

**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, 2017  
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)

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**The Netherlands**  
(Jurisdiction of incorporation or organization)

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**Willemstraat 5  
4811 AH, Breda, the Netherlands**  
(Address of principal executive offices)

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(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:  | Name of each exchange on which registered:                  |
|---|---|
| American Depositary Shares, each representing one ordinary share with a nominal value of €0.10 per share<br>Ordinary shares with a nominal value of €0.10 per share * | NASDAQ Global Select Market<br>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, 2017 32,180,641 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.

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.

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:

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files):

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 <input type="checkbox"/> | Accelerated filer <input type="checkbox"/> | Non-accelerated filer <input checked="" type="checkbox"/> | Emerging growth company <input checked="" type="checkbox"/> |
|--|--|---|---|

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. X

† 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 <input type="checkbox"/> | International Financial Reporting Standards as issued By the International Accounting Standards Board X | Other <input type="checkbox"/> |
|------------------------------------|---|--------------------------------|

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.

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).

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### 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 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 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;
- our plans to enter into collaborations for some of our 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, 2017, 2016 and 2015 and for the years ended December 31, 2017, 2016 and 2015 from our consolidated audited financial statements, included herein. Our 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, 2014 and 2013 and for the years ended December 31, 2014 and 2013 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<br>December 31,                      |                   |                   |                   |                  |
|--|---|-------------------|-------------------|-------------------|------------------|
|  | 2017  | 2016              | 2015              | 2014              | 2013             |
|  | (In thousands, except share and per share data) |                   |                   |                   |                  |
| <b>Consolidated statement of profit and loss and other comprehensive income:</b> |   |                   |                   |                   |                  |
| Revenue  | € 36,415  | € 14,713          | € 6,854           | € 3,756           | € 2,677          |
| Other operating income   | 4,841   | 2,439             | 3,101             | 1,621             | 2,577            |
| Research and development expenses  | (51,740)  | (31,557)          | (20,635)          | (12,641)          | (9,352)          |
| Selling, general and administrative expenses                                     | (12,448)  | (7,011)           | (4,925)           | (3,479)           | (2,132)          |
| <b>Operating loss</b>  | <b>(22,932)</b>                                 | <b>(21,416)</b>   | <b>(15,605)</b>   | <b>(10,743)</b>   | <b>(6,230)</b>   |
| Financial income   | 1,250   | 73                | 112               | 137               | 186              |
| Financial expenses   | —   | —                 | —                 | (3)               | (4)              |
| Exchange gains (losses)  | (5,797)   | (31)              | 181               | 295               | (83)             |
| <b>Loss before taxes</b>   | <b>(27,479)</b>                                 | <b>(21,374)</b>   | <b>(15,312)</b>   | <b>(10,314)</b>   | <b>(6,131)</b>   |
| Income tax expense   | (597)   | —                 | —                 | —                 | —                |
| <b>Loss for the year and total comprehensive loss</b>                            | <b>€ (28,076)</b>                               | <b>€ (21,374)</b> | <b>€ (15,312)</b> | <b>€ (10,314)</b> | <b>€ (6,131)</b> |
| Weighted average number of shares outstanding                                    | 24,609,536                                      | 18,820,612        | 15,734,007        | 7,551,576         | 18,000           |
| Basic and diluted loss per share   | € (1.14)  | € (1.14)          | € (0.97)          | € (1.37)          | € (341.00)       |

|  | As of December 31, |          |          |          |          |
|--|--------------------|----------|----------|----------|----------|
|  | 2017               | 2016     | 2015     | 2014     | 2013     |
|  | (In thousands)     |          |          |          |          |
| <b>Condensed consolidated statement of financial position:</b> |                    |          |          |          |          |
| Cash, cash equivalents and current financial assets            | € 359,775          | € 96,728 | € 42,327 | € 55,973 | € 23,220 |
| Total assets   | 370,908            | 105,772  | 45,962   | 58,510   | 25,013   |
| Deferred revenue   | 10,070             | 30,206   | 4,141    | 3,451    | 456      |
| Total liabilities  | 25,977             | 42,398   | 8,684    | 8,428    | 3,309    |
| Share capital  | 3,217              | 2,012    | 1,580    | 1,571    | 466      |
| Share premium  | 430,518            | 126,358  | 82,169   | 81,940   | 45,304   |
| Total equity   | 344,931            | 63,374   | 37,278   | 50,082   | 21,704   |

|  | As of December 31, |          |          |          |          |
|--|--------------------|----------|----------|----------|----------|
|  | 2017               | 2016     | 2015     | 2014     | 2013     |
|  | (In thousands)     |          |          |          |          |
| <b>Condensed consolidated statement of cash flows:</b>           |                    |          |          |          |          |
| Cash and cash equivalents at beginning of the period             | € 89,897           | € 35,514 | € 32,180 | € 22,720 | € 15,430 |
| Net cash flows (used in) / from operating activities             | (36,546)           | 10,599   | (13,897) | (5,235)  | (6,606)  |
| Net cash flows (used in) / from investing activities             | (162,052)          | (806)    | 16,812   | (23,341) | 671      |
| Net cash flows (used in) / from financing activities             | 305,365            | 44,621   | 238      | 37,741   | 13,308   |
| Effect of exchange rate differences on cash and cash equivalents | (5,797)            | (31)     | 181      | 295      | (83)     |
| Cash and cash equivalents at end of the period                   | € 190,867          | € 89,897 | € 35,514 | € 32,180 | € 22,720 |

## Exchange Rate Information

The euro is our functional currency and the currency in which we report our financial results. The following table sets forth, for each period indicated, the low and high exchange rates of U.S. dollars per euro, the exchange rate at the end of such period and the average of such exchange rates on the last day of each month during such period, based on the noon buying rate of the Federal Reserve Bank of New York for the euro. As used in this document, the term “noon buying rate” refers to the rate of exchange for the euro, expressed in U.S. dollars per euro, as certified by the Federal Reserve Bank of New York for customs purposes. The exchange rates set forth below demonstrate trends in exchange rates, but the actual exchange rates used throughout this annual report may vary.

|                         | Year ended<br>December 31, |        |        |        |        |
|-------------------------|----------------------------|--------|--------|--------|--------|
|                         | 2017                       | 2016   | 2015   | 2014   | 2013   |
| High                    | 1.2041                     | 1.1516 | 1.2015 | 1.3927 | 1.3816 |
| Low                     | 1.0416                     | 1.0375 | 1.0524 | 1.2101 | 1.2774 |
| Rate at end of period   | 1.2022                     | 1.0552 | 1.0859 | 1.2101 | 1.3779 |
| Average rate per period | 1.1301                     | 1.1072 | 1.1096 | 1.3297 | 1.3281 |

The following table sets forth, for each of the last six months, the low and high exchange rates for euros expressed in U.S. dollars and the exchange rate at the end of the month based on the noon buying rate as described above.

|                       | September<br>2017 | October<br>2017 | November<br>2017 | December<br>2017 | January<br>2018 | February<br>2018 |
|-----------------------|-------------------|-----------------|------------------|------------------|-----------------|------------------|
| High                  | 1.2041            | 1.1847          | 1.1936           | 1.2022           | 1.2488          | 1.2482           |
| Low                   | 1.1747            | 1.1580          | 1.1577           | 1.1725           | 1.1922          | 1.2211           |
| Rate at end of period | 1.1813            | 1.1580          | 1.1898           | 1.2022           | 1.2428          | 1.2211           |

On December 31, 2017, the noon buying rate of the Federal Reserve Bank of New York for the euro was €1.00 = US\$1.2022. Unless otherwise indicated, currency translations in this annual report reflect the December 31, 2017 exchange rate.

On March 16, 2018, the noon buying rate of the Federal Reserve Bank of New York for the euro was €1.00 = \$1.2280.

**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. 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 €21.4 million and €28.1 million for the years ended December 31, 2016 and 2017, respectively. As of December 31, 2017, we had accumulated losses of €100.6 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 the future, we intend to continue to conduct research and development, preclinical testing, clinical trials and regulatory compliance activities that, together with anticipated selling, 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 one or more Phase 3 clinical trials of 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 ARGX-113 in ITP and PV and ARGX-110 in CTCL and AML / high-risk MDS;
- continue the research and development of our other clinical- and preclinical-stage product candidates and discovery stage programs;
- continue the research and development of our other product candidates;
- 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.

We expect that our existing cash, cash equivalents and investments will enable us to fund our operating expenses and capital expenditure requirements through at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our future capital requirements for ARGX-113, 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.

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. If adequate funds are not available on commercially acceptable terms when needed, 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 purchasers of ADSs restrict our operations or require us to relinquish rights to our technologies or product candidates.***

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our operations with our existing cash, cash equivalents and current financial assets, the net proceeds from our initial U.S. and follow-on public offerings, revenue from our collaborations, funding from governmental bodies and interest income from the investment of our cash, cash equivalents and financial assets. In order to further advance development of our product candidates, discover additional product candidates and pursue our other business objectives, however, 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, ARGX-113, completed a Phase 2 clinical trial for the treatment of MG and is in a Phase 2 clinical trial of ARGX-113 for the treatment of ITP. In September 2017, we also initiated a third Phase 2 clinical trial of ARGX-113 for the treatment of PV, and in October 2017, we initiated a Phase 1 clinical trial of a subcutaneous formulation of ARGX-113 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 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 ARGX-113 and ARGX-110, 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;
- 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-115, ARGX-112 and ARGX-116, 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. While we have an IND in effect for ARGX-113 for the treatment of MG with the FDA, we have not conducted any of our clinical development to date in the United States. 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, the results from ongoing and future trials may not support this conclusion.

In the single ascending dose part of the Phase 1 clinical trial of ARGX-113, 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). In the multiple ascending dose part of the Phase 1 clinical trial of ARGX-113, 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 the Phase 2 clinical trial of ARGX-113 in MG, most adverse events were characterized as mild and not deemed to be drug-related. Twenty (out of twenty-four) patients reported at least one treatment emergent adverse event, or TEAE, and nearly all were considered as mild (i.e., Grade 1), except for seven patients who experienced a moderate adverse event. No TEAEs Grade 3 or higher were reported. The most frequent TEAEs deemed to be drug-related per investigator were headache in 25.0% of patients, monocyte count decrease in 16.7% of patients and rhinorrhea in 8.3%

of patients receiving ARGX-113, respectively. Herpes zoster (shingles) of moderate intensity was reported in one patient and deemed to be possibly drug-related by the investigator. One patient in the ARGX-113 group moved to rescue therapy. No clinically significant laboratory, vital signs and/or electrocardiogram findings were observed. No deaths, serious adverse events or TEAEs leading to discontinuation of treatment were reported during the trial.

In the dose-escalation part of the Phase 1 part of our Phase 1/2 clinical trial for ARGX-110 in patients with advanced malignancies expressing CD70, we observed serious adverse events in some patients, including seven patient deaths, of which five deaths were attributed to disease progression, one death was attributed to sepsis and one death was attributed to respiratory failure. None of these deaths were deemed to be drug-related according to the investigator. In the first two completed safety-expansion cohorts (one in patients with CD70-positive solid tumors and one in patients with CD70-positive hematological tumors), a similar tolerability profile as seen in the dose-escalation part was observed. Fourteen patient deaths were reported in these cohorts (all at a dose of 5 mg/kg), of which 10 deaths were attributed to disease progression, one death was attributed to aspergillosis, one death was attributed to a fatal pleural hemorrhage, one death was attributed to pneumonia and one death, 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. In this context, heavily pre-treated means having failed multiple lines of prior treatment. In the dose-escalation part, anti-drug antibodies were observed in all doses except the 10 mg dose and appeared to be inversely related to the administered dose. In our two completed safety-expansion cohorts, anti-drug antibodies were detected.

In a preclinical mouse efficacy model of acute lymphocytic leukemia, or ALL, the administration of an ARGX-110 variant at higher doses led to the acute death of some animals with high tumor load. The cause of death in this preclinical mouse study has not been determined, although a literature search conducted on our behalf revealed some similarities of this symptomatology with anecdotal reports in ALL patients treated with compounds having antibody-dependent cell-mediated cytotoxicity enhanced, or ADCC-enhanced, Fc regions who experienced a cytokine storm, a potentially fatal immune reaction to immunotherapy. We are not currently evaluating ARGX-110 for patients with ALL and have no intention of doing so. However, we cannot guarantee that we will not see evidence of cytokine storm or similar adverse events, which could potentially lead to serious life threatening side-effects or even death, in patients with other forms of cancer, such as those being evaluated in our current Phase 1/2 clinical trial in patients with either AML or high-risk MDS.

