EXHIBIT D

FINANCIAL EXHIBIT

[...***...]

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

[...***... (five pages omitted)]

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

EXHIBIT E

COST OF GOODS

[...***...]

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

[...***... (three pages omitted)]

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

EXHIBIT F

CMC PLAN

[...***... (three pages omitted)]

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

EXHIBIT G

ARGENX PRESS RELEASE

Regulated information – Inside information

argenx enters exclusive global collaboration and license agreement with Cilag GmbH International, an affiliate of Janssen, for cusatuzumab (ARGX-110)

- ☐ **Collaboration to develop cusatuzumab in AML, MDS and other hematological malignancies in deal totaling up to \$1.6 billion potentially**
- ☐ **Janssen to pay argenx \$300 million in upfront cash payment**
- ☐ **Johnson & Johnson Innovation – JJDC, Inc. (JJDC) to make \$200 million equity investment in argenx**
- ☐ **argenx to retain right to co-promote cusatuzumab in the U.S. and share economics 50-50 on a royalty basis**
- ☐ **Conference call to be held today at 5:00 PM CET (11:00 AM ET/8:00 AM PT)**

December 3, 2018

Breda, the Netherlands / Ghent, Belgium – argenx (Euronext & Nasdaq: ARGX), a clinical-stage biotechnology company developing a deep pipeline of differentiated antibody-based therapies for the treatment of severe autoimmune diseases and cancer, today announced an exclusive, global collaboration and license agreement for cusatuzumab (ARGX-110), a highly differentiated anti-CD70 SIMPLE Antibody[®], with Cilag GmbH International, an affiliate of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Cusatuzumab is currently in development in a Phase 1/2 combination study with Vidaza[®] for newly diagnosed, elderly patients with acute myeloid leukemia (AML) and high-risk myelodysplastic syndrome (MDS) who are unfit for chemotherapy. Data announced today from the Phase 1/2 study will be presented during a workshop being held in conjunction with the 60th American Society of Hematology Annual Meeting and Exposition.

“AML continues to be an aggressive and deadly cancer of the blood and bone marrow with very high relapse rates. Cusatuzumab offers a novel mode of action targeting leukemic stem cells, which are a known driver of the relapse mechanism, and has shown a compelling response rate and tolerability profile to date,” said Tim Van Hauwermeiren, CEO of argenx. “Janssen is an ideal strategic partner for us to develop this differentiated investigational therapy given its extensive clinical, regulatory and commercial expertise in oncology, and we believe that through this collaboration we are best positioned to reach the broadest number of patients as quickly as possible. The collaboration also strengthens our financial position, enabling our growth into a fully-integrated organization as we continue to exploit our deep pipeline of wholly-owned product candidates, including our lead product candidate efgartigimod which we are evaluating in four severe autoimmune indications.”



argenx and Janssen have agreed to a joint global clinical development plan to evaluate cusatuzumab in AML, MDS and other potential future indications.

Under the terms of the agreement, Janssen will pay argenx \$300 million in an upfront payment and JJDC will purchase \$200 million (1,766,899) of newly issued shares representing 4.68% of argenx's outstanding shares at a price of €100.02 per share (\$113.19). argenx will be eligible to receive potentially up to \$1.3 billion in development, regulatory and sales milestones, in addition to tiered, double-digit royalties. Janssen will be responsible for commercialization worldwide. argenx retains the option to participate in commercialization efforts in the U.S., where the companies have agreed to share economics 50/50 on a royalty basis and outside the U.S., Janssen will pay double-digit sales royalties to argenx.

The transactions are subject to customary closing conditions, including clearance under the Hart-Scott-Rodino Antitrust Improvements Act, and expected to close in the first quarter of 2019.

Conference call details

Dial-in 5 minutes before the start of the conference call and use the conference **ID: 5278105**

Dial-in numbers:

☐ International dial-in:	+44 (0) 207 192 8000
☐ US:	16315107495 (or 18669661396)
☐ UK:	08445718892
☐ Belgium:	024009874
☐ The Netherlands:	0207143545
☐ France:	0176700794
☐ Sweden:	0850692180
☐ Switzerland:	0315800059

About Cusatuzumab

Cusatuzumab (ARGX-110) is an investigational SIMPLE Antibody™ targeting CD70, an immune checkpoint target involved in hematological malignancies, several solid tumors and severe autoimmune diseases. Cusatuzumab is designed to: block CD70, kill cancer cells expressing CD70 through complement dependent cytotoxicity, enhanced antibody-dependent cell-mediated phagocytosis and enhanced antibody-dependent cell-mediated cytotoxicity, and restore immune surveillance against solid tumors (*Silence K. et al. mAbs 2014; 6 (2):523-532*).



Cusatuzumab is currently being evaluated in patients with hematological malignancies, including a Phase 1/2 trial in combination with Vidaza in patients with newly diagnosed acute myeloid leukemia and high-risk myelodysplastic syndromes and the Phase 2 part of a Phase 1/2 trial in patients with relapsed/refractory cutaneous T-cell lymphoma (CTCL). Preclinical work on cusatuzumab in AML was performed in collaboration with the Tumor Immunology Lab of Prof. A. F. Ochsenbein at the University of Bern, who won, together with Prof. Manz at the University Hospital of Zürich, the prestigious 2016 *Otto Naegeli Prize* for his breakthrough research on CD70/CD27 signaling with therapeutic potential for cancer patients.

About argenx

argenx is a clinical-stage biotechnology company developing a deep pipeline of differentiated antibody-based therapies for the treatment of severe auto-immune diseases and cancer. The company is focused on developing product candidates with the potential to be either first-in-class against novel targets or best-in-class against known, but complex, targets in order to treat diseases with a significant unmet medical need. argenx's ability to execute on this focus is enabled by its suite of differentiated technologies. The SIMPLE Antibody™ Platform, based on the powerful llama immune system, allows argenx to exploit novel and complex targets, and its three complementary Fc engineering technologies are designed to expand the therapeutic index of its product candidates.

www.argenx.com

For further information, please contact:

Joke Comijn, Director Corporate Communications & Investor Relations (EU)

+32 (0)477 77 29 44

+32 (0)9 310 34 19

info@argenx.com

Beth DelGiacco, VP Investor Relations (US)

+1 518 424 4980

bdelgiacco@argenx.com

Forward-looking Statements

The contents of this announcement include statements that are, or may be deemed to be, "forward-looking statements." These forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "intends," "may," "will," or "should" and include statements argenx makes concerning the intended results of its strategy and its collaboration with Janssen expected to



close in the first quarter of 2019, including argenx's ability to receive the expected benefits thereof such as future milestones and royalty payments.. By their nature, forward-looking statements involve risks and uncertainties and readers are cautioned that any such forward-looking statements are not guarantees of future performance. argenx's actual results may differ materially from those predicted by the forward-looking statements as a result of various important factors, including argenx's expectations regarding its the inherent uncertainties associated with competitive developments, preclinical and clinical trial and product development activities and regulatory approval requirements; argenx's reliance on collaborations with third parties; estimating the commercial potential of argenx's product candidates; argenx's ability to obtain and maintain protection of intellectual property for its technologies and drugs; argenx's limited operating history; and argenx's ability to obtain additional funding for operations and to complete the development and commercialization of its product candidates. A further list and description of these risks, uncertainties and other risks can be found in argenx's U.S. Securities and Exchange Commission (SEC) filings and reports, including in argenx's most recent annual report on Form 20-F filed with the SEC as well as subsequent filings and reports filed by argenx with the SEC. Given these uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. These forward-looking statements speak only as of the date of publication of this document. argenx undertakes no obligation to publicly update or revise the information in this press release, including any forward-looking statements, except as may be required by law.

EXHIBIT H

JANSSEN PRESS RELEASE

Media Contacts:

Brian Kenney
Phone: 215-620-0111
Email: bkenney1@its.jnj.com

Satu Glawe
Phone: +49 172 294 6264
Email: sschmid2@its.jnj.com

Investor Contacts:

Christopher DelOrefice
Phone: 732-524-2955

Lesley Fishman
Phone: 732-524-3922

Janssen Affiliate Cilag GmbH International Enters Worldwide Collaboration and License Agreement with argenx for Cancer Immunotherapy Cusatuzumab

Addition of investigational antibody cusatuzumab to robust oncology pipeline reflects Janssen's commitment to advance innovative therapies for blood cancers where unmet medical needs remain

Zug, Switzerland (December X, 2018) - Cilag GmbH International, an affiliate of the Janssen Pharmaceutical Companies of Johnson & Johnson, announced today it has entered into a worldwide collaboration and license agreement with argenx BVBA and argenx SE, to develop and commercialize cusatuzumab (ARGX-110). Cusatuzumab is an investigational therapeutic antibody that targets CD70, an immune checkpoint implicated in numerous cancers, including hematological malignancies. This first-in-class SIMPLE Antibody™ is currently in Phase 1/2 clinical trials to evaluate its safety, tolerability and efficacy in the treatment of acute myeloid leukemia (AML) and high-risk myelodysplastic syndromes (MDS). Separately, an equity investment by Johnson & Johnson Innovation - JJDC, Inc. (JJDC) will be made in argenx SE.

Updated data from the ongoing Phase 1/2 clinical study evaluating cusatuzumab in combination with azacytidine in newly diagnosed patients with AML unfit for intensive chemotherapy are being presented during an argenx workshop held in conjunction with the 60th Annual Meeting of the American Society of Hematology (ASH). The data showed promising anti-leukemia activity in these patients.ⁱ

“We believe CD70 is an important target in the biology of select cancers, and we are eager to accelerate the development of this innovative antibody together with argenx,” said Yusri Elsayed, M.D., MHSc, Ph.D., Vice President, Hematologic Malignancies Disease Area Leader, Janssen Research & Development, LLC. “Phase 1/2 data in acute myeloid leukemia showed the activity of cusatuzumab, and we hope to translate these findings to improve outcomes for patients with myeloid malignancies.”