We are conducting one Phase 2 clinical trial in cutaneous T-cell lymphoma, or CTCL; and one Phase 1/2 clinical trial in AML and high-risk MDS; and one Phase 1 clinical trial in nasopharyngeal carcinoma. In the Phase 1 safety-expansion cohorts in patients with CD70-positive CTCL and in patients with CD70-positive PTCL and Phase 2 clinical trial in CTCL, one Grade 3 event deemed to be drug-related was observed in 1 mg/kg and 5 mg/kg doses. No grade 4 drug-related toxicities were observed among this patient population. In the dose-escalation part of the Phase 1/2 clinical trial of ARGX-110 in combination with azacitidine in patients with AML or high-risk MDS, in the first set of six evaluable patients receiving doses of 1 mg/kg and 3 mg/kg we observed 17 Grade 3 and 4 adverse events in patients receiving the 1 mg/kg dose (one with intermittent cases of thrombocytopenia) and 14 Grade 3 and 4 adverse events in patients receiving the 3 mg/kg dose (one with intermittent cases of anemia). Evaluation of the 10 mg/kg cohort is ongoing, and to date the observed tolerability profile in the 10 mg/kg dose cohort appears to be in line with the lower dose cohorts.

In the dose-escalation part of the Phase 1 clinical trial for ARGX-111 in treatment-refractory patients whose tumors overexpress c-Met, we observed 19 serious adverse events 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. In the completed safety-expansion cohort of ARGX-111 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.



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 ARGX-113, 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 space 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 (Benlysta/lupus); F. Hoffmann-La Roche AG, or Roche (Rituxan/often used off label) and Janssen Pharmaceuticals Inc., or 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. has received FDA approval for 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 and Millennium Pharmaceuticals, Inc., among others, are developing drugs that may have utility for the treatment of MG. We are aware that Rigel Pharmaceuticals, Inc.; Eisai Inc.; Bristol-Myers Squibb; Shire Immunomedics; Protalex Inc. and others are developing drugs that may have utility for the treatment of ITP. We are aware that Roche and Syntimmune, Inc. 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.; Momena, Inc.; Syntimmune, Inc. and Hannal Biotech.

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 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 ARGX-110 in the future. We anticipate that we will face intense and increasing competition as new treatments enter the market and advanced technologies become available.

Similarly, other companies have monoclonal antibody drug discovery platforms 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 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 FDA, the EMA 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;
- creation of the Independent Payment Advisory Board, or IPAB, which, if impaneled, would have authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription products; 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).

There have been legal and political challenges to certain aspects of the ACA. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. 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, the future of the ACA remains uncertain. We continue to evaluate how the ACA and recent efforts to repeal and replace or limit the implementation of the ACA will impact 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 2013 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 2025 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. For example, CMS may develop new payment and delivery models, such as bundled payment models. The U.S. Department of Health and Human Services has set a goal of moving 30% of Medicare payments to alternative payment models by 2016 and 50% of Medicare payments into these alternative payment models by the end of 2018. 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 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 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 states in which we conduct our business. 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 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 preempted 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.

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. 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.

***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 ARGX-113 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.

***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.***

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford products such as our product candidates, assuming approval. Our ability to achieve acceptable levels of coverage and reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize, and attract additional collaboration partners to invest in the development of our product candidates. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the European Union or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular 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.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, 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. 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.

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, 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.

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.

***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.

***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 biological 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, 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 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.***

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

**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 AbbVie and 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;
- 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, including AbbVie and Shire, 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;
- 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.

## 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 unenforceable. 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 ARGX-110 and ARGX-111. The patent relating to ARGX-110 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 involve 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 our employees or we 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; 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; Debbie Allen, our Senior Vice President of Business Development; and Dirk Beeusaert, 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 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 employee stock plan;



- 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 year 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 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

***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 expected to commence 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 adversely 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, 2017, we had €113.6 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. As such, our redomiciliation as described in “Item 4.A.—Overview of Our Restructuring and Anticipated Redomiciliation—Transfer of Our Registered Office from the Netherlands to Belgium,” will have no impact on the tax loss carry forwards of argenx BVBA. For a description of the tax impact of our restructuring, see the risk factor below and “Item 4.A.—Overview of Our Restructuring and Anticipated Redomiciliation.”

Furthermore, the Belgian government recently announced its intention to limit the use of tax loss carry forwards as of January 1, 2018. If adopted, this rule would result in the tax loss carry forwards (and certain other tax deductions) being no longer tax deductible against 30% of our profits exceeding the first €1.0 million.

***The restructuring and its contemplated tax treatment is subject to approval by the Belgian tax authorities.***

We have engaged with the Dutch and Belgian tax authorities in order to reach an agreement on the tax effects of our proposed restructuring. The Dutch tax authorities have confirmed in a ruling dated April 20, 2017 that they agree (i) that, for Dutch corporate income tax purposes, the economic ownership of our intellectual property rights was transferred to argenx BVBA on August 28, 2009 and (ii) that the indemnification payment to be paid by argenx BVBA to argenx SE entails an arm’s length consideration for (a) the value of economic ownership of our intellectual property rights at that time, (b) accrued interest thereon and (c) related transfer pricing adjustments. See “Item 4.A.—Overview of Our Restructuring and Anticipated Redomiciliation.”

The Belgian tax authorities have not yet issued a binding ruling confirming these points and may take a different position. The Belgian tax authorities may consider that the economic ownership of the intellectual property rights will not be transferred to argenx BVBA until the completion of our restructuring. The Belgian tax authorities may

not accept the amount of the indemnification payment to be paid by argenx BVBA to argenx SE as agreed upon with the Dutch tax authorities and may disagree with its arm's length character and its qualification as a deductible cost for argenx BVBA. If the Belgian tax authorities do not accept the qualification of the indemnification payment as a deductible cost for argenx BVBA, we will not be allowed to treat the amount of €80 million as a deductible cost and would thus not be able to offset this amount against potential taxable profits in the future. See "Item 4.A.—Overview of Our Restructuring and Anticipated Redomiciliation." In addition, as long as our redomiciliation is not successfully completed, we will not qualify for a recently introduced Belgian tax scheme under which argenx SE may transfer losses to argenx BVBA (subject to certain conditions and limitations), which scheme could result in a reduction of argenx BVBA's corporate tax due.

***If our redomiciliation is not successfully completed, we will not be able to reduce our compliance burden and costs.***

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 in Belgium. Accordingly, depending on the entry into force of major changes to Belgian corporate law, we may seek shareholder approval for our redomiciliation from the Netherlands to Belgium. The redomiciliation is expected to be implemented through a series of complex cross-border steps, including obtaining shareholder and governmental approvals, all of which are beyond our control. See "Item 4.A.—Overview of Our Restructuring and Anticipated Redomiciliation." We cannot assure you that we will receive these approvals, and we may be unable to implement our redomiciliation.

If our redomiciliation is not successfully completed, we will remain a European public company with limited liability under Dutch law. In such event, we will not be able to reduce our compliance burden. Our legal and financial compliance costs will remain higher and some activities will continue to be more time-consuming and costly than if we would be a company incorporated under Belgian law. For example, if our redomiciliation is not successfully completed, we would 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. In addition, if our redomiciliation is not successfully completed, we would need to continue leasing our office in Breda, the Netherlands.

## **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. And you may not be able to resell the ADSs at or above the public offering price.***

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.

Since the ADSs were sold at our initial U.S. public offering in May 2017 at a price of \$17.00 per ADS, the price per ADS has ranged as low as \$17.33 and as high as \$87.00 through March 20, 2018. During this same period, ordinary share prices have ranged from as low as €15.15 to as high as €70.50. 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 the 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.

***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 new compliance initiatives and corporate governance practices.***

As a public company, and particularly after we no longer qualify as an emerging growth 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*). If our redomiciliation is completed, we will be a Belgian 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 will 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. However, while we remain an emerging growth company, we will not be 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 both costly and challenging. In this regard, we will need to continue to dedicate internal resources, 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 7.A.—Major Shareholders.”

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.

***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.***

If our existing shareholders sell, or indicate an intent to sell, substantial amounts of our securities in the public market, the trading price of the ADSs could decline significantly. In addition, ordinary shares subject to outstanding options under our equity incentive plans and the ordinary shares reserved for future issuance under our equity incentive plan will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. In addition, we intend to register all ordinary shares that we may issue under our equity compensation plans. Once we register these ordinary shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and lock-up agreements.

***Provisions of our Articles of Association or Dutch corporate law, or, following our redomiciliation, our Belgian Articles of Association or Belgian 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. If we complete our redomiciliation, Belgian corporate law will allow for various protective measures. In addition, several provisions of Belgian corporate law and certain other provisions of Belgian law, such as obligations to disclose significant shareholdings and merger control regulations, may apply to us following completion of our redomiciliation and may make an unsolicited tender offer, merger, change in management or other change in control of our company more difficult. 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. In addition, the board of directors of Belgian companies may in certain instances, and subject to prior authorization by the shareholders, deter or frustrate public takeover bids through dilutive issuances of equity securities (pursuant to the authorized capital) or through share buy-backs. Although the authorization of the board of directors to increase a company’s share capital through contributions in kind or in cash with restriction or limitation of the preferential subscription right of the existing shareholders is suspended upon the notification to the company by the FSMA of a public takeover bid on the securities of the company, the company’s shareholders at the General Meeting can, under certain conditions, expressly authorize the board of directors to increase the capital of the company by issuing shares in an amount of not more than 10% of the existing shares of the company at the time of such a public takeover bid. If

Belgian corporate law is amended, these and/or other provisions may have a similar effect. See “Management Upon Redomiciliation.”

***Fluctuations in exchange rates may increase the risk of holding 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 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 will 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, notably with the opening of our U.S. office in October 2017, 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. 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 ordinary 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.

***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. If we complete our 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. See "Description of Share Capital and Group Structure Upon Completion of Our Redomiciliation." 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.

***Holders of our ordinary shares outside the Netherlands, or, if we complete our redomiciliation, Belgium, and ADS holders, may not be able to exercise preemptive rights.***

In the event of an increase in our share capital, holders of our ordinary shares are generally entitled under Dutch law to full preemptive 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). If we complete our redomiciliation, in the event of a share capital increase for cash by way of the issue of new shares, or in the event of an issue of shares, convertible bonds or warrants, or equity interests, all our shareholders will generally have a preferential subscription right unless these rights are restricted or canceled either by a resolution of the shareholders at the General Meeting or by a resolution of our board of directors in Belgium, or our Belgian Board, (if the Belgian Board has been authorized by the shareholders at the General Meeting for

this purpose). See “Description of Share Capital and Group Structure Upon Completion of Our Redomiciliation—Preferential Subscription Rights.” If Belgian corporate law is amended, these and/or similar provisions may contain similar rights. See “Description of Share Capital and Group Structure Upon Completion of Our Redomiciliation.” However, making preemptive 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 located in the United States and holders of the ADSs would not be able to participate in a preemptive 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 preemptive rights offering unless we made arrangements with the depository 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). If we complete our redomiciliation, we will be a Belgian 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*). If we complete our redomiciliation, we will be a Belgian European public company with limited liability (*Societas Europaea* or *SE*). Our corporate affairs are, or will be, governed by our Articles of Association and by the laws governing companies incorporated in the Netherlands, and if we complete our redomiciliation, by our Belgian Articles of Association and by the laws governing companies incorporated in Belgium, respectively. The rights of shareholders and the responsibilities of members of our board of directors or if our redomiciliation is completed our Belgian Board 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, and the Belgian Board may under Belgian law, 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. See “Item 16G.—Corporate Governance” and “Description of Share Capital and Group Structure Upon Completion of Our Redomiciliation—Comparison of Belgian Corporate Law and U.S. Corporate Law—Corporate Governance.”

***We are not obligated to, and do not comply with, all the best practice provisions of the Dutch Corporate Governance Code, and we do not expect to comply with all principles and provisions of the Belgian Corporate Governance Code if we complete our redomiciliation, 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 dated December 8, 2016, which is in force as of the financial year starting on or after January 1, 2017, 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.”