Under the terms of the agreement, Janssen will jointly develop and globally commercialize cusatuzumab in AML, MDS, and potential future indications, as well as next generation CD70 antibodies. Janssen will make an upfront payment of \$300 million USD and additional payments based upon the achievement of certain development, regulatory and sales milestones. Janssen is responsible for commercialization worldwide. In the U.S., argenx has the option to participate in

commercialization efforts. Janssen will record worldwide net trade sales. In the U.S., the companies have agreed to share the economics 50/50, and outside the U.S., Janssen will pay double-digit sales royalties to argenx.

“We are pleased to enter into this strategic partnership with argenx and advance a promising antibody for the treatment of AML and other blood cancers where current treatment is limited and effective new interventions are needed for patients,” said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development, LLC. “The addition of cusatuzumab deepens our portfolio and adds to our expertise in oncology, and more importantly, it reflects our commitment to combine Janssen’s strengths with those of other outstanding teams to advance science that we believe can transform the treatment of diseases and the lives of patients worldwide.”

The transactions are subject to customary closing conditions, including clearance under the Hart-Scott-Rodino Antitrust Improvements Act, and expected to close in the first quarter of 2019.

About Cusatuzumab

Cusatuzumab (ARGX-110) is an investigational SIMPLE Antibody™ targeting CD70, an immune checkpoint target involved in hematological malignancies, several solid tumors and severe autoimmune diseases. Cusatuzumab is designed to: block CD70; kill cancer cells expressing CD70 through complement-dependent cytotoxicity, enhanced antibody-dependent cell-mediated phagocytosis and enhanced antibody-dependent cell-mediated cytotoxicity; and restore immune surveillance against solid tumors. ⁱⁱ

About AML

Acute myeloid leukemia (AML) starts in the bone marrow (the soft inner part of certain bones, where new blood cells are made), but most often it quickly moves into the blood, as well. It can sometimes spread to other parts of the body including the lymph nodes, liver, spleen, central nervous system (brain and spinal cord), and testicles. ⁱⁱⁱ

About MDS

Myelodysplasia Syndromes (MDS) are a group of diverse bone marrow disorders in which the bone marrow does not produce enough healthy blood cells. MDS is often referred to as a “bone marrow failure disorder”. MDS is primarily a disease of the elderly (most patients are older than age 65), but MDS can affect younger patients as well. ^{iv}

About Cilag GmbH International

Cilag GmbH International was founded in 1984 as the supply chain coordination center for the pharmaceuticals sector in Zug. Today, it offers a wide range of support activities for numerous Swiss companies in the pharmaceutical, consumer and medical device and diagnostics segments of the Johnson & Johnson Family of Companies.

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science. We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at www.janssen.com. Follow us at [@JanssenGlobal](https://twitter.com/JanssenGlobal). Cilag GmbH International and Janssen Research & Development, LLC are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

About Johnson & Johnson Innovation - JJDC, Inc.

Johnson & Johnson Innovation - JJDC, Inc. (JJDC) is the strategic venture capital arm of Johnson & Johnson and a long-term investment partner to global healthcare entrepreneurs. Founded in 1973, JJDC continues a legacy of customizing deals for data-driven companies across the continuum of healthcare, with the goal of turning great ideas into transformative new pharmaceutical, medical device and consumer healthcare products. Visit our website at www.iidc.com.

About Johnson & Johnson

At Johnson & Johnson, we believe good health is the foundation of vibrant lives, thriving communities and forward progress. That's why for more than 130 years, we have aimed to keep people well at every age and every stage of life. Today, as the world's largest and most broadly-based health care company, we are committed to using our reach and size for good. We strive to improve access and affordability, create healthier communities, and put a healthy mind, body and environment within reach of everyone, everywhere. We are blending our heart, science and ingenuity to profoundly change the trajectory of health for humanity.

###

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development and the potential benefits and treatment impact of the collaboration and license agreement with Argenx to develop and commercialize cusatuzumab (ARGX-110). The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Cilag GmbH International, Janssen Research & Development, LLC, Johnson & Johnson Innovation - JJDC, Inc. any of the other Janssen Pharmaceutical Companies of Johnson & Johnson and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: the satisfaction of closing conditions for the transactions, including clearance under the Hart-Scott-Rodino Antitrust Improvements Act; the potential that the expected benefits and opportunities related to the collaboration may not be realized or may take longer to realize than expected; challenges inherent in new product development, including the uncertainty of clinical success and obtaining regulatory approvals; competition, including technological advances, new products and patents attained by competitors; uncertainty of commercial success for new products; the ability of the company to successfully execute strategic plans; impact of business combinations and divestitures; challenges to patents; changes in behavior and spending patterns or financial

distress of purchasers of health care products and services; and global health care reforms and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 31, 2017, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. Neither the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

-
- ⁱ Ochsenbein, Adrian (2018, December). 2680 Argx-110 Targeting CD70, in Combination with Azacitidine, Shows Favorable Safety Profile and Promising Anti-Leukemia Activity in Newly Diagnosed AML Patients in an Ongoing Phase 1/2 Clinical Trial. American Society of Hematology Annual Meeting, San Diego, CA, U.S.
 - ⁱⁱ Silence K. et al. *mAbs* 2014; 6 (2):523-532
 - ⁱⁱⁱ What Is Acute Myeloid Leukemia (AML)?" American Cancer Society. Retrieved from <https://www.cancer.org/cancer/acute-myeloid-leukemia/about/what-is-aml.html>
 - ^{iv} What is MDS?" MDS Foundation. Retrieved <https://www.mds-foundation.org/what-is-mds/>
-

SCHEDULE 1.10

ARGENX PATENT RIGHTS

[...***...]

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

[...***... (three pages omitted)]

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

SCHEDULE 1.80

LEAD ANTI-CD70 ANTIBODY – HUMAN IgG1

[...***...]

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

[...***...]

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

SCHEDULE 1.118

SPECIFIED MANUFACTURING PATENTS

[...***... (10 pages omitted)]

* Confidential Information, indicated by [...***...], has been omitted from this filing and filed separately with the U.S. Securities and Exchange Commission.

2 December 2018

INVESTMENT AGREEMENT

Between

argenx SE

and

Johnson & Johnson Innovation – JJDC, Inc.

(the *Agreement*)

INVESTMENT AGREEMENT

BETWEEN:

- (1) **argenx SE**, a European company with limited liability (“*societas europaea*” or SE), incorporated under the laws of the Netherlands, having its official seat in Rotterdam, the Netherlands, its office address at Willemstraat 5, 4811 AH Breda, the Netherlands and registered with the Dutch Chamber of Commerce under number 24435214 (the **Issuer**); and
- (2) **Johnson & Johnson Innovation – JJDC, Inc.**, a company organised and existing under the laws of the State of New Jersey (U.S.A.), having its registered office at 410 George Street, New Brunswick, NJ 08901, USA (the **Investor**).

The Issuer and the Investor are hereinafter each referred to as a **Party** and collectively as the **Parties**.

WHEREAS:

- (A) On even date herewith the Issuer, argenx BVBA and Cilag GmbH International (an Affiliate of the Investor) entered into a Collaboration and License Agreement with respect to Licensed Compounds and Licensed Products (each as defined in the Collaboration and License Agreement);
- (B) The Issuer wishes to obtain additional equity financing inter alia in order to finance the further development of its pipeline or for general corporate purposes either through an equity investment by selected parties or through other means including public offerings or private placements;
- (C) On the terms and conditions of this Agreement, the Issuer undertakes to issue, offer and sell an aggregate of 1,766,899 Investment Securities, and deliver to the Investor or the Investor’s custodian 1,766,899 Investment Securities, and the Investor undertakes to subscribe to and pay for such number of Investment Securities at the Issue Price.

IT HAS BEEN AGREED AS FOLLOWS:

1 Definitions and interpretation

1.1 Definitions

- 1.1.1 In this Agreement, the following words and expressions shall have the following meaning, save where the context requires otherwise:

Admission means the admission to trading of the Investment Securities on the regulated market Euronext Brussels organised by Euronext Brussels NV/SA;

Affiliate means, with respect to a Person, any other Person directly or indirectly controlling, controlled by, or under common control with, such first Person at any time for so long as such Person controls, is controlled by or is under common control with such first Person. For purposes of this definition, the term “control” (including the correlative meanings of the terms “controlled by” and “under common control with”), as used with respect to any Person, means (i) in the case of a Person that is a corporate entity, direct or indirect

ownership of 50% or more of the stock or shares having the right to vote for the election of directors and (ii) in the case of a Person that is an entity, but is not a corporate entity, the possession, directly or indirectly, of the power to direct or cause the direction of the management policies of such Person, whether through the ownership of voting securities, or by contract, or otherwise;

Antitrust Laws means the HSR Act and any other antitrust laws applicable to the Transactions;

Business Day means a day, other than a Saturday and a Sunday, on which commercial banks are open for business in the Netherlands and in the United States;

Change of Control has the meaning given in the Collaboration and License Agreement;

Closing Date has the meaning given in Clause 4.1;

Collaboration and License Agreement means the collaboration and license agreement of even date herewith between the Issuer, argenx BVBA and Cilag GmbH International;

Encumbrance means a mortgage, charge, pledge, lien, option, restriction, right of first refusal, right of pre-emption, third party right or interest, other encumbrance or security interest of any kind, or another type of preferential arrangement (including, without limitation, a title transfer or retention arrangement) having similar effect or any irrevocable mandate or undertaking to create any of the same;

Governmental Authority means any national, federal, state or local government, or political subdivision thereof, or any multinational organization or authority or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof), or any governmental arbitrator or arbitral body;

HSR Act means United States Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rules and regulations promulgated thereunder;

Investment Securities means Ordinary Shares;

Issue Price has the meaning given in Clause 2.2;

Lock-Up Period has the meaning given in Clause 6.2.1;

Notary means the Dutch civil-law notary before whom the deed of issue regarding the Investment Securities will be executed;

Notary Letter means a detailed letter of instruction to the Notary on customary terms to be agreed between the Investor and the Issuer regarding the procedures of payment of the aggregate Issue Price by the Investor to the Issuer at Closing;

Ordinary Share means an ordinary share of the Issuer each with a nominal value of EUR 0.10;

Person means any individual, corporation (including not-for-profit), general or limited partnership, limited liability company, joint venture, estate, trust, association, organization, Governmental Authority or other entity of any kind or nature;

Regulation S means Regulation S under the Securities Act;

Securities Act means the U.S. Securities Act of 1933, as amended;

Transactions means the Issuer's issuance of Investment Securities to the Investor pursuant to this Agreement and the transactions contemplated pursuant to the Collaboration and License Agreement.