If we complete our redomiciliation, as a Belgian European public company with limited liability (*Societas Europaea* or *SE*), we will be subject to the Belgian Corporate Governance Code of March 12, 2009, or the Belgian Corporate Governance Code. The Belgian Corporate Governance Code contains principles, provisions and guidelines for the management and control of companies. The Belgian Corporate Governance Code applies to all Belgian companies listed on a regulated market, including Euronext Brussels. If we complete our redomiciliation, the principles, provisions

and guidelines will apply to the Belgian Board (in relation to role and composition, conflicts of interest and independency requirements, board committees and remuneration), our executive management (in relation to role and composition, conflicts of interest and remuneration) and shareholders and the General Meeting (for example, regarding their role and our obligations to provide information to our shareholders). We do not expect to comply with all the provisions and guidelines of the Belgian Corporate Governance Code. If we complete our redomiciliation, under the Belgian Corporate Governance Code, as a Belgian company, we will be required to include a corporate governance statement in our annual report describing whether we comply with all provisions of the Belgian Corporate Governance Code. If we do not comply with the provisions of the Belgian Corporate Governance Code (for example, because of a conflicting Nasdaq requirement or otherwise), we must explain our reasons for any deviation from the Belgian Corporate Governance Code in this corporate governance statement. See “Description of Share Capital and Group Structure Upon Completion of Our Redomiciliation—Comparison of Belgian Corporate Law and U.S. Corporate Law—Belgian Corporate Governance Code.” If the Belgian Corporate Governance Code is replaced, these and/or other provisions will apply. See “Management Upon Redomiciliation.”

This may affect your rights as a shareholder and you may not have the same level of protection as a shareholder in another Dutch or Belgian European public company with limited liability (*Societas Europaea* or *SE*) listed on a regulated market that fully complies with the DCGC or, respectively, the Belgian Corporate Governance Code, as applicable.

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

We are incorporated under the laws of the Netherlands. If we complete our 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 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.

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 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.” In addition, if we complete our redomiciliation, these and other variations from the corporate governance requirements of Nasdaq may exist. 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, 2018 (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, 2018. 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 16, 2018, 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 lost 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 are an "emerging growth company," and we cannot be certain if the reduced reporting requirements applicable to "emerging growth companies" will make the ADSs less attractive to investors.***

We are an "emerging growth company," as defined in the U.S. Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we continue to be an "emerging growth company," we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including not being required to comply with the auditor attestation requirements of Section 404, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. As an "emerging growth company," we are required to report only two years of financial results and selected financial data compared to three and five years, respectively, for comparable data reported by other public companies. We may take advantage of these exemptions until we are no longer an "emerging growth company." We could be an "emerging growth company" for up to the last day of the fiscal year ending after the fifth anniversary of our initial U.S. public offering, although circumstances could cause us to lose that status earlier, including if the aggregate market value of our ordinary shares held by non-affiliates exceeds \$700 million as of any June 30 (the end of our second fiscal quarter) before that time, in which case we would no longer be an "emerging growth company" as of the following December 31 (our fiscal year-end). We cannot predict if investors will find the ADSs less attractive because we may rely on these exemptions. If some investors find the ADSs less attractive as a result, there may be a less active trading market for the ADSs and the price of the ADSs may be more volatile.

***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. However, for as long as we are an “emerging growth company” under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an “emerging growth company” for up to five years from the closing of our initial U.S. public offering. An independent assessment of the effectiveness of our internal controls 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.

***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 current 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 our 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 current taxable year, and should not be treated as such for subsequent taxable years. 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 8<sup>th</sup> Avenue, New York, NY 10011.

Our actual capital expenditures for the years ended December 31, 2015, 2016 and 2017 amounted to €0.3 million, €0.9 million, and €0.4 million respectively. These capital expenditures primarily consisted of office and laboratory equipment and IT 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 2018 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 Anticipated 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. 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 been performing all research and development activities under a license provided by argenx N.V. (since April 26, 2017, argenx SE) and has been assigning 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.

The diagram below sets out our group structure and legal ownership of our intellectual property, or IP, rights as of December 31, 2016:





Since all our research and development activities have been performed by the Belgian BVBA since August 28, 2009, we believe that value creation is 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. Additionally, 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. Accordingly, we have implemented a business restructuring, as described below, and we intend to seek shareholder approval to reorganize under the laws of Belgium.

### **Restructuring**

In view of the above considerations, a business restructuring has been implemented, which we refer to as the restructuring, which involves two principal steps as described below.

#### *Step 1: Conversion of argenx N.V. to argenx SE*

In order to allow for the transfer of our registered office from the Netherlands to Belgium, we have converted to a Dutch European public company with limited liability (*Societas Europaea* or *SE*), since there is currently no clear legal framework under Dutch law for such transfer of registered office 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. 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.

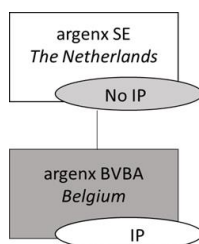
The diagram below sets out our group structure and legal ownership of intellectual property rights effective as of April 26, 2017:



#### *Step 2: Transfer of ownership of intellectual property rights to the Belgian BVBA*

On May 5, 2017, we transferred the legal ownership of all intellectual property rights of argenx SE to the Belgian BVBA, effective as of January 1, 2017, resulting in the Belgian BVBA holding all legal and economic ownership of our intellectual property rights. As a consequence, the research and development agreement between argenx SE and the Belgian BVBA has been terminated effective as of January 1, 2017.

The diagram below sets out our group structure and legal ownership of intellectual property rights following completion of the transfer of ownership of intellectual property rights to the Belgian BVBA, as of the date of this annual report:



### ***Transfer of Our Registered Office from the Netherlands to Belgium***

Following our restructuring, and also in view of the above considerations, we intend to transfer our corporate seat located in Rotterdam, the Netherlands and our registered office located at Willemstraat 5, 4811 AH, Breda, the Netherlands, to Industriepark Zwijnaarde 7, Building C, 9052 Zwijnaarde (Ghent), Belgium, or our redomiciliation. If we complete our redomiciliation, we will no longer have any presence in the Netherlands. We may seek shareholder approval to reorganize under the laws of Belgium, and in light of the contemplated legislative changes in Belgium, we may postpone our redomiciliation until these changes have entered into force. On July 20, 2017, the Belgian council of ministers approved a draft new Belgian companies code, which will replace the current Belgian Companies Code and will contain major changes in Belgian corporate law. Following the approval by the Belgian council of ministers, the draft new Belgian companies code has been submitted for review by the Belgian Council of State and will subsequently go through the parliamentary approval process, resulting in the publication of the new Belgian companies code in the Belgian Official Gazette (*Belgisch Staatsblad*), the timing of which is unclear as of the date of this annual report. It is contemplated that the new Belgian companies code will enter into force on January 1 of the year following publication of the new Belgian companies code in the Belgian Official Gazette (*Belgisch Staatsblad*). In addition, a new Belgian corporate governance code replacing the Belgian Corporate Governance Code and incorporating the draft new Belgian companies code is being prepared. Given these contemplated major changes to Belgian corporate law, we may postpone seeking shareholder approval for our redomiciliation until the entry into force of the new companies code, which decision may depend on the actual timing of the entry into force of the new Belgian companies code. If we seek to implement our 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 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 redomiciliation and indicating the implications for our shareholders and for the employees;
- following the filing and announcement of these draft terms of our redomiciliation, a two-month waiting period will commence in which creditors may file their objections against our proposed redomiciliation and in which the Dutch Minister of Justice has the right to object to our 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 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 have approved our redomiciliation, a Dutch civil notary will issue a certificate confirming that the procedural rules in relation to our redomiciliation have been complied with; and
- following receipt of this Dutch civil notary certificate, our redomiciliation will be recorded in a notarial deed passed before a Belgian notary.

The diagram below sets out our group structure and legal ownership of intellectual property rights effective upon the completion of our redomiciliation:



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

### **Tax Considerations**

In view of the above considerations, on April 20, 2017, we reached an agreement with the Dutch tax authorities on the following aspects of the restructuring:

- 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 business restructuring, the Belgian BVBA will pay an arm's length compensation to argenx SE in the form of an indemnification payment effective as of January 1, 2017;
- the indemnification payment consists 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;
- based on a transfer pricing analysis performed by our tax advisers, the total indemnification payment is expected to be €80 million and will be charged by argenx SE to the Belgian BVBA. argenx SE will be able to off-set the full amount of its tax loss carry forwards against the taxable profits it will realize as a result of the indemnification payment;
- as part of the business restructuring, argenx SE will transfer the legal ownership of our intellectual property rights to the Belgian BVBA effective January 1, 2017 with the aim to align the legal reality with the underlying economics. The mere 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 therefore does not result in an additional transfer subject to tax in the Netherlands;

- the conversion of argenx SE into a Dutch European public company with limited liability (*Societas Europaea* or SE) and our redomiciliation are also an integral part of the restructuring and do not have any additional Dutch tax consequences. Although they are an integral part of the business restructuring, the tax consequences of this agreement, including the indemnification payment, will not be affected or impacted in case the SE is not redomiciled; and
- altogether, the restructuring results in a taxable amount for argenx SE of €2.4 million which will be subject to corporate income tax in the Netherlands at a tax rate of 25% (20% for the first €200,000 of taxable income).

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 to be 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 in the context of 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 contemplated restructuring is 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 will result 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.

## **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 seven product candidates. Two of our product candidates are in clinical proof-of-concept trials for three indications, one of which has achieved clinical proof-of-concept and is being prepared for Phase 3 clinical development.

We recently completed a Phase 2 clinical trial for ARGX-113, our most advanced product candidate, for the treatment of the rare autoimmune disease myasthenia gravis, or MG, and we reported topline data from this trial in December 2017. ARGX-113 demonstrated strong clinical improvement and statistically significant benefit over placebo. ARGX-113 treatment resulted in a strong clinical improvement over placebo during the entire duration of the study as measured by all four predefined clinical efficacy scales. In addition, ARGX-113 was observed to have a favorable tolerability profile consistent with that observed in our Phase 1 clinical trial. In March 2017, we initiated a Phase 2 clinical trial of ARGX-113 for the treatment of another rare autoimmune disease, primary immune thrombocytopenia, or ITP. In September 2017, we initiated a Phase 2 clinical trial of ARGX-113 for the treatment of a third rare autoimmune disease, pemphigus vulgaris, or PV. We are currently developing our second lead product candidate, ARGX-110, for rare and aggressive hematological cancers, initially for T-cell lymphoma, or TCL, and acute myeloid leukemia, or AML, as well as high-risk myelodysplastic syndrome, or MDS. In December 2016, we commenced a Phase 1/2 clinical trial of ARGX-110 in combination with azacitidine for the treatment of newly diagnosed AML or high-risk MDS patients, and in April 2017, we initiated the Phase 2 part of a Phase 1/2 clinical trial of ARGX-110 for the treatment of cutaneous TCL, or CTCL. We reported interim data for both clinical trials in December 2017.


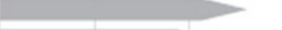














We have a disciplined strategy to maximize the value of our pipeline whereby we plan to retain development and commercialization rights to those product candidates that we believe we can ultimately commercialize successfully on our own if they are approved. We plan to collaborate on product candidates 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 AbbVie S.A.R.L. or AbbVie, for ARGX-115, a cancer immunotherapy-focused product candidate against the novel target glycoprotein A repetitions predominant, or GARP. We received a \$40.0 million (€35.1 million based on the exchange rate in effect as of the date the payment was received) upfront payment and a \$10.0 million (€8.9 million based on the exchange rate in effect as of the date the payment was received) preclinical milestone payment in connection with this collaboration.

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 POTE LLIGENT—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. While we have an investigational new drug application, or IND, in effect for ARGX-113 for the treatment of MG with the U.S. Food and Drug Administration, or FDA, we have only conducted part of our Phase 2 clinical development in MG in the United States.