1.2 Interpretation

1.2.1 In this Agreement, a reference to:

- (i) times and dates are to Amsterdam times and dates;
- (ii) the singular shall include the plural and vice versa; and
- (iii) a Recital, Clause or Schedule, unless the context requires otherwise, is a reference to a Recital or Clause of, or a Schedule to, this Agreement. The Recitals and Schedules will have effect as part of this Agreement.

1.2.2 The headings in this Agreement do not affect its interpretation.

1.2.3 The words "including", "includes" or "included" will be construed as being by way of illustration or emphasis only and will not be construed as, and nor will they have the effect of, limiting the generality of any preceding words.

1.2.4 General words introduced by the word "other" will not be given a restrictive meaning by reason of the fact that they are preceded by words indicating a particular class of acts, matters or things.

1.2.5 The Schedules to this Agreement form an integral part hereof and any reference to this Agreement includes the Schedules thereto and *vice versa*.

2 Investment

2.1 Subject to the conditions set out in this Agreement:

2.1.1 the Issuer undertakes that it shall issue to the Investor (and deliver to the Investor or to its custodian) on the Closing Date 1,766,899 of Investment Securities on the basis of the current authority of the board of directors of the Issuer as granted by the general shareholders meeting dated May 8, 2018; and

2.1.2 the Investor undertakes vis-à-vis the Issuer to subscribe to and pay for 1,766,899 of Investment Securities at the Issue Price on the Closing Date.

2.2 The price per Investment Security (the **Issue Price**) to be paid by the Investor shall be EUR 100.02 . The total amount to be paid by the Investor on the Closing Date for all Investment Securities shall be EUR 176,725,237.98.

3 Conditions Precedent

3.1 The obligations of the Investor under this Agreement are subject to the satisfaction or waiver of each of the following conditions precedent:

- 3.1.1 the Issuer shall have duly executed and delivered to the Investor the Collaboration and License Agreement, the Collaboration and License Agreement shall be in full force and effect on the Closing Date and no termination notice has been given on or prior to the Closing Date;
- 3.1.2 on the Closing Date, the Investor shall have received a certified copy of the minutes or resolutions of the Issuer resolving, inter alia, to approve the execution by the Issuer of this Agreement and the Admission of the Investment Securities, to exclude the preferential subscription rights of the existing shareholders of the Issuer, to increase the Issuer's share capital and to issue the Investment Securities at the Issue Price;
- 3.1.3 on or prior to the Closing Date since the date of execution of the Investment Agreement, no Material Adverse Change has occurred nor is reasonably likely to occur. A **Material Adverse Change** means a material adverse effect on the business, assets (including intangible assets), liabilities, financial condition, property, or results of operations of the Issuer or any of its Affiliates except to the extent such Material Adverse Change arises from or relates to (i) any change in economic, business or financial market conditions in Europe, the United States or other regions in which the Issuer or its Affiliates operate (ii) changes in any laws, regulations or in accounting rules or standards or (iii) any natural disaster, act of terrorism or war, or the outbreak of hostilities, in each case, so long as the effects of such changes or events do not disproportionately and adversely impact the Issuer or argenx BVBA.
- 3.1.4 none of the representations or warranties as set out in Schedule 1 (*Issuer's Representations and Warranties*) hereto being untrue or inaccurate in any material respect as of the date of this Agreement and as of the Closing Date;
- 3.1.5 all waiting periods under the Antitrust Laws that apply in relation to the Transactions have terminated or expired or approval from the competent regulatory authority has been obtained and shall be in full force and effect on the Closing Date and not appealed by a third party;
- 3.1.6 (i) no judicial or administrative proceeding opposing consummation of all or any part the Transactions shall be pending and (ii) no injunction (whether temporary, preliminary or permanent) prohibiting consummation of the Transactions shall be in effect; and
- 3.1.7 the Investor shall have received the Officer's Certificate dated the Closing Date as set out in Schedule 3.
- 3.2 Any or all of the conditions precedent set out in Clause 3.1 other than the condition set out in Clause 3.1.5 may be waived at any time on or prior to the Longstop Date by the Investor acting in its sole discretion.
- 3.3 The obligations of the Issuer under this Agreement are subject to the satisfaction or waiver of each of the following conditions precedent:
- 3.3.1 none of the representations or warranties as set out in Schedule 2 (*Investor's Representations and Warranties*) hereto being untrue or inaccurate in any material respect as of the date of this Agreement and as of the Closing Date;

- 3.3.2 the Issuer shall have received the Officer's Certificate dated the Closing Date as set out in Schedule 3;
- 3.3.3 all waiting periods under the Antitrust Laws that apply in relation to the Transactions have terminated or expired or approval from the competent regulatory authority has been obtained and shall be in full force and effect on the Closing Date and not appealed by a third party; and
- 3.3.4 (i) no judicial or administrative proceeding opposing consummation of all or any part the Transactions shall be pending and (ii) no injunction (whether temporary, preliminary or permanent) prohibiting consummation of the Transactions shall be in effect.
- 3.4 Any or all of the conditions precedent set out in Clause 3.3 other than the condition set out in Clause 3.3.3 may be waived at any time on or prior to the Longstop Date by the Issuer acting in its sole discretion.

4 Settlement and Payment

- 4.1 The closing date shall be no later than five Business Days following the fulfilment or (if applicable) the waiver of all conditions contained in Clause 3 (or such other time and/or date as the Issuer and the Investor agree) (the **Closing Date**).
- 4.2 On the Closing Date:
- 4.2.1 by no later than 11 a.m CET, and against payment of the Issue Price multiplied by the number of Investment Securities issued, the Issuer shall issue 1,766,899 Investment Securities and shall procure that through the intervention of its agent ABN AMRO Bank N.V. the Investment Securities are credited through the facilities and in accordance with the procedures of the Nederlands Centraal Instituut voor Giraal Effectenverkeer B.V. and in accordance with the Act on Securities Book-Entry Transactions (*Wet giraal effectenverkeer*), to the securities account in the name of the custodian for the account of the Investor's securities account, details of which shall be provided by the Investor to the Issuer in a timely manner.
- 4.2.2 by no later than 11 a.m. CET and against issue and delivery of the Investment Securities the Investor shall pay to the Issuer, to an account or accounts specified by the Issuer in writing (in a letter on the Issuer's letterhead signed by a duly authorized representative of the Issuer), an amount equal to the number of Investment Securities subscribed to by such Investor multiplied by the Issue Price in euro in same-day funds.

5 Representations and warranties

- 5.1 The Issuer hereby represents, warrants and undertakes to the Investor that each of the representations and warranties set forth in Schedule 1 (*Issuer's Representations and Warranties*) hereto is true, accurate and not misleading in all material respect on the date hereof and on and as of the Closing Date and the representations and warranties shall be deemed to be repeated on and as of the Closing Date.
- 5.2 The Investor hereby represents, warrants and undertakes to the Issuer that each of the representations and warranties set forth in Schedule 2 (*Investor's Representations and*

Warranties) hereto is true, accurate and not misleading in all material respect on the date hereof and on and as of the Closing Date and the representations and warranties shall be deemed to be repeated on and as of the Closing Date.

- 5.3** Each Party acknowledges that the other Party is entering into this Agreement in reliance upon each of these representations and warranties.
- 5.4** Each Party shall indemnify the other Party from and against all losses incurred by the other Party as a result of any representations or warranties made by it in this Agreement not being true, accurate and not misleading.
- 5.5** The Issuer will notify the Investor on or prior to the Closing Date in the event that any of the representations or warranties set out in Schedule 1 (*Issuer's Representations and Warranties*) hereto (i) ceases to be true and accurate in any material respect, (ii) there has been any breach by the Issuer of any such representations or warranties or (iii) any failure by the Issuer to comply with any of its agreements contained herein or therein, as the case may be.
- 5.6** The Investor will notify the Issuer on or prior to the Closing Date in the event that any of the Investor's Representations and Warranties hereto (i) ceases to be true and accurate in any material respect, (ii) there has been any breach by an Investor of any such representations or warranties or (iii) any failure by an Investor to comply with any of its agreements contained herein or therein, as the case may be.

6 Undertakings

6.1 Undertakings of the Issuer

- 6.1.1** During the period between the date hereof and the Closing Date the Issuer undertakes to, and will instruct its subsidiaries to, operate its business in the ordinary course in linewith past practices.
- 6.1.2** During the period between the date hereof and the Closing Date, the Issuer shall, and shall procure that its subsidiaries shall, (i) refrain from imposing and (ii) use commercially reasonable efforts to prevent the imposition of, any Encumbrance on any Licensed Compound or Licensed Product (as such terms are defined in the Collaboration and License Agreement), other than (for the avoidance of doubt) pursuant to the Transactions.
- 6.1.3** Until 1 February 2019, the Issuer will not announce the intention, commit to or consummate the issuance of Ordinary Shares or any other securities convertible into Ordinary Shares prior to Closing, other than the Transactions.
- 6.1.4** The Issuer shall cause the Investment Securities to be admitted to listing and trading on Euronext Brussels promptly following the Closing Date and at the latest 10 Business Day following the Closing Date.
- 6.1.5** The Issuer undertakes to the Investor to make all such announcements concerning the issue of the Investment Securities or the Admission as shall be necessary to comply with the market rules and/or any other applicable law or regulation to which the Issuer is subject.