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

| Product Candidate                      | Target | Technology Used                     | Indication   | Preclinical  | Phase 1  | Phase 2  | Phase 3 | Key Commentary / Next Anticipated Milestone   |
|--|--------|-------------------------------------|--|--|--|--|---------|---|
| <b>Wholly-Owned Product Candidates</b> |        |                                     |  |  |  |  |         |   |
| ARGX-113 (ofgartimod)                  | FcRn   | ABDEG                               | Myasthenia gravis<br>Primary immune thrombocytopenia<br>Pemphigus Vulgaris<br>Chronic autoimmune diseases (subcutaneous) |  |                |  |         | <ul style="list-style-type: none"> <li>■ YE2018 — Launch Phase 3</li> <li>■ 2H2018 — Announce Phase 2 topline results</li> <li>■ 2H2018 — Announce interim Phase 2 data</li> <li>■ 2H2018 — Announce Phase 1 topline results</li> </ul> |
| ARGX-110 (cusatuzumab)                 | CD70   | SIMPLE Antibody POTELLIGENT         | T-Cell lymphoma<br>Acute myeloid leukemia  |  | Phase 1/2*<br> |  |         | <ul style="list-style-type: none"> <li>■ 2H2018 — Announce Phase 2 topline results in CTCL</li> <li>■ 2H2018 — Transition into Phase 2 in AML/MDS</li> </ul>  |
| ARGX-111                               | C-MET  | SIMPLE Antibody POTELLIGENT Nihance | Solid tumors with MET amplification  |  |                |  |         | <ul style="list-style-type: none"> <li>■ Intend to partner</li> </ul>   |
| <b>Partnered Product Candidates</b>    |        |                                     |  |  |  |  |         | <b>Partner</b>  |
| ARGX-109 (gorimzumab)                  | IL-6   | SIMPLE Antibody Nihance             | Rheumatoid arthritis   |  |                |  |         | <ul style="list-style-type: none"> <li>■ Bird Rock Bio</li> </ul>   |
| ARGX-112                               | IL-22R | SIMPLE Antibody                     | Skin inflammation  |  |                |  |         | <ul style="list-style-type: none"> <li>■ LEO Pharma</li> </ul>  |
| ARGX-115                               | GARP   | SIMPLE Antibody                     | Cancer immunotherapy   |  |                |  |         | <ul style="list-style-type: none"> <li>■ AbbVie</li> </ul>  |
| ARGX-116                               | ApoC3  | SIMPLE Antibody                     | Dyslipidemia   |  |               |  |         | <ul style="list-style-type: none"> <li>■ Staton Biotechnology</li> </ul>  |

\* Our Phase 1/2 clinical trials of ARGX-110 meet the requirements for both a Phase 1 and Phase 2 trial because they are designed to (1) determine the optimal or maximum tolerated dose of ARGX-110 and/or the recommended Phase 2 dose, as a monotherapy and in combination with standard of care, through a dose-escalation component and gather pharmacokinetics, immunogenicity and safety data and (2) assess efficacy, both as a monotherapy and in combination with standard of care.

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 90 employees and consultants with experience across the spectrum of antibody drug discovery and development and business development. Members of our board of directors and management team have extensive experience in the life sciences industry and have previously served at companies including Cambridge Antibody Technology Group Plc; Celgene Corporation; Galapagos NV; GlaxoSmithKline plc; Janssen Pharmaceuticals, Inc.; Micromet, Inc.; Nicox S.A.; The Procter & Gamble Company; Quintiles IMS Holdings, Inc. and Unilever NV.

## 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-ready lead product candidate with clinical proof-of-concept in MG; pipeline-in-a-product opportunity with ongoing Phase 2 clinical trials in two additional indications.** We announced topline data from the Phase 2 clinical trial in MG of our lead product candidate, ARGX-113, in December 2017. We expect to prepare for Phase 3 clinical development in this indication before the end of 2018, subject to discussions at an end-of-Phase 2 meeting with the FDA, which we intend to schedule in 2018. We initiated two additional Phase 2 clinical trials of ARGX-113, in ITP in March 2017 and in PV in September 2017. MG, ITP and PV are three rare, severe autoimmune diseases in which there is high unmet medical need. MG, ITP and PV are each characterized by high levels of pathogenic immunoglobulin G, or IgG, antibodies, and we designed ARGX-113 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. As such, we believe ARGX-113 is a pipeline-in-a-product opportunity for us in these three, and potentially other, indications. In a Phase 1 clinical trial of ARGX-113 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 report topline data from our clinical trial in patients with ITP in the second half of 2018 and interim data from our clinical trial in patients with PV in the second half of 2018. Depending on the outcome of the ITP and PV clinical trials, and subject to discussions with regulatory agencies, we intend to enter into Phase 3 clinical development in one or both of these indications.
- **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 four product candidates into clinical development—ARGX-113, ARGX-110, ARGX-111 and ARGX-109; three into the preclinical stage—ARGX-115, ARGX-112 and ARGX-116; and we currently have multiple programs in the discovery stage. Our second lead product candidate, ARGX-110, is currently being investigated in Phase 1/2 clinical trials, and we reported initial interim proof-of-concept results from these trials in December 2017. 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 POTE LLIGENT—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 AbbVie for ARGX-115, a cancer immunotherapy-focused product candidate against the novel target GARP.

For a breakdown of our total revenues by activity and geographic market, please see “Note 5.3—Segment reporting” in our consolidated financial statements appended to this annual report.

## 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 ARGX-113 to regulatory approval in MG and through clinical proof-of-concept in two additional indications.** We are currently developing our lead product candidate, ARGX-113, for the treatment of patients with MG, ITP and PV. 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 reported topline data from our Phase 2 clinical trial of ARGX-113 for the treatment of patients with MG in December 2017. We plan to advance ARGX-113 into Phase 3 clinical development before the end of 2018, subject to discussions at an end-of-Phase 2 meeting with the FDA, which we intend to schedule in 2018, aiming for a first approval in MG. We announced in September 2017 that the FDA granted orphan drug designation for the use of ARGX-113 for the treatment of MG. We are also currently evaluating ARGX-113 in two Phase 2 clinical trials for the treatment of patients with ITP and PV. We expect to report topline data from the ITP clinical trial and interim data from the PV clinical trial in the second half of 2018. Depending on the outcome of the ITP and PV clinical trials, and subject to discussions with regulatory agencies, we intend to enter into Phase 3 clinical development in one or both of these indications.
- **Advance ARGX-110 through clinical proof-of-concept in selected hematological tumors.** We initiated the Phase 2 part of an open-label Phase 1/2 clinical trial of ARGX-110 for the treatment of adult relapsed or refractory CD70-positive CTCL patients in April 2017. We reported interim results from this clinical trial in December 2017, and we expect to report topline results in the second half of 2018. In December 2016, we initiated an open-label, Phase 1/2 clinical trial of ARGX-110 in combination with the standard of care, azacitidine, in newly diagnosed AML and high-risk MDS patients. We reported interim results from the dose-escalation part of this clinical trial in December 2017, and we expect to transition into the Phase 2 part of this clinical trial in the second half of 2018.
- **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 ARGX-113 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 three Phase 2 clinical trials in different indications, MG, ITP and PV, where we believe this mechanism of action may have therapeutic benefit. In addition, we believe there are other autoimmune diseases beyond MG, ITP and PV that may benefit from treatment with ARGX-113. 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 subcutaneous version of ARGX-113, which is currently being 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.

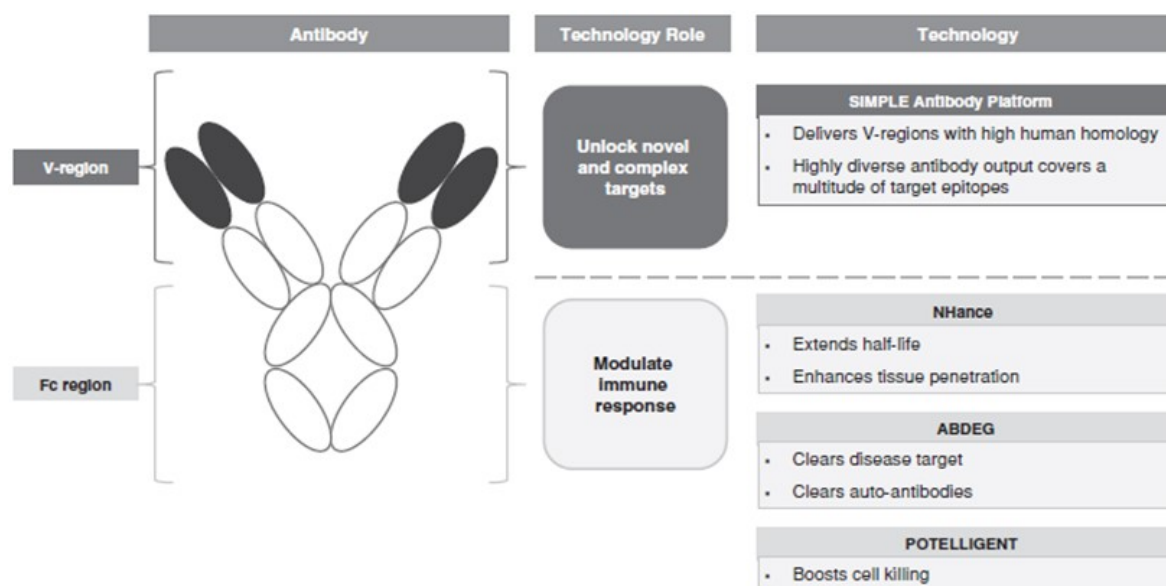
- ***Independently commercialize our product candidates in indications and geographies where we believe we can extract maximum value.*** We plan to independently develop and commercialize those product candidates that we believe have a clear clinical and regulatory approval pathway and that we believe 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.

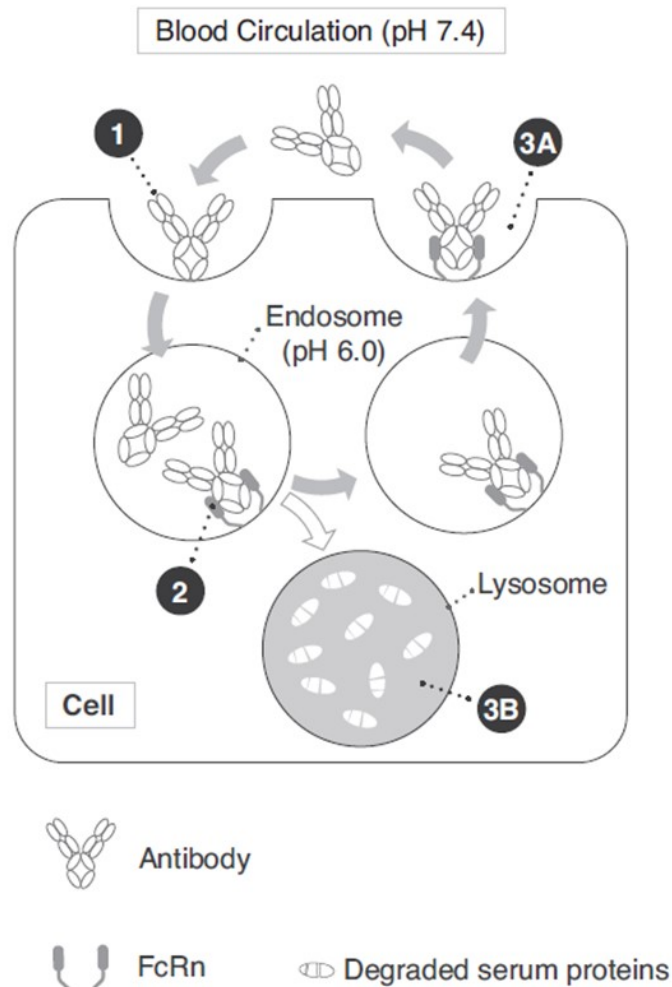
### ***Our Fc Engineering Technologies***

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*

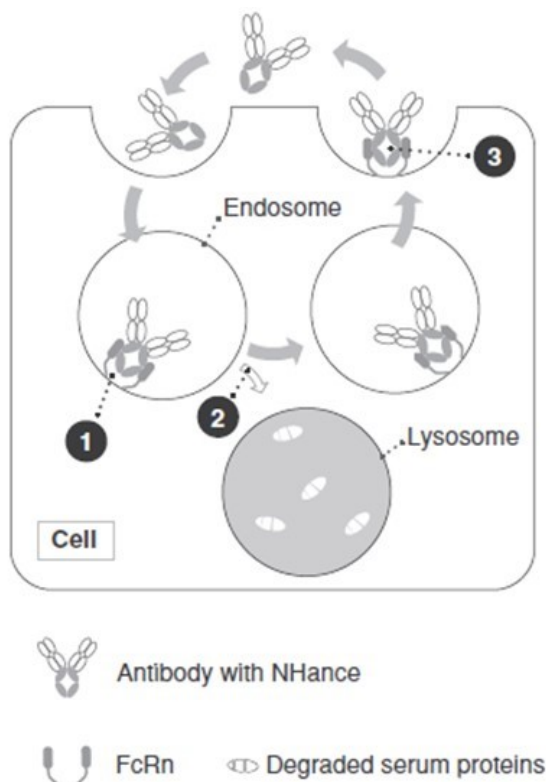
An illustration of the FcRn-mediated antibody recycling mechanism is shown in *Figure 2*. (1) Serum proteins, including IgG antibodies, are routinely removed from the circulation by cell uptake. (2) Antibodies can bind to FcRn, which serves as a dedicated recycling receptor in the endosomes, which have an acidic environment, and then (3A) return to the circulation by binding with their Fc region to FcRn. (3B) 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*, (1) NHance antibodies bind to FcRn with higher affinity, specifically under acidic pH conditions. (2) Due to these tighter bonds, NHance FcRn-mediated antibody recycling is strongly favored over lysosomal degradation, although some degradation does occur. (3) 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.