- 6.1.6** The Issuer undertakes to pay (i) any stamp or other duties or any taxes due on or in connection with the issue, subscription, sale, distribution and delivery of the Investment Securities in accordance with this Agreement.
- 6.1.7** The Issuer shall determine each year whether or not it is a “passive foreign investment company” (a **PFIC**) or a “controlled foreign corporation” (a **CFC**) as defined for U.S. tax purposes. Unless it has made such information public earlier, not later than 45 days after the approval of the annual accounts by the general shareholders meeting of the Issuer, the Issuer will inform the Investor whether it is a “passive foreign investment company” (a **PFIC**) or a “controlled foreign corporation” (a **CFC**) as defined for U.S. tax purposes for the fiscal year relating to such annual accounts. For each fiscal year of the Issuer, commencing with the first fiscal year for which it is determined to be a PFIC, the Issuer shall no later than 90 days after the approval of the annual accounts by the general shareholders meeting of the Issuer with respect to such fiscal year, furnish the Investor with all information necessary for them to make a qualified electing fund (**QEF**) election, including (1) a PFIC Annual Information Statement under Section 1295(b) of the U.S. Internal Revenue Code, as amended (the **Code**) and (2) all information necessary for it to complete IRS Form 8621 (or successor form), including by making the information referred to in this section publicly available on its website.
- 6.1.8** To the extent applicable, for each fiscal year of the Issuer in which the Investor holds a percentage of 10% or more of the shares in the Issuer and subject to the Investor having crossed the 10% share ownership threshold due to resolutions or transactions by or on behalf of the Issuer including corporate restructurings, redemption, reduction and repurchase of shares, the Issuer will (1) provide or cause its affiliates to provide sufficient information to enable the Investor to accurately complete its annual U.S. tax reporting obligations as a 10% shareholder of the Issuer and each of its subsidiaries under the Code, and (2) if necessary, permit the Investor (or its authorized representative) to examine and copy the books of account, records, and other documentation of the Issuer and each of its affiliates in order to verify the required information. In addition, the Issuer will covenant to retain all records relevant for calculating the earnings and profits of and taxes paid by the Issuer and each of its subsidiaries for as long as the Investor and its affiliates own in the aggregate 10% or more of the Issuer and will provide such information to the Issuer (or its authorized representative) upon the Investor's request within 45 days after the end of the Issuer's fiscal year in which the calculation of a deemed paid foreign tax credit becomes relevant to the Investor under the Code. All information shall be provided in English.

6.2 Undertakings of the Investor

6.2.1 Lock-Up

During the period commencing on and including the Closing Date and ending on and including the one-hundred and eightieth (180th) day following the Closing Date (the **Lock-Up Period**), the Investor will not, without the prior written consent of the Issuer (which consent may be withheld at the sole discretion of the Issuer), directly or indirectly offer, sell (including, without limitation, any short sale), assign, transfer, pledge, contract to sell, enter into a put arrangement, enter into a derivative transaction as a result of which the economic

rights of the underlying assets are transferred or otherwise dispose of, or announce any of the foregoing in respect of the Investment Securities other than a transfer (i) as a result of a public takeover bid on the Issuer or (ii) a transfer to an Affiliate of the Investor subject to (x) there being, to the satisfaction of the Issuer, an arrangement in place whereby the Investment Securities are re-transferred to the Investor (or another Affiliate of the Investor) immediately prior to the time such Affiliate ceases to be an Affiliate of the Investor and (y) such Affiliate agrees in writing to be bound by the terms of this Agreement.

6.2.2 Standstill

Prior to 24 months after the Closing Date (such period, as it may be earlier terminated by Section 6.2.3(i), the **Standstill Period**), unless and to the extent the Investor or any of its Affiliates shall have been specifically invited in writing by the Issuer (or other body or executive with authority to make such determination on behalf of the Issuer), including in connection with the procedures set forth in Section 16.2.1 of the Collaboration and License Agreement, neither the Investor nor any of its Affiliates shall: (i) make, effect, initiate, cause or participate in (A) any acquisition of beneficial ownership of any voting securities of the Issuer other than pursuant to the Transactions, (B) any tender offer, exchange offer, merger, business combination, recapitalization, reorganization, restructuring, liquidation or dissolution involving the Issuer or any securities of the Issuer or (C) any “solicitation” of “proxies” (as those terms are used in Regulation 14A of the U.S. Securities Exchange Act of 1934 (the **Exchange Act**) and the rules promulgated thereunder) or shareholder written consents with respect to any securities of the Issuer; (ii) form, join or participate in a “group” (as defined in the Exchange Act and the rules promulgated thereunder) with respect to the beneficial ownership of any voting securities of the Issuer in excess of the amounts permitted under subclause (i)(A); (iii) act, alone or in concert with others, to seek to control the management or Board of Directors of the Issuer; (iv) agree or offer to take, or knowingly encourage or propose (publicly or otherwise) the taking of, any action referred to in clause (i), (ii), or (iii) of this sentence; (v) induce or knowingly encourage any other person or entity to take any action of the type referred to in clause (i), (ii), (iii), or (iv) of this sentence; or (vi) publicly request or propose that the Issuer amends, waives or considers the amendment or waiver of any provision set forth in this standstill provision.

6.2.3 Exceptions to Standstill Provisions

- (i) If (A) argenx BVBA or the Issuer publicly announces that it is considering strategic alternatives or that it is engaging in a process designed to solicit offers relating to transactions that, if consummated, would result in a Change of Control of argenx BVBA or the Issuer (whether in response to an unsolicited offer or otherwise); (B) any Person or Persons acting in concert shall have commenced, publicly proposed the intention to commence or published a tender offer or exchange offer for more than 50% of the Issuer’s outstanding voting securities; or (C) argenx or the Issuer enters into a definitive agreement with any third party with respect to any Change of Control transaction, the Standstill Period shall immediately terminate and the provisions of Section 6.2.2 shall cease to apply; provided, however, that the Investor and its Affiliates shall only be entitled to acquire voting securities of

the Issuer, pursuant to a tender offer or exchange offer for more than 50% of the Issuer's outstanding voting securities (whether unsolicited or otherwise).

- (ii) Nothing in Section 6.2.2 shall prohibit the Investor or any of its Affiliates from (A) submitting a confidential, non-public proposal to argenx BVBA's or the Issuer's CEO, its Chairman of the Board of Directors, its Board of Directors or any committee thereof with respect to any transaction of the type referred to in Section 6.2.2(i), (B) acquiring beneficial ownership of securities of the Issuer by or through (1) a diversified mutual or pension fund managed by an independent investment adviser or pension plan established for the benefit of the employees of the Investor or any of its Affiliates or (2) any employee benefit plan of the Investor or any of its Affiliates, (C) acquiring securities of a third party that beneficially owns any securities of the Issuer or any of its Affiliates or (D) consummating the transactions contemplated by this Agreement.
- (iii) Notwithstanding anything to the contrary herein but subject to applicable laws, the Investor and its Affiliates shall be permitted to use Confidential Information (as defined in the Collaboration and License Agreement) or confidential information (as described in Clause 8 in furtherance of any action or transaction that it is permitted to pursue under Sections 6.2.2 and 6.2.3 (including any action or transaction it is permitted to pursue following the termination of the Standstill Period).

6.2.4 Undertakings with respect to antitrust clearance

- (i) The Parties shall, as soon as practicable, and, in any event, no later than ten (10) Business Days after the date of this Agreement, file or cause to be filed with the U.S. Federal Trade Commission (the **FTC**) and the Department of Justice (the **DOJ**) the notification and report forms (the **HSR Forms**) required to be filed under the HSR Act with respect to the Transactions. The Parties will use all reasonable efforts to respond on a timely basis to any requests for additional information made by either of such agencies.
- (ii) Each of Investor and Issuer shall: (i) reasonably coordinate and cooperate with each other in connection with any investigation or other inquiry relating to the Transactions; (ii) reasonably keep the other party informed of any communication received by such party from, or given by such party to, the FTC, the DOJ or any other merger control authority and of any communication received or given in connection with any proceeding by a private party, in each case regarding the Transactions; (iii) promptly respond at the earliest reasonable practicable and advisable date to any inquiries or requests received from the FTC or the DOJ for additional information or documentation; (iv) reasonably consult with each other in advance of any meeting or conference with the FTC, the DOJ or any other merger control authority, and to the extent permitted by the FTC, the DOJ or such other merger control authority and reasonably determined by such party to be

appropriate under the circumstances, give the other party or their counsel the opportunity to attend and participate in such meetings and conferences; and (v) permit the other party or their counsel to the extent reasonably practicable to review in advance, and in good faith consider the views of the other party or their counsel concerning, any submission, filing or communication (and documents submitted therewith) intended to be given by it to the FTC, the DOJ or any other merger control authority; provided, however, such party shall be under no obligation to reschedule any meetings or conferences with the FTC, the DOJ or any other merger control authority to enable the other party to attend. Neither the Issuer nor the Investor shall request early termination of the HSR waiting period. The Investor shall have the principal responsibility for devising and implementing the antitrust strategy and shall lead and direct all submissions to, meetings and communications with the FTC, the DOJ or any other party in connection with antitrust matters.

- (iii) Investor shall use its reasonable best efforts to take such actions as may be required under the HSR Act in order to satisfy the conditions set forth in Section 6.2.4. Notwithstanding anything to the contrary in this Agreement, the terms “commercially reasonable efforts” or “reasonable best efforts” do not require that either party (i) offer, negotiate, commit to or effect, by consent decree, hold separate order, trust or otherwise, the sale, divestiture, license or other disposition of any capital stock, assets, rights, products or businesses of Investor, Issuer or their respective Affiliates, (ii) agree to any restrictions on the activities of Investor, Issuer or their respective Affiliates, or (iii) pay any material amount or take any other action to prevent, effect the dissolution of, vacate, or lift any decree, order, judgment, injunction, temporary restraining order, or other order in any suit or proceeding that would otherwise have the effect of preventing or delaying any of the Transactions.

7 Termination

- 7.1** Notwithstanding anything herein contained to the contrary, this Agreement may be terminated on or prior to the Closing Date:
 - 7.1.1** by the Investor, by written notice to the Issuer if a Material Adverse Change occurs in the period as from the date hereof till the Closing Date.
 - 7.1.2** by each Party in case of a material breach by the other Party of its obligations under this Agreement.
- 7.2** Upon the giving of notice in writing as aforesaid this Agreement shall be terminated and the Parties shall (except for any liability arising before or in relation to such termination) be released and discharged from their respective obligations hereunder, provided that Clauses 8 and 9 shall survive any such termination and remain in full force and effect.
- 7.3** This Agreement shall automatically terminate if the Closing Date does not occur on or before 31 March 2019 (the **Long Stop Date**) and the Parties shall (except for any liability

arising before or in relation to such termination in respect of breaches of this Agreement that precede the termination) be released and discharged from their respective obligations hereunder, provided that Clauses 8 and 9 shall survive any such termination and remain in full force and effect.