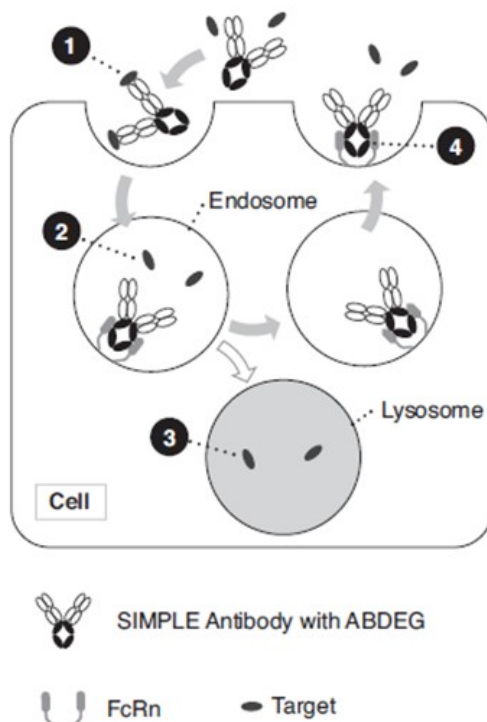


**Figure 3: NHance mutations favor the FcRn-mediated recycling of IgG antibodies**

### 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 ARGX-113.

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. ARGX-110 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 | Technology Used                     | Indication   | Preclinical | Phase 1   | Phase 2 | Phase 3 | Key Commentary / Next Anticipated Milestone   |
|--|--------|-------------------------------------|--|-------------|-----------|---------|---------|---|
| <b>Wholly-Owned Product Candidates</b> |        |                                     |  |             |           |         |         |   |
| ARGX-113<br>(efgartigimod)             | FcRn   | ABDEG                               | Myasthenia gravis<br>Primary immune thrombocytopenia<br>Pemphigus Vulgaris<br>Chronic autoimmune diseases (subcutaneous) |             |           |         |         | <ul style="list-style-type: none"> <li>■ YE.2018 — Launch Phase 3</li> <li>■ 2H.2018 — Announce Phase 2 topline results</li> <li>■ 2H.2018 — Announce Interim Phase 2 data</li> <li>■ 2H.2018 — Announce Phase 1 topline results</li> </ul> |
| ARGX-110<br>(ousatzumab)               | CD70   | SIMPLE Antibody POTELLIGENT         | T-Cell lymphoma<br>Acute myeloid leukemia  |             | Phase 1/2 |         |         | <ul style="list-style-type: none"> <li>■ 2H.2018 — Announce Phase 2 topline results in CTCL</li> <li>■ 2H.2018 — Transition into Phase 2 in AML/MDS</li> </ul>  |
| ARGX-111                               | C-MET  | SIMPLE Antibody POTELLIGENT Nihance | Solid tumors with MET amplification  |             |           |         |         | <ul style="list-style-type: none"> <li>■ Intend to partner</li> </ul>   |

### ARGX-113

We are currently developing our lead product candidate, ARGX-113, for the treatment of patients with MG, ITP and PV, 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. ARGX-113 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 intravenous 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 have completed the single and multiple ascending dose parts of a double-blind, placebo-controlled Phase 1 clinical trial of ARGX-113 in 62 healthy volunteers. This clinical trial was conducted at one site in Belgium.

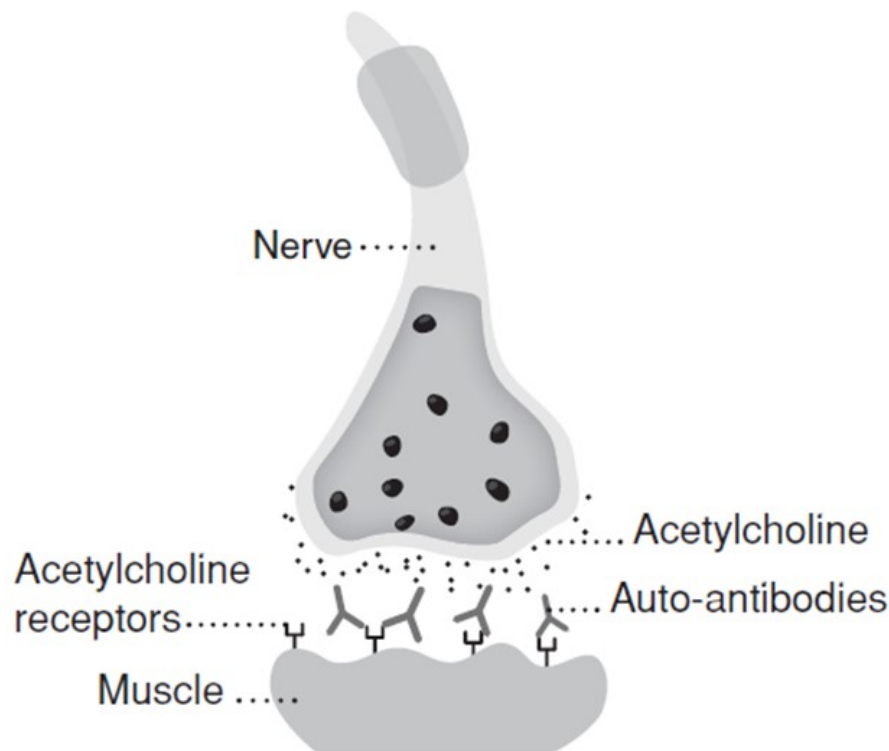
We announced topline data from a double-blind, placebo-controlled Phase 2 clinical trial of ARGX-113 in 24 patients with generalized MG in December 2017. This clinical trial has been performed at multiple sites in Europe, Canada and the United States. We plan to advance ARGX-113 into Phase 3 clinical development before the end of 2018, subject to discussions at an end-of-Phase 2 meeting with the FDA, which we intend to schedule in 2018, aiming for a first approval in this indication. We announced in September 2017 that the FDA granted orphan drug designation for the use of ARGX-113 for the treatment of MG.

In parallel, we are performing a second Phase 2 clinical trial of ARGX-113 in patients with ITP in Europe and expect to report topline data in the second half of 2018. In addition, we launched a third Phase 2 clinical trial of ARGX-113 in patients with PV in September 2017 at multiple sites in Europe, Ukraine and Israel. Depending on the outcome of the ITP and PV clinical trials and subject to discussions with regulatory agencies, we intend to enter into Phase 3 clinical development of ARGX-113 in one or both of these indications. In addition to the intravenous formulation of ARGX-113 that we are using in our current clinical trials, we are also developing a subcutaneous formulation designed to make ARGX-113 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 subcutaneous formulation of ARGX-113 in October 2017 for the treatment of chronic autoimmune diseases.



## 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 ARGX-113 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 subcutaneous formulation of ARGX-113 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 intravenous 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 carries infusion reaction risks, including anaphylaxis, and the risk of opportunistic infections, including progressive multifocal leukoencephalopathy, a rare and usually fatal viral disease.

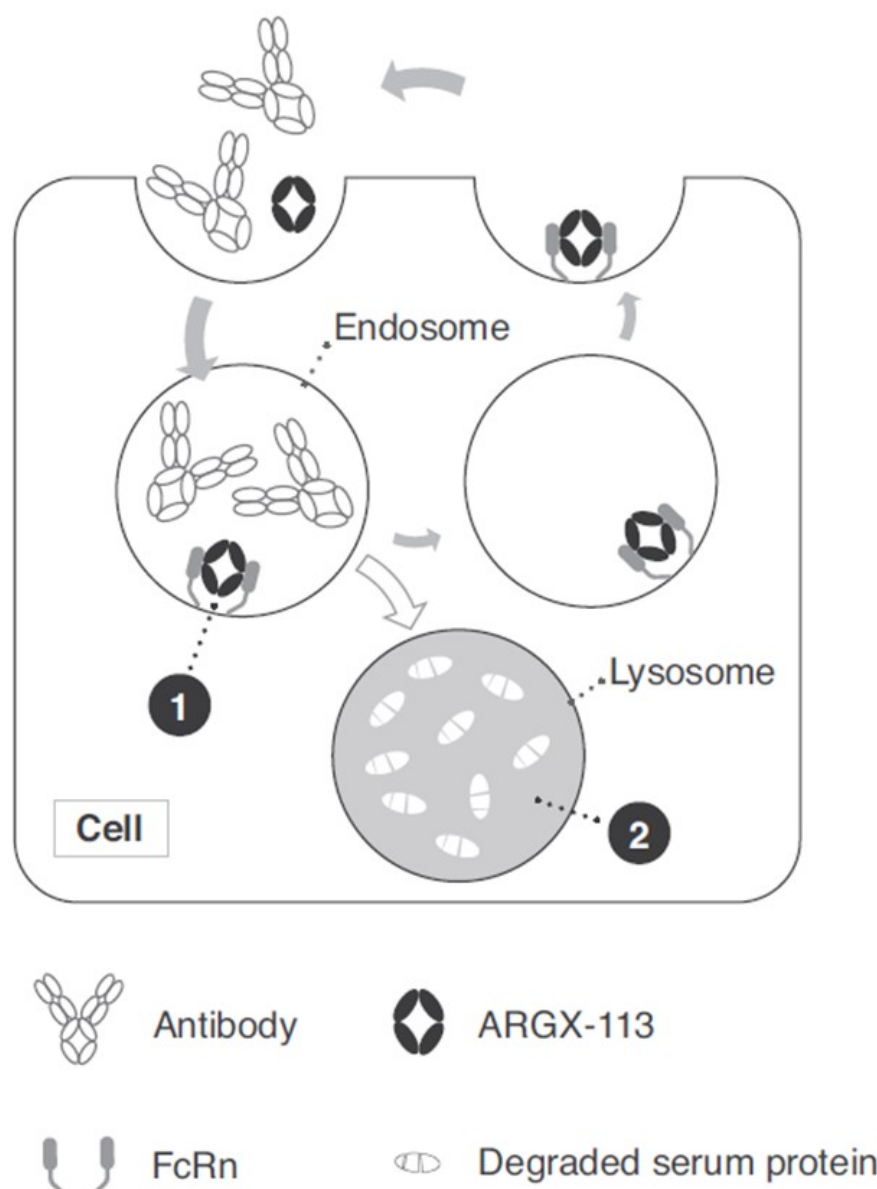
Even with aggressive PV therapy, it takes two to three weeks for blisters to stop forming and about six to eight weeks for blisters to heal. Even with IVIg and Rituxan, complete remissions may take several months, and some patients do not respond to these treatments. The serious complications that can 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.

### *Our Solution: ARGX-113*

Our lead product candidate, ARGX-113, 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 ARGX-113 using our ABDEG Fc engineering technology.

ARGX-113 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*, ARGX-113'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. [(1)] As a result of our ABDEG technology and the modifications we made to the Fc region, ARGX-113 binds to FcRn with high affinity making this receptor unavailable to circulating IgG antibodies. [(2)] 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, ARGX-113 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: ARGX-113'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 ARGX-113 has the potential to reduce levels of pathogenic IgG antibodies. Our clinical data suggest that ARGX-113 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 ARGX-113 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 ARGX-113 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 ARGX-113 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 recently completed a Phase 2 clinical trial of ARGX-113 in patients with MG, and we are currently evaluating ARGX-113 in two Phase 2 clinical trials, one in patients with ITP and one in patients with PV. We reported topline data from the MG clinical trial in December 2017, and we expect to report topline data from the ITP clinical trial and interim data from the PV clinical trial in the second half of 2018. We plan to advance ARGX-113 into Phase 3 clinical development before the end of 2018, subject to discussions at an end-of-Phase 2 meeting with the FDA, which we intend to schedule in 2018, aiming for a first approval in MG. Depending on the outcome of the ITP and PV clinical trials and subject to discussions with regulatory agencies, we intend to enter into Phase 3 clinical development of ARGX-113 in one or both of these indications. In addition to the current intravenous formulation of ARGX-113, we are also developing a subcutaneous formulation designed to make ARGX-113 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 subcutaneous formulation of ARGX-113 in October 2017 for the treatment of chronic autoimmune diseases.

#### 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 ARGX-113. 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 ARGX-113, 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 ARGX-113 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 ARGX-113 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 topline data from this Phase 2 clinical trial in December 2017.