8 Confidentiality

- 8.1** The Parties acknowledge that all information exchanged in connection with this Agreement and the transaction described in this Agreement was and is provided under a duty of confidentiality. For the avoidance of doubt, such information shall not include information that is in the public domain at the date of this Agreement other than as a result of a breach of any provision of this Agreement. Each Party shall be responsible for breach of the above confidentiality undertaking by it or its Affiliates.
- 8.2** Each Party will only use such information for the purposes of the transactions contemplated by this Agreement.
- 8.3** Notwithstanding anything to the contrary contained herein, (a) the Issuer and the Investor will each make a public announcement containing the names of the Parties, the number of Investment Securities issued, the Issue Price, the Lock-Up Period and the standstill obligation of the Investor, copies will be annexed to this Agreement as Schedule 4 and (b) each Party may disclose such information or portions thereof and further details of the transaction (i) at the request of any regulatory, supervisory or governmental authority, institution or department; or (ii) under court process or pursuant to statutory requirement; or (iii) to the Parties' auditors, external counsel, insurers or accountants that have a reasonable need to know and are bound by professional secrecy or have entered into customary confidentiality undertakings.
- 8.4** If a Party is required by law, court or regulatory, supervisory or governmental authority, institution or department to make any disclosure (including as a result of any actions taken by a Party not in violation of this Agreement or the Collaboration and License Agreement), to the extent not prohibited by applicable law or regulations it must first provide to the other Party the content of the proposed disclosure, the reasons such disclosure is required by applicable law or regulations, and the time and place the disclosure will be made. Any public announcement will comply with the applicable laws and regulations, including not requiring additional securities registration. The disclosing Party will consider in good faith any comments of the other Party related to such disclosure
- 8.5** The confidentiality obligation owed to the Parties shall expire after a period of 3 years after the date of this Agreement.

9 Miscellaneous

9.1 Severability

If any provision in this Agreement is held to be illegal, invalid or unenforceable, in whole or in part, under any applicable law, then such provision or part of it shall be deemed not to form part of this Agreement, and the legality, validity or enforceability of the remainder of this Agreement shall not be affected. In such case, each Party shall use its best efforts to

immediately negotiate in good faith a valid replacement provision that is as close as possible to the original intention of the Parties and has the same or as similar as possible economic effect.

9.2 Waiver

No failure on the part of any Party to exercise, or delay on its part in exercising, any right shall operate as a waiver thereof, nor shall any single or partial exercise by any Party of any right preclude any further or other exercise of such right or the exercise by such Party of any other right.

9.3 Survival

The representations, warranties, agreements, undertakings and indemnities in this Agreement shall continue in full force and effect despite any completion of the arrangement for the issue, subscription and placement of the Investment Securities under this Agreement or the termination of this Agreement pursuant to Clause 7.

9.4 Assignment

Except as otherwise provided herein, no Party may assign or transfer, or purport to assign or transfer, this Agreement, all or any of their respective rights or obligations arising under or out of this Agreement, or the benefit of all or any of the other Parties' obligations under this Agreement. Notwithstanding the foregoing, the Investor shall be entitled to transfer its rights under the Agreement and any Investment Securities to one of its Affiliates subject to (x) there being, to the satisfaction of the Issuer, an arrangement in place whereby the Investment Securities are re-transferred to the Investor (or another Affiliate of the Investor) immediately prior to the time such Affiliate ceases to be an Affiliate of the Investor and (y) such Affiliate agrees to be bound in writing by the terms of this Agreement.

9.5 Entire Agreement

This Agreement contains the entire agreement between the Parties with respect to the subject matter of this Agreement.

9.6 Amendments and Variations

No amendment or variation to this Agreement shall be valid unless it is made in writing and signed by all Parties or their duly authorised representatives.

9.7 Rescission, Annulment, Dissolution

Except as explicitly provided in this Agreement, each Party waives any right to wholly or partly dissolve (*ontbinden*) or nullify (*vernietigen*) this Agreement or to demand the whole or partial dissolution (*ontbinding*) or nullification (*vernietiging*) in legal proceedings thereof pursuant to Sections 6:258, 6:265 through 6:272 of the Dutch Civil Code and Section 6:228 of the Dutch Civil Code respectively, and waives any right to request amendment of the legal consequences of this Agreement pursuant to Section 6:230, subsection 2, of the Dutch Civil Code. Parties exclude the applicability of Title 1 Book 7 of the Dutch Civil Code.

9.8 Notices

All statements, requests, notices and agreements hereunder shall be in writing and shall be delivered or sent by e-mail (confirmed by post or internationally recognised courier) to the following addresses:

If to the Issuer:

argenx SE.
p/a Industriepark Zwijnaarde 7
9052 Zwijnaarde
Belgium
Attn.: Tim Van Hauwermeiren
E-mail: TVanHauwermeiren@argenx.com

If to the Investor:

Johnson & Johnson Innovation – JJDC, Inc
p/a 410 George Street
New Brunswick, NJ 08901
USA

Attn.: Linda Vogel
E-mail: LVogel@its.jnj.com

with a copy to:

Kevin Norman
Johnson & Johnson Innovation (JJDC)
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
E-mail: KNorman6@its.jnj.com

and

NautaDutilh BVBA/SPRL
Chaussée de La Hulpe 120
B-1000 Brussels
Attn: Philippe Remels
E-mail: philippe.remels@nautadutilh.com

9.9 Expenses

Each Party will bear its own costs and expenses as it incurs in connection with the negotiation and execution of the Investment Agreement, provided that any costs associated with or relating to the issuance and admission to trading of the Investment Securities shall be borne by the Issuer.

9.10 Governing law

This Agreement and any non-contractual obligations arising out of or in connection with it shall be governed by Dutch law unless explicitly otherwise provided in this Agreement.

9.11 Jurisdiction

Each of the Parties irrevocably agrees that the courts of Amsterdam are to have non-exclusive jurisdiction to settle any dispute which may arise out of or in connection with this Agreement and the documents to be entered into pursuant to it and that accordingly any proceedings arising out of or in connection with this Agreement and the documents to be entered into pursuant to it may be brought in such courts. Each of the Parties irrevocably waives any objection to proceedings in any such courts on the ground of venue or on the ground that proceedings have been brought in an inconvenient forum, and irrevocably agrees that a judgment or order of any such court in connection with such proceedings shall be conclusive and binding on them and may be enforced against it in the courts of any other jurisdiction.

9.12 Counterparts

This Agreement may be signed in counterparts, in the number of originals stated hereinafter on the signature page. When taken together, the counterparts signed by all Parties shall constitute one and the same instrument.

[Remainder of the page is intentionally left blank]

argenx SE

/s/ Tim Van Hauwermeiren

Name: Tim Van Hauwermeiren

Title: CEO

/s/ Peter Verhaeghe

Name: Peter Verhaeghe

Title: Chairman of the Board

Johnson & Johnson Innovation – JJDC, Inc

/s/ Marian Nakada

Name: Marian Nakada

Title: VP Venture Investments

Schedule 1: Issuer's Representations and Warranties

The Issuer hereby makes the following representations and warranties and undertakings to, and agreements with, the Investor on and as of the date hereof and on and as of the Closing:

1 Organisation of the Issuer

The Issuer has been duly incorporated and is validly existing as a Dutch European company with limited liability ("*societas europaea* or SE) and has all power and authority necessary to own or hold its properties and to conduct its businesses in which it is engaged.

2 Organisation of Subsidiaries

Each subsidiary of the Issuer has been duly incorporated and is validly existing under the laws of the jurisdiction in which it is incorporated and has all power and authority necessary to own or hold its properties and to conduct its businesses in which it is engaged.

3 Investment Securities

- 3.1** On the Closing Date, the Investment Securities have been duly authorised and, when issued, delivered and paid for pursuant to this Agreement, will have been duly and validly issued and delivered in accordance with the laws and regulations of the Netherlands, and the articles of association of the Issuer, fully paid and free from all Encumbrances; will have the benefit of all rights attaching thereto and will rank *pari passu* in all respects with, and be identical to, the existing Investment Securities of the Issuer then in issue and will rank in full for all dividends and other distributions declared, made or paid on the Investment Securities of the Issuer after the date of issue.
- 3.2** Upon delivery to the securities accounts in the name of the custodian for the account of the Investor in accordance with the facilities and procedures of the Nederlands Centraal Instituut voor Firaal Giraal Effectenverkeer B.V. and in accordance with the Act on Securities Book-Entry Transactions (*Wet giraal effectenverkeer*), legal entitlement to the Investment Securities in accordance with the Act on Securities Book-Entry Transactions (*Wet giraal effectenverkeer*) shall have passed to the relevant subscriber free and clear from all Encumbrances and there are no legal restrictions affecting the issue and delivery of such Investment Securities by the Issuer.
- 3.3** None of the Investment Securities have been or will be issued or delivered in violation of the pre-emptive rights, co-sale rights, rights of first refusal or other rights to purchase any of the Investment Securities of any holder of Shares.
- 3.4** Save as publicly disclosed on or prior to the date of this Agreement, and other than in respect of employee stock option plans of the Issuer, there are no outstanding securities convertible into or exchangeable for, or warrants, rights or options to purchase from the Issuer or any Subsidiary, or obligations, commitments or intentions of the Issuer or any Subsidiary to create the same or to issue, sell or otherwise dispose of, any shares of the Issuer or of any Subsidiary.

4 Due Authorisation

The Issuer has full right, power and authority to execute and deliver this Agreement. The Issuer has full right, power and authority to perform its obligations under this Agreement (including to issue and deliver the Investment Securities), all action required to be taken for the due and proper authorisation, execution and delivery of this Agreement and the performance of the obligations contemplated hereby has been duly and validly taken (including any necessary filings, registrations and consents). This Agreement has been duly authorised, executed and delivered by the Issuer and is a valid, binding and enforceable agreement of the Issuer in accordance with its terms, except as such enforcement may be limited by bankruptcy or other laws of general application.

5 No Conflicts

The execution, delivery and performance of the Agreement by the Issuer and its subsidiaries does not contravene: (i) the constitutional documents of the Issuer or its subsidiaries, (ii) any law or regulation to which the Issuer or its subsidiaries are subject, (iii) the rules of any stock exchange as they relate to the Issuer or its subsidiaries, (iv) any agreement binding upon the Issuer or its subsidiaries, or any judgement, order or decree of any governmental body, agency or court having jurisdiction over the Issuer, its subsidiaries or any of their assets.

6 No Consents Required

No consent, approval, authorisation, order, registration or qualification of or with any court or arbitrator or governmental or regulatory authority is required for the execution, delivery and performance by the Issuer of this Agreement, except for Euronext Brussels approving the admission to trading of the Investment Securities, other than the expiration or termination of the applicable waiting period under the HSR Act.

7 Disclosures

7.1 Except for the Transactions, the Issuer is not aware of any non-public fact or circumstance that (i) if made public would be expected to have a material effect upon the market price of the Ordinary Shares or (ii) would require the Issuer to make a publication and/or notification or publish a supplement pursuant to the applicable laws and regulations, or (iii) in respect of which it is relying on a legal exemption from an obligation to immediately disclose any such information.

7.2 As far as the Issuer is aware the information released by the Issuer publicly since 1 January 2018, does not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

8 Foreign Corrupt Practices.

None of the Issuer, its subsidiaries or, to the knowledge of the Issuer, any director, officer, agent, or employee of the Issuer or any of its subsidiaries has taken any action, directly or indirectly, that is in violation by such persons of the Foreign Corrupt Practices Act of 1977, as amended, and the rules and regulations promulgated thereunder (the *FCPA*), including, without limitation, making use of the mails or any means or instrumentality of interstate commerce corruptly in furtherance of an offer, payment, promise to pay or authorization of the payment of any money, or other property, gift, promise to give, or authorization of the

giving of anything of value to any “foreign official” (as such term is defined in the FCPA) or any foreign political party or official thereof or any candidate for foreign political office, in contravention of the FCPA.

* * *

Schedule 2: Investor's Representations and Warranties

The Investor, severally and not jointly, hereby makes the following representations and warranties and undertakings to, and agreements with, the Issuer on and as of the date hereof and on and as of the Closing:

1 Organisation of the Investor

The Investor has been duly incorporated and is validly existing as a corporation organised and existing under the laws of the State of New Jersey (U.S.A.), and has all power and authority necessary to own or hold its properties and to conduct its businesses in which it is engaged.

2 Due Authorisation

The Investor has full right, power and authority to execute and deliver this Agreement. The Investor has full right, power and authority to perform its obligations under this Agreement, all action required to be taken for the due and proper authorisation, execution and delivery of this Agreement and the performance of the obligations contemplated hereby has been duly and validly taken (including any necessary filings, registrations and consents). This Agreement has been duly authorised, executed and delivered by such Investor and is a valid, binding and enforceable agreement of such Investor in accordance with its terms, except as such enforcement may be limited by bankruptcy or other laws of general application.

3 No Conflicts

The execution, delivery and performance of the Agreement, including the subscription to the Investment Securities, by the Investor does not contravene: (i) the constitutional documents of the Investor, (ii) any law or regulation to which the Investor is subject, (iii) the rules of any stock exchange as they relate to the Investor, (iv) any agreement binding upon the Investor, or any judgement, order or decree of any governmental body, agency or court having jurisdiction over such Investor or any of its assets.

4 No Consents Required

No consent, approval, authorisation, order, registration or qualification of or with any court or arbitrator or governmental or regulatory authority is required for the execution, delivery and performance by the Investor of this Agreement, other than the expiration or termination of the applicable waiting period under the HSR Act.

5 No prior holding

The Investor nor, to the best of the Investor's knowledge, any of its Affiliates hold on the date hereof or will hold on the Closing Date (other than pursuant to this Agreement) any Ordinary Shares, ADRs or options to acquire Ordinary Shares or ADRs or securities exchangeable for or giving right to Ordinary Shares or ADRs. Neither the Investor nor any of its Affiliates has entered into an arrangement with a third party whereby the Investor or any of its Affiliates would control the voting power of the Ordinary Shares or ADR's held by such third party or whereby the Investor or any of its Affiliates can direct such third party with respect to the disposal of its Ordinary Shares or ADRs.

6 QIB Investor Representations and Warranties

- a. In making any decision to purchase the Investment Securities, the Investor confirms that it has knowledge and experience in financial, business and international investment matters as is required to evaluate the merits and risks of purchasing the Investment Securities. The Investor is experienced in investing in securities of this nature in this sector and is aware that it may be required to bear, and is able to bear, the economic risk of, and is able to sustain a complete loss in connection with the Transaction. The Investor has relied on its own examination and due diligence of the Issuer and its Affiliates taken as a whole (the **Group**) and of the terms of the Transaction, including the merits and risks involved.
- b. The Investor has: (a) made its own assessment and satisfied itself concerning legal, regulatory, tax, business and financial considerations in connection herewith to the extent it deems necessary; (b) had access to review publicly available information concerning the Group that it considers necessary or appropriate and sufficient in making an investment decision; (c) reviewed such information as it believes is necessary or appropriate in connection with its purchase of the Investment Securities; (d) had the opportunity to ask management of the Issuer questions while making its investment decision; and (e) made its investment decision based upon its own judgement, due diligence and analysis and not upon any view expressed nor upon any information or reports provided by or on behalf of the Issuer, any of its Affiliates or any person acting on its or their behalf.
- c. The Investor acknowledges and agrees that no offering document, listing particulars or prospectus has been or will be prepared in connection with the Transaction.
- d. With respect to any Investment Securities offered to or purchased by the Investor in the United States, it understands and agrees: (1) that it is a "qualified institutional buyer" (**QIB**) within the meaning of Rule 144A under the Securities Act; (2) that the Investment Securities are being offered and sold to it pursuant to an exemption under the Securities Act in a transaction not involving a public offering of securities in the United States and that the Investment Securities have not been, and will not be, registered under the Securities Act or with any state or other jurisdiction of the United States; (3) that the Investment Securities are not being offered and sold to it pursuant to Rule 144A of the Securities Act; (4) that the Investment Securities may not be reoffered, resold, pledged or otherwise transferred by it except (a) outside the

United States in an offshore transaction pursuant to Rule 903 or Rule 904 of Regulation S, (b) pursuant to Rule 144 under the Securities Act (if available), (c) to the Issuer, or (d) pursuant to an effective registration statement under the Securities Act, in each case in compliance with all applicable laws including applicable state or “Blue Sky” laws; (5) that the Investment Securities are “restricted securities” as defined in Rule 144(a)(3) under the Securities Act; (6) to notify any transferee to whom it subsequently reoffers, resells, pledges or otherwise transfers the Investment Securities of the foregoing restrictions on transfer; (7) for so long as the Investment Securities are “restricted securities” (within the meaning of Rule 144(a)(3) under the Securities Act), it will segregate such Investment Securities from any other shares that it holds that are not restricted securities, shall not deposit such shares in any unrestricted depository facility established or maintained by a depository bank and will only transfer such Investment Securities in accordance with this paragraph; (8) if it is acquiring the Investment Securities as a fiduciary or agent for one or more investor accounts, each such account is a QIB, it has investment discretion with respect to each such account and it has full power and authority to make the acknowledgements, representations, warranties and agreements herein on behalf of each such account; (9) it is acquiring such Investment Securities for its own account (or the account of a QIB as to which it has full investment discretion) for investment purposes and (subject to the disposition of its property being at all times within its control) not with a view to any distribution of the Investment Securities; and (10) that no representation has been made as to the availability of the exemption provided by Rule 144, Rule 144A or any other exemption under the Securities Act or any applicable state or “Blue Sky” laws for the reoffer, resale, pledge or transfer of the Investment Securities.

- e. The Investor represents that its interest in the Investment Securities was neither generated by, nor the result of, any general solicitation or general advertising, including any advertisements, articles, notices, or other communications published in any newspaper, magazine or similar media or broadcast over radio or television, or any seminar or meeting whose attendees have been invited by general solicitation or general advertising.
- f. The Investor acknowledges that the Issuer will rely upon the truth and accuracy of the representations, warranties and acknowledgements set forth herein. The Investor irrevocably authorizes the Issuer and its Affiliates to produce this letter, pursuant to and as may be required by any applicable law or regulation, administrative or legal proceeding or official inquiry with respect to the matters set forth herein.
- g. The terms and provisions of these representations, warranties and undertakings shall inure to the benefit of the Issuer and its successors and permitted assigns, and the terms and provisions hereof shall be binding on the Investor’s permitted successors in title, permitted assigns and permitted transferees.
- h. All representations, warranties, acknowledgements, undertakings and agreements that the Investor has made in this letter shall survive the Transaction and delivery of the Investment Securities.

- i. These “QIB Investor Representations and Warranties” and any non-contractual obligations arising out of or in connection with these “QIB Investor Representations and Warranties” shall be governed by, and construed in accordance with, the laws of the state of New York.
- j. The Investor is empowered, authorized and qualified to purchase the Investment Securities, and the person signing this letter on its behalf has been duly authorized by it to do so.

* * *

Schedule 3 – Officers’ Certificate

1. Officer’s Certificate of the Issuer

[on the headed notepaper of the Issuer]

To : Johnson & Johnson Innovation – JJDC, Inc
410 George Street
New Brunswick, NJ 08901
USA
Attn. Linda Vogel

Breda, [*Closing Date*]

Dear all,

Re : Investment Agreement dated 2 December 2018 between argenx SE and Johnson & Johnson Innovation – JJDC, Inc (the *Agreement*)

We refer to the Agreement and to the condition precedent set out in Clause 3.1.7 of the Agreement.