Primary endpoint analysis demonstrated ARGX-113 to be well-tolerated in all patients, with most adverse events observed characterized as mild and not deemed to be drug-related. The majority of treatment emergent adverse events, or TEAEs, observed were considered as mild (*i.e.*, Grade 1). No TEAEs Grade 3 or higher were reported. No

clinically significant laboratory, vital signs and/or electrocardiogram findings were observed. No deaths, serious adverse events or TEAEs leading to discontinuation of treatment were reported during the trial. The observed tolerability profile was consistent with the Phase 1 healthy volunteer trial.

In total, 20 out of 24 (83.3%) patients reported at least one TEAE, and nearly all TEAEs were considered mild by the investigator, except for seven patients who experienced a moderate adverse event. No patients reported experiencing vomiting during the clinical trial. We did not observe any clinically significant increase in C-reactive protein in the clinical trial.

The most frequent TEAEs deemed to be drug-related per investigator were headache in 25.0% of patients, monocyte count decrease in 16.7% of patients and rhinorrhea in 8.3% of patients receiving ARGX-113, respectively. Herpes zoster (shingles) of moderate intensity was reported in one patient and deemed to be possibly drug-related by the investigator. One patient in the ARGX-113 group moved to rescue therapy.

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 ARGX-113 Phase 2 Clinical Trial in MG**

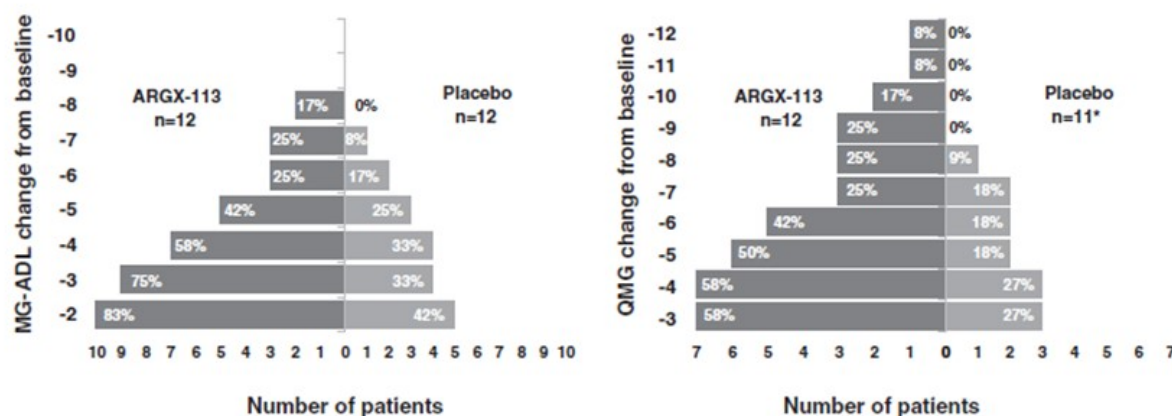
| TEAEs reported in at least two patients   | Number of patients |                    |
|---|--------------------|--------------------|
|   | Placebo (n=12)     | ARGX-113 (n=12)    |
| <b>TEAEs (total)</b>                      | <b>10 (83.3) %</b> | <b>10 (83.3) %</b> |
| Headache                                  | 3 (25.0) %         | 4 (33.3) %         |
| Nausea                                    | 1 (8.3) %          | 1 (8.3) %          |
| Diarrhea                                  | 1 (8.3) %          | 1 (8.3) %          |
| Abdominal pain upper                      | 1 (8.3) %          | 1 (8.3) %          |
| Arthralgia                                | 2 (16.7) %         | —                  |
| B-lymphocyte decrease                     | —                  | 2 (16.7) %         |
| Lymphocyte count decrease                 | —                  | 2 (16.7) %         |
| Monocyte count decrease                   | —                  | 2 (16.7) %         |
| Neutrophil count increase                 | —                  | 2 (16.7) %         |
| Myalgia                                   | —                  | 2 (16.7) %         |
| Pruritus                                  | 2 (16.7) %         | 1 (8.3) %          |
| Rhinorrhea                                | 1 (8.3) %          | 1 (8.3) %          |
| Tooth abscess                             | 2 (16.7) %         | —                  |
| Toothache                                 | 2 (16.7) %         | —                  |
| <b>ARGX-113-related TEAEs (any grade)</b> | <b>3 (25.0) %</b>  | <b>8 (66.7) %</b>  |
| Headache                                  | 1 (8.3) %          | 3 (25.0) %         |
| Monocyte count decrease                   | —                  | 2 (16.7) %         |
| Rhinorrhea                                | 1 (8.3) %          | 1 (8.3) %          |

The secondary endpoint measures relating to efficacy showed ARGX-113 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 ARGX-113 achieved a clinically meaningful response (MG-ADL $\geq$ 2). 75% of patients treated with ARGX-113 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 ARGX-113 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 ARGX-113 treatment group versus placebo with increasing MG-ADL and QMG thresholds as shown in *Figure 7*.



\* Missing data point in one patient

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

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. Moreover, we observed a reduction of acetylcholine receptor autoantibodies following a similar kinetic as the total IgG level reduction.

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 ARGX-113 and in three out of 12 patients receiving placebo. Positive ADA titers were detected in one active-treated patient 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 ARGX-113 pharmacokinetics or pharmacodynamics.

#### Phase 2 Clinical Trial in ITP

We are conducting a randomized, double-blind, placebo-controlled Phase 2 clinical trial to evaluate the safety, efficacy and pharmacokinetics of ARGX-113 in 36 ITP patients, who have platelet counts lower than  $30 \times 10^9/L$  and who are stable on standard-of-care treatment, consisting of corticosteroids, permitted immunosuppressants and/or thrombopoietin receptor agonists. We intend to conduct the clinical trial at approximately 35 sites across Europe. Patients will be randomly assigned to three arms of 12 patients each. All patients in this clinical trial will continue to receive standard-of-care treatment. One treatment arm will receive 5 mg/kg ARGX-113, the second arm will receive 10 mg/kg ARGX-113 and the third arm will receive placebo. Dosing will take place in a three-week period with four weekly doses of ARGX-113 or placebo. The ITP trial protocol was amended by extending the follow-up period from 8 weeks to 21 weeks. In addition, a one-year open label extension study was added as a second amendment to allow (re)treatment of ITP patients from the first study (dosed at 10mg/kg).

The primary objectives of this Phase 2 clinical trial are to evaluate safety and tolerability of ARGX-113 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 include evaluation of efficacy, based on platelet count, use of rescue treatment and bleeding events; pharmacokinetics; pharmacodynamics; and immunogenicity.

In September 2017, we announced that the clinical trial had achieved 50% enrollment.

#### 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 ARGX-113 in 12 patients with mild to moderate PV who are either newly diagnosed or relapsing. We intend to conduct the clinical trial at 12 sites across Europe, Ukraine and Israel. The trial design comprises three cohorts of four patients each. The first cohort will receive 10 mg/kg of ARGX-113 in four weekly doses as induction therapy, followed by five weeks of maintenance therapy with ARGX-113 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 ARGX-113. In newly diagnosed patients and relapsing patients off-therapy, ARGX-113 will be dosed as monotherapy, in absence of standard of care therapy. In relapsing patients on prednisone, ARGX-113 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 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 ARGX-113, 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 1 Clinical Trial for Subcutaneous Formulation of ARGX-113

In addition to the intravenous product formulation of ARGX-113 that we are currently using in our clinical trials, we are also developing a subcutaneous product formulation designed to enable administration of ARGX-113 to larger patient populations, including patients requiring chronic therapy, potentially outside the hospital setting.

We evaluated the intravenous and subcutaneous formulations of ARGX-113 head-to-head in a preclinical cynomolgus monkey model. The results suggest that both formulations result in comparable half-life in circulation of ARGX-113, a favorable bioavailability of 75% of the subcutaneous formulation and a comparable pharmacodynamic effect shown by reduction of total IgG antibodies. We believe these results suggest subcutaneous dosing of ARGX-113 in humans may be feasible. We initiated a Phase 1 clinical trial in healthy volunteers for a subcutaneous formulation in October 2017 for the treatment of chronic autoimmune diseases.

We are evaluating a subcutaneous formulation of ARGX-113 in a randomized, open-label, parallel group, single-center study in approximately 32 healthy male subjects to compare the pharmacokinetics, pharmacodynamics, safety and tolerability of this formulation with the current intravenous formulation being administered in our ongoing Phase 2 clinical trials. Single and repeat dosing regimens are being studied, and doses are aligned with doses used in the continuing Phase 2 clinical trials of ARGX-113 using the intravenous formulation. This clinical trial is taking place in a single clinical center in the Netherlands.

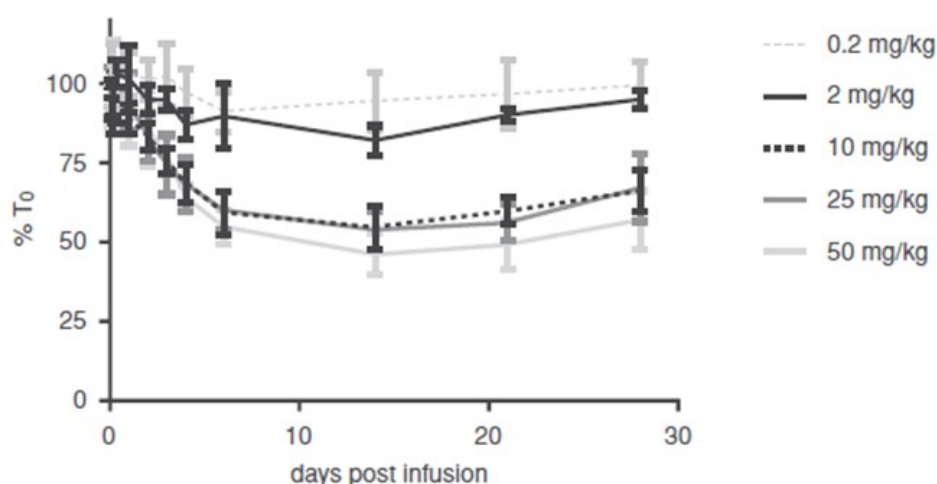
## Phase 1 Clinical Data

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.

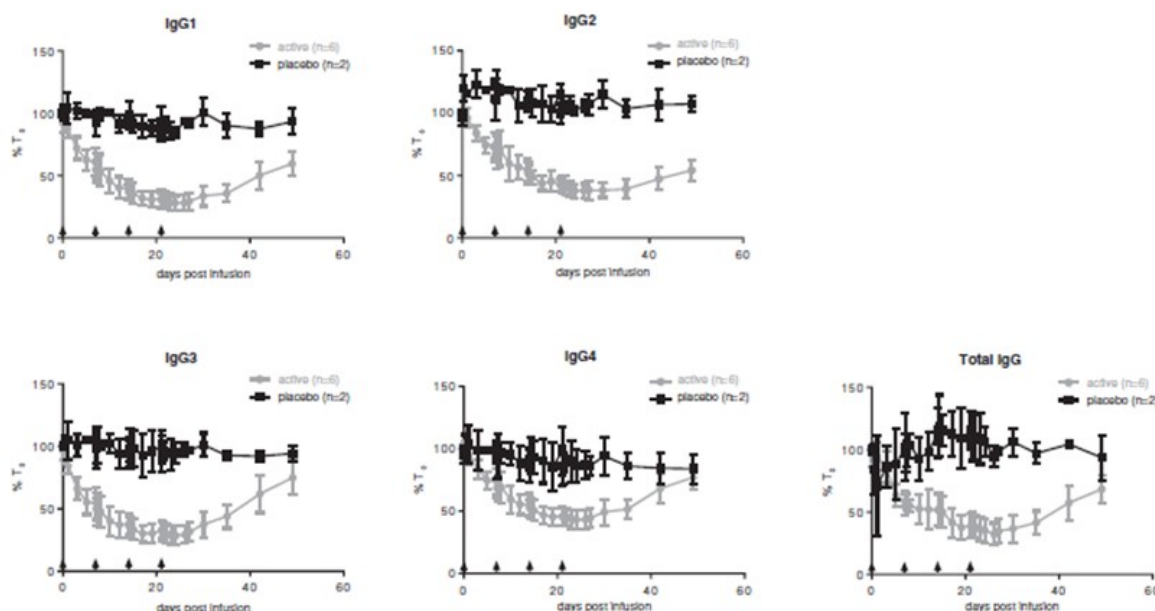


**Figure 8. Selective reduction of IgG by administration of ARGX-113 to healthy volunteers in the single ascending dose part of our Phase 1 clinical trial**

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.