References in this letter to Clauses are to Clauses of the Agreement and words and expressions defined in the Agreement have the same meaning therein.

With reference to our obligation in Clause 3.1.7 of the Agreement, I, in my capacity as chief executive officer of the Issuer and acting hereby in the name of and on behalf of the Issuer, hereby confirm that:

- (a) none of the representations and warranties referred to in Schedule 1 of the Agreement was breached or untrue or inaccurate at the date of the Agreement in any respect and there has been no change in circumstances such that if repeated by reference to facts and circumstances subsisting at the date hereof any of such representations or warranties would be breached or untrue or inaccurate in any respect; and
- (b) the Issuer is not in breach of any obligations contained in the Agreement and has duly respected and performed its obligations under the undertakings set out in Clause 6.1 of the Agreement that are required to be performed on the date hereof;

The above certification is made on the understanding and acceptance by the Investor that all claims in respect of this certificate, except in case wilful misrepresentation or fraud by us, will not be directed to us personally but to the Issuer.

Yours faithfully

In the name of and on behalf of the Issuer:

[Signature required by the CEO]

2. Officer's Certificate of the Investor

[on the headed notepaper of the Investor]

To : argenx SE.

Industriepark Zwijnaarde 7

9052 Zwijnaarde

Belgium

Attn.: Tim Van Hauwermeiren

[Closing Date]

Dear all,

Re : Investment Agreement dated 2 December 2018 between argenx SE and Johnson & Johnson Innovation – JJDC, Inc (the *Agreement*)

We refer to the Agreement and to the condition precedent set out in Clause 3.3.2 of the Agreement.

References in this letter to Clauses are to Clauses of the Agreement and words and expressions defined in the Agreement have the same meaning therein.

With reference to our obligation in Clause 3.3.2 of the Agreement, I, in my capacity as chief executive officer of the Investor and acting hereby in the name of and on behalf of the Investor, hereby confirm that:

- (c) none of the representations and warranties referred to in Schedule 2 of the Agreement was breached or untrue or inaccurate at the date of the Agreement in any respect and there has been no change in circumstances such that if repeated by reference to facts and

circumstances subsisting at the date hereof any of such representations or warranties would be breached or untrue or inaccurate in any respect; and

- (d) the Investor is not in breach of any obligations contained in the Agreement and has duly respected and performed its obligations under the undertakings set out in Clause 6.2 of the Agreement that are required to be performed on the date hereof;

The above certification is made on the understanding and acceptance by the Issuer that all claims in respect of this certificate, except in case wilful misrepresentation or fraud by us, will not be directed to us personally but to the Investor.

Yours faithfully

In the name of and on behalf of the Investor:

[Signature required by the CEO or other authorized officer]

Regulated information – Inside information

argenx enters exclusive global collaboration and license agreement with Cilag GmbH International, an affiliate of Janssen, for cusatuzumab (ARGX-110)

- **Collaboration to develop cusatuzumab in AML, MDS and other hematological malignancies in deal totaling up to \$1.6 billion potentially**
- **Janssen to pay argenx \$300 million in upfront cash payment**
- **Johnson & Johnson Innovation – JJDC, Inc. (JJDC) to make \$200 million equity investment in argenx**
- **argenx to retain right to co-promote cusatuzumab in the U.S. and share economics 50-50 on a royalty basis**
- **Conference call to be held today at 5:00 PM CET (11:00 AM ET/8:00 AM PT)**

December 3, 2018

Breda, the Netherlands / Ghent, Belgium – argenx (Euronext & Nasdaq: ARGX), a clinical-stage biotechnology company developing a deep pipeline of differentiated antibody-based therapies for the treatment of severe autoimmune diseases and cancer, today announced an exclusive, global collaboration and license agreement for cusatuzumab (ARGX-110), a highly differentiated anti-CD70 SIMPLE Antibody□, with Cilag GmbH International, an affiliate of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Cusatuzumab is currently in development in a Phase 1/2 combination study with Vidaza® for newly diagnosed, elderly patients with acute myeloid leukemia (AML) and high-risk myelodysplastic syndrome (MDS) who are unfit for chemotherapy. Data announced today from the Phase 1/2 study will be presented during a workshop being held in conjunction with the 60th American Society of Hematology Annual Meeting and Exposition.

“AML continues to be an aggressive and deadly cancer of the blood and bone marrow with very high relapse rates. Cusatuzumab offers a novel mode of action targeting leukemic stem cells, which are a known driver of the relapse mechanism, and has shown a compelling response rate and tolerability profile to date,” said Tim Van Hauwermeiren, CEO of argenx. “Janssen is an ideal strategic partner for us to develop this differentiated investigational therapy given its extensive clinical, regulatory and commercial expertise in oncology, and we believe that through this collaboration we are best positioned to reach the broadest number of patients as quickly as possible. The collaboration also strengthens our financial position, enabling our growth into a fully-integrated organization as we continue to exploit our deep pipeline of wholly-owned product candidates, including our lead product candidate efgartigimod which we are evaluating in four severe autoimmune indications.”

argenx and Janssen have agreed to a joint global clinical development plan to evaluate cusatuzumab in AML, MDS and other potential future indications.

Under the terms of the agreement, Janssen will pay argenx \$300 million in an upfront payment and JJDC will purchase \$200 million (1,766,899) of newly issued shares representing 4.68% of argenx’s outstanding shares at a price of €100.02 per share (\$113.19). argenx will be eligible to receive potentially up to \$1.3 billion in development, regulatory and sales milestones, in addition to tiered, double-digit royalties. Janssen will be



responsible for commercialization worldwide. argenx retains the option to participate in commercialization efforts in the U.S., where the companies have agreed to share economics 50/50 on a royalty basis and outside the U.S., Janssen will pay double-digit sales royalties to argenx.

The transactions are subject to customary closing conditions, including clearance under the Hart-Scott-Rodino Antitrust Improvements Act, and expected to close in the first quarter of 2019.

Conference call details

Dial-in 5 minutes before the start of the conference call and use the conference **ID: 5278105**

Dial-in numbers:

<input type="checkbox"/> International dial-in:	+44 (0) 207 192 8000
<input type="checkbox"/> US:	16315107495 (or 18669661396)
<input type="checkbox"/> UK:	08445718892
<input type="checkbox"/> Belgium:	024009874
<input type="checkbox"/> The Netherlands:	0207143545
<input type="checkbox"/> France:	0176700794
<input type="checkbox"/> Sweden:	0850692180
<input type="checkbox"/> Switzerland:	0315800059

About Cusatuzumab

Cusatuzumab (ARGX-110) is an investigational SIMPLE Antibody™ targeting CD70, an immune checkpoint target involved in hematological malignancies, several solid tumors and severe autoimmune diseases. Cusatuzumab is designed to: block CD70, kill cancer cells expressing CD70 through complement dependent cytotoxicity, enhanced antibody-dependent cell-mediated phagocytosis and enhanced antibody-dependent cell-mediated cytotoxicity, and restore immune surveillance against solid tumors (*Silence K. et al. mAbs 2014; 6 (2):523-532*). Cusatuzumab is currently being evaluated in patients with hematological malignancies, including a Phase 1/2 trial in combination with Vidaza in patients with newly diagnosed acute myeloid leukemia and high-risk myelodysplastic syndromes and the Phase 2 part of a Phase 1/2 trial in patients with relapsed/refractory cutaneous T-cell lymphoma (CTCL). Preclinical work on cusatuzumab in AML was performed in collaboration with the Tumor Immunology Lab of Prof. A. F. Ochsenbein at the University of Bern, who won, together with Prof. Manz at the University Hospital of Zürich, the prestigious 2016 *Otto Naegeli Prize* for his breakthrough research on CD70/CD27 signaling with therapeutic potential for cancer patients.

About argenx

argenx is a clinical-stage biotechnology company developing a deep pipeline of differentiated antibody-based therapies for the treatment of severe auto-immune diseases and cancer. The company is focused on developing product candidates with the potential to be either first-in-class against novel targets or best-in-class against known, but complex,



targets in order to treat diseases with a significant unmet medical need. argenx's ability to execute on this focus is enabled by its suite of differentiated technologies. The SIMPLE Antibody™ Platform, based on the powerful llama immune system, allows argenx to exploit novel and complex targets, and its three complementary Fc engineering technologies are designed to expand the therapeutic index of its product candidates.

www.argenx.com

For further information, please contact:

Joke Comijn, Director Corporate Communications & Investor Relations (EU)

+32 (0)477 77 29 44

+32 (0)9 310 34 19

info@argenx.com

Beth DelGiacco, VP Investor Relations (US)

+1 518 424 4980

bdelgiacco@argenx.com

Forward-looking Statements

The contents of this announcement include statements that are, or may be deemed to be, "forward-looking statements." These forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "intends," "may," "will," or "should" and include statements argenx makes concerning the intended results of its strategy and its collaboration with Janssen expected to close in the first quarter of 2019, including argenx's ability to receive the expected benefits thereof such as future milestones and royalty payments.. By their nature, forward-looking statements involve risks and uncertainties and readers are cautioned that any such forward-looking statements are not guarantees of future performance. argenx's actual results may differ materially from those predicted by the forward-looking statements as a result of various important factors, including argenx's expectations regarding its the inherent uncertainties associated with competitive developments, preclinical and clinical trial and product development activities and regulatory approval requirements; argenx's reliance on collaborations with third parties; estimating the commercial potential of argenx's product candidates; argenx's ability to obtain and maintain protection of intellectual property for its technologies and drugs; argenx's limited operating history; and argenx's ability to obtain additional funding for operations and to complete the development and commercialization of its product candidates. A further list and description of these risks, uncertainties and other risks can be found in argenx's U.S. Securities and Exchange Commission (SEC) filings and reports, including in argenx's most recent annual report on Form 20-F filed with the SEC as well as subsequent filings and reports filed by argenx with the SEC. Given these uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. These forward-looking statements speak only as of the date of publication of this document. argenx undertakes no obligation to publicly update or revise the information in this press release, including any forward-looking statements, except as may be required by law.