### Preclinical Data

We conducted several preclinical studies of ARGX-113. The role of FcRn in maintaining IgG homeostasis was observed in knockout mice lacking functional FcRn. In preclinical *in vitro* studies, ARGX-113 bound to human FcRn with an affinity that was 30 to 500 times higher than the naturally occurring Fc region of human IgG1. In preclinical testing in cynomolgus monkeys, ARGX-113 specifically blocked IgG antibody recycling and did not lead to reductions in IgA, IgM or serum albumin levels. In preclinical animal efficacy models of MG, ITP, rheumatoid arthritis and MS, different prototypes of ARGX-113 showed the potential to reduce pathogenic IgG antibodies, thereby reducing disease symptoms.

### **ARGX-110**

We are developing ARGX-110 in cancer indications, initially for TCL and AML, as well as high-risk MDS. TCL and AML are rare and aggressive hematological cancers for which significant unmet medical needs exist. MDS, a rare bone marrow disorder, is often a precursor to AML. ARGX-110 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 POTELOGENT technology.

ARGX-110 is currently being evaluated in an open-label Phase 1/2 clinical trial, in combination with azacitidine, in newly diagnosed AML patients who are unfit for intensive chemotherapy or in patients with high-risk MDS and an open-label Phase 1/2 clinical trial in 27 patients (13 patients in the Phase 1 part and 14 patients in the Phase 2 part) relapsed or refractory CD70-positive CTCL patients.

We reported interim results for the first six patients from the dose-escalation part of the Phase 1/2 clinical trial in combination with azacitidine in AML or high-risk MDS in December 2017, which demonstrated a favorable tolerability profile of the combination therapy and suggested evidence of biological activity across the evaluated doses. We expect to report topline data for this trial in the second half of 2018.

We reported interim data from the Phase 2 part of the Phase 1/2 clinical trial in CTCL in December 2017, which demonstrated a favorable tolerability profile and disease control in six out of nine evaluable patients. We expect to report topline data from the Phase 2 part of this clinical trial in the second half of 2018.

In addition, ARGX-110 is being evaluated in an open-label Phase 1 clinical trial in patients with nasopharyngeal carcinoma. To date, 11 patients have been enrolled in this clinical trial.

### *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.

### *Overview of T-Cell Lymphoma*

Lymphoma is the most common type of blood cancer and occurs when lymphocytes, a type of white blood cell such as B-cells and/or T-cells, grow and multiply uncontrollably. Cancerous lymphocytes can travel to many parts of the body, including the blood and bone marrow, giving rise to leukemias, and to lymph nodes, spleen, skin or other organs, forming a mass known as a tumor.

TCL accounts for 6% of all cases of lymphoma and can be divided into various subtypes. These subtypes differ by location, distribution and aggressiveness of the primary tumor as well as by specific changes to the affected lymphocytes. CTCL is a subtype of TCL and overall, there are approximately 7,900 new cases of TCL in the United States each year. According to the Cutaneous Lymphoma Foundation, the incidence of CTCL in the United States is approximately 3,000 new cases per year.

The two most common types of CTCL are mycosis fungoides, representing approximately 50% of CTCL patients, and a more advanced form known as Sézary syndrome, representing approximately 15% of CTCL patients. In both mycosis fungoides and Sézary syndrome, visible skin lesions offer an ongoing means with which to monitor both the progression of disease and the impact of treatment. Sézary syndrome is distinguished by the presence of malignant lymphocytes in the blood, an extensive rash covering over 80% of the body and tumors visible on the skin.

Advanced TCL is generally very aggressive and is typically treated with standard anticancer chemotherapy agents used in combination with or without the addition of biologics. The five-year survival for TCL patients is 65%, with poor prognosis for subtypes such as Sézary syndrome underscoring the unmet need for effective, long-lasting TCL treatments.

### *Our Solution: ARGX-110*

Our product candidate ARGX-110 is an antibody that we believe has the potential to add to the treatment paradigm for lymphomas and leukemias by both increasing the response rates and extending the duration of response for patients with CD70-positive advanced-stage cancers.

We developed ARGX-110 using our SIMPLE Antibody Platform and the POTELLIGENT Fc engineering technology. ARGX-110 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. ARGX-110 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.

Based on the broad overexpression of CD70 in hematological cancers, we may decide to study ARGX-110 in additional hematological cancer indications beyond TCL, AML and MDS. In addition to ARGX-110's potential as a

monotherapy, we believe that it may be suitable for combination therapy given its reported tolerability to date; the fact that certain cancer treatments, such as histone deacetylase inhibitors, hypomethylating agents and irradiation, may upregulate CD70; and resistance to certain treatment with tyrosine kinase inhibitors may be effected through CD70 overexpression.

#### *Clinical Development Plan*

In December 2016, we initiated an open-label Phase 1/2 clinical trial of ARGX-110 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 2017. Patient recruitment is currently ongoing, and we have recruited nine AML patients to date.

We are also currently evaluating ARGX-110 in an open-label, multi-site Phase 1/2 clinical trial in Europe in patients with relapsed or refractory CD70-positive CTCL, with interim data from the Phase 1 and Phase 2 parts of this clinical trial reported in December 2017. We expect to report topline results from the Phase 2 part of this clinical trial in the second half of 2018.

Prior to this, ARGX-110 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): a dose-escalation part (60 patients) and four safety-expansion cohorts in solid tumors (20 patients), hematological cancers (19 patients), CTCL patients (14 patients, of whom 13 have been treated) and PTCL (seven patients). This clinical trial design was adaptive in that it allowed us to make data driven decisions and open-up new cohorts in indications where we have seen the most promising early signals of biological activity. While the primary goal of the Phase 1 part of this clinical trial is to investigate safety and pharmacokinetics, we have also observed evidence of biological activity in several of the patients treated. These results led us to pursue the further evaluation of ARGX-110 in AML and CTCL.

In addition, ARGX-110 is being evaluated in an open-label Phase 1 clinical trial in patients with nasopharyngeal carcinoma. To date, 11 patients have been enrolled in this clinical trial.

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

We are evaluating ARGX-110 in an open-label, dose-escalating Phase 1/2 clinical trial to evaluate its safety, tolerability and efficacy in combination with azacitidine 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 ARGX-110 in combination with 75 mg/m<sup>2</sup> azacitidine (standard of care for AML). During the dose-escalation part of the clinical trial, three doses of ARGX-110, 1 mg/kg, 3 mg/kg and 10 mg/kg administered bi-weekly are being evaluated. This trial design was amended in February 2018 by adding a 20 mg/kg dose cohort to the dose-escalation part to best inform the recommended dose for a Phase 2 trial.

Patients will be dosed every two weeks until disease progression for a maximum duration of 12 months. The primary objective of the Phase 1 part of the clinical trial is to determine the maximum tolerated dose of ARGX-110 and/or the recommended Phase 2 dose in combination with azacitidine. Once the dose for the combination therapy is selected, efficacy will be evaluated in a dedicated Phase 2 clinical trial. This is a multi-center clinical trial conducted in Europe, with three sites currently open in Switzerland. To date, we have enrolled a total of nine patients in the Phase 1 part of this clinical trial. We reported interim results for a first set of six evaluable patients from the dose-escalation part of this clinical trial in December 2017 representing the data as of November 15, 2017. These six patients constituted the 1 mg/kg and 3 mg/kg dose cohorts. Three patients have also been enrolled in the 10 mg/kg dose cohort, but were non-evaluable at the time of the interim data. Six out of nine patients were still on treatment at the time of the interim data. These interim results showed for the first six patients that no dose-limiting toxicity was observed for ARGX-110 and that ARGX-110 was overall reported to be well-tolerated with signs of clinical activity. To date, the tolerability profile of ARGX-110 in this Phase 1/2 clinical study in combination with azacitidine appears to be similar to what we observed in the other ARGX-110 clinical trials. We believe that the observed Grade 3 and 4 hematological toxicity for ARGX-110



in combination with azacitidine corresponds to the reported safety profile of azacitidine monotherapy and can be seen in Table 2.

**Table 2. Grade 3 and 4 adverse events of ARGX-110 in combination with azacitidine open-label, Phase 1 dose-escalation part (first set of six evaluable patients, ongoing, uncleaned data as of November 15, 2017\*)**

|                     | 1 mg/kg<br># events (# of<br>patients) | 3 mg/kg<br># events (# of<br>patients) |
|---------------------|--|--|
| Anemia              | 2 (1)                                  | 7** (2)                                |
| Thrombocytopenia    | 9** (2)                                | 2 (1)                                  |
| Neutropenia         | 1 (1)                                  | —                                      |
| Leukopenia          | 1 (1)                                  | —                                      |
| Febrile neutropenia | 2 (2)                                  | —                                      |
| Pleuropericarditis  | 1 (1)                                  | —                                      |
| Lung infection      | 1 (1)                                  | —                                      |
| Constipation        | —                                      | 1 (1)                                  |
| Proctitis           | —                                      | 1 (1)                                  |
| Hypertension        | —                                      | 2 (1)                                  |
| Hypokalemia         | —                                      | 1 (1)                                  |

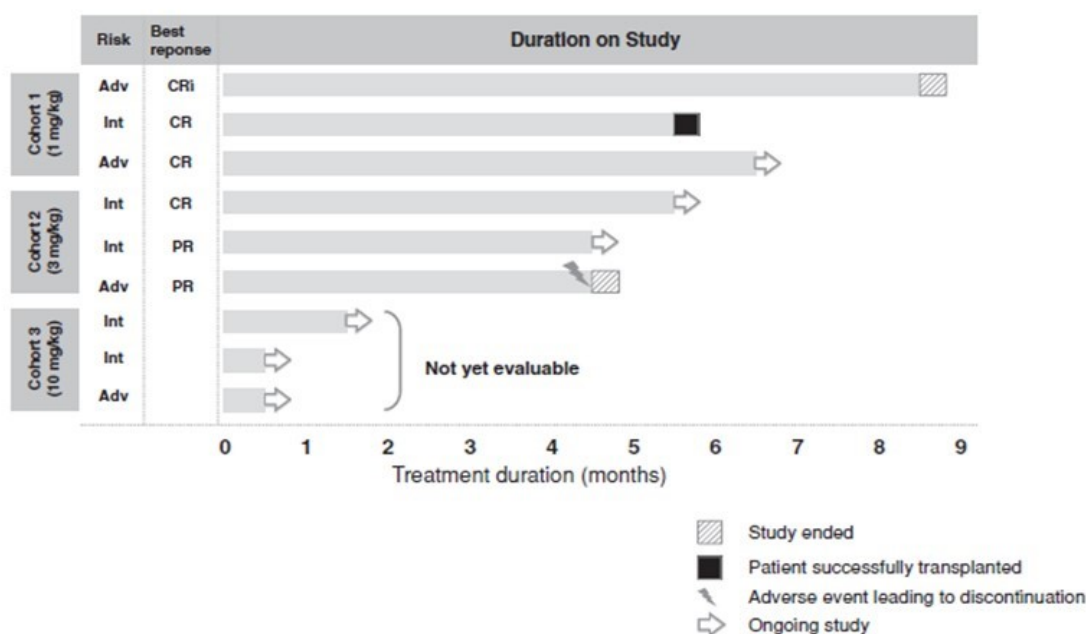
\* The collection of safety data for the three patients enrolled in the 10 mg/kg dose cohort is ongoing. Through November 15, 2017, the observed tolerability profile in the 10 mg/kg dose cohort appeared to be in line with the lower dose cohorts.

\*\* Intermittent toxicities for the same patient.

More specifically, at the time of the interim data, six out of six AML patients showed signs of clinical activity, including complete remission in three out of six patients, complete remission with incomplete blood count recovery in one out of six patients and partial response in two out of six 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. The preliminary responses as of November 15, 2017, observed in the first six evaluable AML patients can be seen in Table 3.

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 suggest ARGX-110 could be active both at the circulating and bone marrow blast level and at the leukemic stem cell level.

**Table 3. Overview of six AML patients treated with ARGX-110 in the Phase 1 dose-escalation part of the Phase 1/2 clinical trial in combination with azacitidine in patients with AML or high-risk MDS (uncleaned data as of November 15, 2017)**



**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)**

A Phase 1 safety-expansion cohort completed enrollment, consisting of heavily pre-treated patients with CD70-positive CTCL. In total, we have recruited 14 CTCL patients (13 of whom have been treated). We transitioned into the open-label Phase 2 part of our Phase 1/2 clinical trial of ARGX-110 in 14 adult, relapsed or refractory CD70-positive CTCL patients in April 2017. We announced interim results from the 13 patients in the CTCL safety-expansion cohort of the Phase 1 part and nine patients in the Phase 2 part of the clinical trial in December 2017 for a total of 22 CTCL patients, who demonstrated signs of clinical activity and a favorable tolerability profile in line with what was observed earlier in the dose-escalation part of the Phase 1 trial and previous safety-expansion cohorts of the Phase 1/2 clinical trial in patients with advanced malignancies expressing CD70.