News Release

Media Contacts:

Brian Kenney

Phone: 215-620-0111

Email: bkenney1@its.jnj.com

Satu Glawe

Phone: +49 172 294 6264

Email: sschmid2@its.jnj.com

Investor Contacts:

Christopher

DelOrefice

Phone: 732-524-2955

Lesley Fishman

Phone: 732-524-3922

Janssen Affiliate Cilag GmbH International Enters Worldwide Collaboration and License Agreement with argenx for Cancer Immunotherapy Cusatuzumab

Addition of investigational antibody cusatuzumab to robust oncology pipeline reflects Janssen's commitment to advance innovative therapies for blood cancers where unmet medical needs remain

Zug, Switzerland (December X, 2018) - Cilag GmbH International, an affiliate of the Janssen Pharmaceutical Companies of Johnson & Johnson, announced today it has entered into a worldwide collaboration and license agreement with argenx BVBA and argenx SE, to develop and commercialize cusatuzumab (ARGX-110). Cusatuzumab is an investigational therapeutic antibody that targets CD70, an immune checkpoint implicated in numerous cancers, including hematological malignancies. This first-in-class SIMPLE Antibody™ is currently in Phase 1/2 clinical trials to evaluate its safety, tolerability and efficacy in the treatment of acute myeloid leukemia (AML) and high-risk myelodysplastic syndromes (MDS). Separately, an equity investment by Johnson & Johnson Innovation - JJDC, Inc. (JJDC) will be made in argenx SE.

Updated data from the ongoing Phase 1/2 clinical study evaluating cusatuzumab in combination with azacytidine in newly diagnosed patients with AML unfit for intensive chemotherapy are being presented during an argenx workshop held in conjunction with the 60th Annual Meeting of the American Society of Hematology (ASH). The data showed promising anti-leukemia activity in these patients.ⁱ

“We believe CD70 is an important target in the biology of select cancers, and we are eager to accelerate the development of this innovative antibody together with argenx,” said Yusri Elsayed, M.D., MHSc, Ph.D., Vice President, Hematologic Malignancies Disease Area Leader, Janssen Research & Development, LLC. “Phase 1/2 data in acute myeloid leukemia showed the activity of cusatuzumab, and we hope to translate these findings to improve outcomes for patients with myeloid malignancies.”

Under the terms of the agreement, Janssen will jointly develop and globally commercialize cusatuzumab in AML, MDS, and potential future indications, as well as next generation CD70 antibodies. Janssen will make an upfront payment of \$300 million USD and additional payments based upon the achievement of certain development, regulatory and sales milestones. Janssen is responsible for commercialization worldwide. In the U.S., argenx has the option to participate in commercialization efforts. Janssen will record

worldwide net trade sales. In the U.S., the companies have agreed to share the economics 50/50, and outside the U.S., Janssen will pay double-digit sales royalties to argenx.

“We are pleased to enter into this strategic partnership with argenx and advance a promising antibody for the treatment of AML and other blood cancers where current treatment is limited and effective new interventions are needed for patients,” said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development, LLC. “The addition of cusatuzumab deepens our portfolio and adds to our expertise in oncology, and more importantly, it reflects our commitment to combine Janssen’s strengths with those of other outstanding teams to advance science that we believe can transform the treatment of diseases and the lives of patients worldwide.”

The transactions are subject to customary closing conditions, including clearance under the Hart-Scott-Rodino Antitrust Improvements Act, and expected to close in the first quarter of 2019.

About Cusatuzumab

Cusatuzumab (ARGX-110) is an investigational SIMPLE Antibody™ targeting CD70, an immune checkpoint target involved in hematological malignancies, several solid tumors and severe autoimmune diseases. Cusatuzumab is designed to: block CD70; kill cancer cells expressing CD70 through complement-dependent cytotoxicity, enhanced antibody-dependent cell-mediated phagocytosis and enhanced antibody-dependent cell-mediated cytotoxicity; and restore immune surveillance against solid tumors.ⁱⁱ

About AML

Acute myeloid leukemia (AML) starts in the bone marrow (the soft inner part of certain bones, where new blood cells are made), but most often it quickly moves into the blood, as well. It can sometimes spread to other parts of the body including the lymph nodes, liver, spleen, central nervous system (brain and spinal cord), and testicles.ⁱⁱⁱ

About MDS

Myelodysplasia Syndromes (MDS) are a group of diverse bone marrow disorders in which the bone marrow does not produce enough healthy blood cells. MDS is often referred to as a “bone marrow failure disorder”. MDS is primarily a disease of the elderly (most patients are older than age 65), but MDS can affect younger patients as well.^{iv}

About Cilag GmbH International

Cilag GmbH International was founded in 1984 as the supply chain coordination center for the pharmaceuticals sector in Zug. Today, it offers a wide range of support activities for numerous Swiss companies in the pharmaceutical, consumer and medical device and diagnostics segments of the Johnson & Johnson Family of Companies.

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent,

intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science. We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at www.janssen.com. Follow us at @JanssenGlobal. Cilag GmbH International and Janssen Research & Development, LLC are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

About Johnson & Johnson Innovation - JJDC, Inc.

Johnson & Johnson Innovation - JJDC, Inc. (JJDC) is the strategic venture capital arm of Johnson & Johnson and a long-term investment partner to global healthcare entrepreneurs. Founded in 1973, JJDC continues a legacy of customizing deals for data-driven companies across the continuum of healthcare, with the goal of turning great ideas into transformative new pharmaceutical, medical device and consumer healthcare products. Visit our website at www.iidc.com.

About Johnson & Johnson

At Johnson & Johnson, we believe good health is the foundation of vibrant lives, thriving communities and forward progress. That's why for more than 130 years, we have aimed to keep people well at every age and every stage of life. Today, as the world's largest and most broadly-based health care company, we are committed to using our reach and size for good. We strive to improve access and affordability, create healthier communities, and put a healthy mind, body and environment within reach of everyone, everywhere. We are blending our heart, science and ingenuity to profoundly change the trajectory of health for humanity.

###

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development and the potential benefits and treatment impact of the collaboration and license agreement with Argenx to develop and commercialize cusatuzumab (ARGX-110). The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Cilag GmbH International, Janssen Research & Development, LLC, Johnson & Johnson Innovation - JJDC, Inc. any of the other Janssen Pharmaceutical Companies of Johnson & Johnson and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: the satisfaction of closing conditions for the transactions, including clearance under the Hart-Scott-Rodino Antitrust Improvements Act; the potential that the expected benefits and opportunities related to the collaboration may not be realized or may take longer to realize than expected; challenges inherent in new product development, including the uncertainty of clinical success and obtaining regulatory approvals; competition, including technological advances, new products and patents attained by competitors; uncertainty of commercial success for new products; the ability of the company to successfully execute strategic plans; impact of business combinations and divestitures; challenges to patents; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; and global health care reforms and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on

DRAFT

Form 10-K for the fiscal year ended December 31, 2017, including in the sections captioned “Cautionary Note Regarding Forward-Looking Statements” and “Item 1A. Risk Factors,” in the company’s most recently filed Quarterly Report on Form 10-Q, and the company’s subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. Neither the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

ⁱ Ochsenbein, Adrian (2018, December). 2680 Argx-110 Targeting CD70, in Combination with Azacitidine, Shows Favorable Safety Profile and Promising Anti-Leukemia Activity in Newly Diagnosed AML Patients in an Ongoing Phase 1/2 Clinical Trial. American Society of Hematology Annual Meeting, San Diego, CA, U.S.

ⁱⁱ Silence K. et al. mAbs 2014; 6 (2):523-532

ⁱⁱⁱ “What Is Acute Myeloid Leukemia (AML)?” American Cancer Society. Retrieved from <https://www.cancer.org/cancer/acute-myeloid-leukemia/about/what-is-aml.html>

^{iv} “What is MDS?” MDS Foundation. Retrieved <https://www.mds-foundation.org/what-is-mds/>

**Certification by the Principal Executive Officer pursuant to
Securities Exchange Act Rules 13a-14(a) and 15d-14(a)
as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Tim Van Hauwermeiren, certify that:

1. I have reviewed this annual report on Form 20-F of argenx SE;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 26, 2019

/s/ Tim Van Hauwermeiren

Name: Tim Van Hauwermeiren

Title: Chief Executive Officer

(Principal Executive Officer)

**Certification by the Principal Financial Officer pursuant to
Securities Exchange Act Rules 13a-14(a) and 15d-14(a)
as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Eric Castaldi, certify that:

1. I have reviewed this annual report on Form 20-F of argenx SE;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 26, 2019

/s/ Eric Castaldi

Name: Eric Castaldi

Title: Chief Financial Officer

(Principal Financial Officer)

**Certification by the Principal Executive Officer pursuant to
18 U.S.C. Section 1350, as adopted pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the annual report of argenx SE (the "Company") on Form 20-F for the fiscal year ended December 31, 2018 as filed with the U.S. Securities and Exchange Commission on the date hereof (the "Report"), I, Tim Van Hauwermeiren, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 26, 2019

/s/ Tim Van Hauwermeiren

Name: Tim Van Hauwermeiren

Title: Chief Executive Officer

(Principal Executive Officer)

**Certification by the Principal Financial Officer pursuant to
18 U.S.C. Section 1350, as adopted pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the annual report of argenx SE (the "Company") on Form 20-F for the fiscal year ended December 31, 2018 as filed with the U.S. Securities and Exchange Commission on the date hereof (the "Report"), I, Eric Castaldi, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 26, 2019

/s/ Eric Castaldi

Name: Eric Castaldi

Title: Chief Financial Officer

(Principal Financial Officer)

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-225375) and the Registration Statement on Form F-3 (No. 333-225370) of our reports dated March 26, 2019, relating to the consolidated financial statements of argenx SE and its subsidiaries and the effectiveness of argenx SE's internal control over financial reporting (which report expresses an adverse opinion on the effectiveness of argenx SE's internal control over financial reporting because of multiple material weaknesses), appearing in this Annual Report on Form 20-F of argenx SE for the year ended December 31, 2018.

Rotterdam, March 26, 2019

Deloitte Accountants B.V.

/s/ Deloitte Accountants B.V.

P.J. Seegers