Based on the ongoing biomarker and pharmacokinetic analysis from those CTCL patients treated in the Phase 1 part of the Phase 1/2 clinical trial, we decided to increase the dose of ARGX-110 from 1 mg/kg to 5 mg/kg every three weeks for the Phase 1 safety-expansion CTCL cohort. All patients in the Phase 2 part of the clinical trial will receive a 5 mg/kg dose of ARGX-110 monotherapy. We are conducting this Phase 2 part of the clinical trial at multiple centers in Europe. Patients will cease treatment if necessary for either safety reasons or disease progression. The primary endpoint of this part of the clinical trial is efficacy, and secondary endpoints include safety and characterization of pharmacokinetics and immunogenicity. We expect to report topline results from this clinical trial in the second half of 2018.

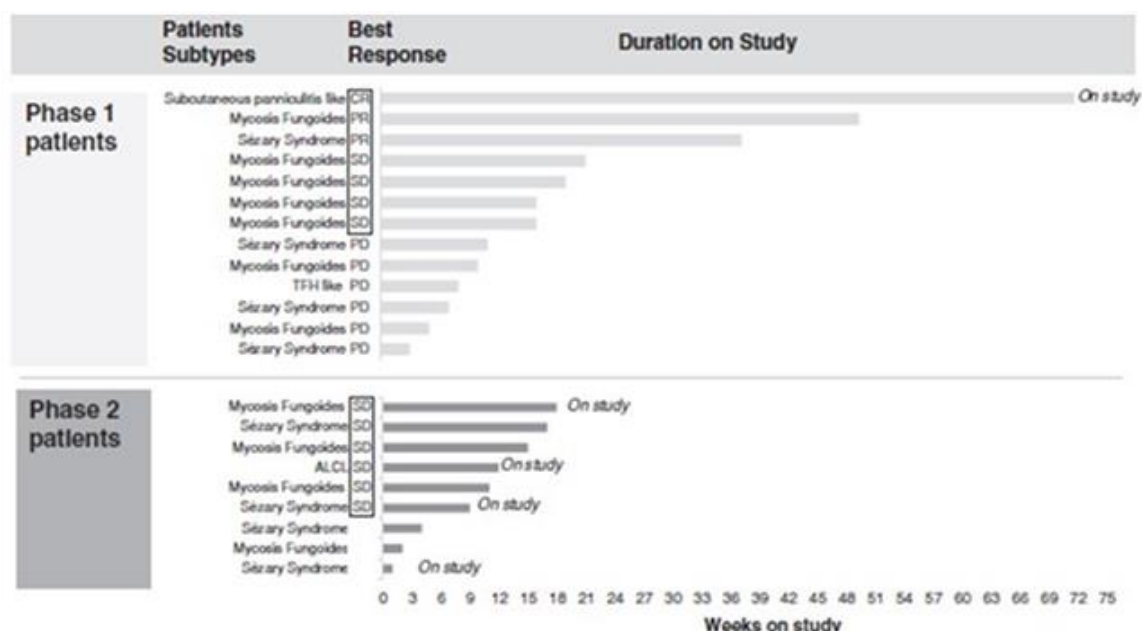
As of December 2017, of the 22 patients under analysis, we observed one complete response, two partial responses and 10 patients with stable disease, and five patients were still on the study at a 5 mg/kg dose. As of December 2017, ARGX-110 has continued to show a favorable tolerability profile in these patients. Grade 3 and 4 drug-related adverse events from the CTCL safety expansion cohort of the Phase 1 and the Phase 2 parts of the clinical trial are

summarized in Table 4. No Grade 4 drug-related toxicities were observed among this patient population. The preliminary responses as of November 7, 2017, observed in the first 22 evaluable CTCL patients can be seen in Table 5.

**Table 4. Grade 3 and 4 adverse events in 1 mg/kg and 5 mg/kg doses of ARGX 110 in open-label, Phase 1 safety-expansion CTCL cohort and Phase 2 CTCL part (ongoing, uncleaned data as of November 7, 2017)**

| Adverse Event | N (patients) |
|---------------|--------------|
| QTc prolonged | 1 (Grade 3)  |

**Table 5. Overview of 13 CTCL patients treated with ARGX-110 in the CTCL safety expansion cohort of the Phase 1 part and nine CTCL patients treated with ARGX-110 in the CTCL Phase 2 part of the Phase 1/2 clinical trial (uncleaned data as of November 7, 2017)**



Note: Best responses are based on the modified Severity Weighted Assessment Tool, or mSWAT, a widely used method for scoring of skin lesions in CTCL. The mSWAT score takes into account the number and severity of skin lesions as well as the total body surface area affected. A stable disease score is given if the mSWAT score does not increase by more than 25%. A partial response is deemed to have occurred with a 50% reduction in the mSWAT score. A complete response requires a 100% reduction in mSWAT score.

#### Phase 1 Part of Phase 1/2 Clinical Trial in Patients with Advanced Malignancies Expressing CD70 (ongoing, completed enrollment)

ARGX-110 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 to date): a dose-escalation part (26 patients) and four safety-expansion cohorts in solid tumors (20 patients), hematological cancers (19 patients), PTCL (seven patients) and the previously mentioned cohort in CTCL patients (14 patients, of whom 13 have been treated). This clinical trial design was adaptive in that it allowed us to make data driven decisions and open-up new cohorts in indications where we have seen the most promising early signals of biological activity. While the primary goal of the Phase 1 part of this clinical trial was to

investigate safety and pharmacokinetics, we also observed evidence of biological activity in several of the patients treated.

No dose-limiting toxicities were observed. The most frequent 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 POTELLIGENT 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)

In addition, ARGX-110 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 ARGX-110, 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, and no Grade 3 or 4 drug-related adverse events have been reported to date.

#### Preclinical Data

We conducted preclinical studies of ARGX-110 in support of our clinical program. In preclinical testing in cynomolgus monkeys, ARGX-110 was well-tolerated. In preclinical mouse efficacy models, ARGX-110 variants

showed the potential to prolong survival in Burkitt's lymphoma, overcome tyrosine kinase inhibitor resistance thereby prolonging survival in chronic myeloid leukemia, or reduce blast and leukemic stem cell burden thereby prolonging survival in AML. In a preclinical mouse efficacy model of acute lymphocytic leukemia, the administration of an ARGX-110 variant led to the acute death of some animals with high tumor load.

### **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 | Technology Used         | Indication           | Preclinical   | Phase 1 | Phase 2 | Phase 3 | Partner                |
|------------------------------|--------|-------------------------|----------------------|---|---------|---------|---------|------------------------|
| Partnered Product Candidates |        |                         |                      |   |         |         |         |                        |
| ARGX-109 (gerlinzumab)       | IL-6   | SIMPLE Antibody N-Hance | Rheumatoid arthritis |    |         |         |         | • Bird Rock Bio        |
| ARGX-112                     | IL-22R | SIMPLE Antibody         | Skin inflammation    |    |         |         |         | • LEO Pharma           |
| ARGX-115                     | GARP   | SIMPLE Antibody         | Cancer immunotherapy |   |         |         |         | • AbbVie               |
| ARGX-116                     | ApoC3  | SIMPLE Antibody         | Dyslipidemia         |  |         |         |         | • Staten Biotechnology |

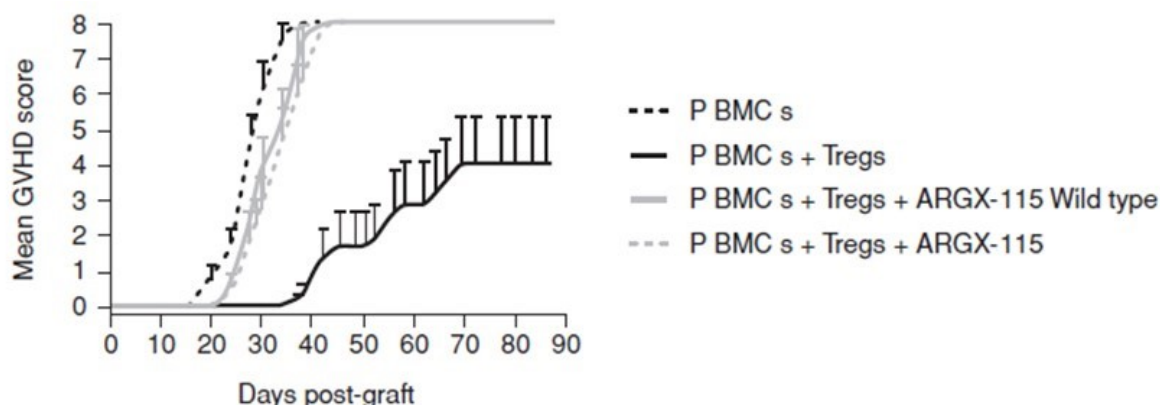
### ARGX-115 (partnered with AbbVie)

We are developing ARGX-115 as a cancer immunotherapy against the novel target GARP, a protein present on the surface of activated regulatory T-cells, or Tregs. We are developing ARGX-115 with our collaboration partner AbbVie. See “—Collaborations.”

ARGX-115 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- $\beta$ , 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- $\beta$ , ARGX-115 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- $\beta$  release by Tregs is

potentially superior as a therapy to systemic inhibition of TGF- $\beta$  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 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 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 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 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 devoid of cell-killing ability was as effective as ARGX-115 with cell-killing ability as shown in Figure 10, leading us to believe the effect of ARGX-115 is mainly due to blocking Treg activity.



**Figure 10. Preclinical data of ARGX-115 in a graft-versus-host disease model**

We are currently advancing ARGX-115 through preclinical studies up to completion of IND-enabling studies, at which point AbbVie has the right to exercise an option to obtain a worldwide, exclusive license to ARGX-115.

#### **ARGX-109 (partnered with Bird Rock Bio)**

ARGX-109 (gerilimumab) 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.

#### ***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-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.

#### ***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, 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 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 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 will jointly develop 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 may exercise an exclusive option to license the program and assume 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.

ARGX-113, ARGX-110, 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 Pharmaceuticals, Inc., or 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. has received FDA approval for 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, Inc.; and Millennium Pharmaceuticals, Inc., among others, are developing drugs that may have utility for the treatment of MG. We are aware that Rigel Pharmaceuticals, Inc.; Eisai Inc.; Bristol-Myers Squibb; Shire Immunomedics; Protalex Inc. and others are developing drugs that may have utility for the treatment of ITP. We are aware that Roche and Syntimmune, Inc. 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.; Momena, Inc.; Syntimmune, Inc. and Hannal Biotech.

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 Hakkō 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 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 ARGX-110 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 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 AbbVie (for ARGX-115)***

In April 2016, we entered into a collaboration agreement with AbbVie S.À.R.L., or AbbVie, to develop and commercialize ARGX-115. Under the terms of the collaboration agreement, we will be responsible for conducting and funding all ARGX-115 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 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, 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 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.

If AbbVie does not exercise its option to license ARGX-115, we have the right to pursue development and commercialization of ARGX-115 by ourselves or with another partner.

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 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 will fund 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. 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.

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 received a non-refundable, non-creditable upfront payment from LEO Pharma of €3.0 million in cash. In February 2016 and in June 2017, we achieved preclinical milestones under this collaboration for which we received milestone payments. 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 will seek to discover and characterize antibodies against at least one and up to three different human gene targets that have therapeutic relevance in the field of dyslipidemia and/or cardiovascular disease. Each research program will last no more than 24 months from commencement unless the parties agree otherwise. The first research program under this agreement has commenced and been extended to December 2017. ARGX-116 will be the initial product candidate under the collaboration, and Staten exercised its exclusive option to license ARGX-116 in March 2017. 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. 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, 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.

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) fulfilment 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 POTEILLIGENT technology of BioWa, Inc. The initial three year term of this

expanded agreement expires on May 30, 2017, and Shire has opted to extend the collaboration term for a further year until May 30, 2018.

Shire may exercise 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 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, 2017, 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) \$12.0 million in research and development fees. 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 the 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 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 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, regulatory and commercial milestone payment obligations and must report on our progress in achieving these milestones on a quarterly basis. The maximum amount of milestone payments we would be required to make is approximately \$0.5 million. Through December 31, 2017, we have paid UoT an aggregate of \$0.5 million, which includes reimbursement for UoT's patent prosecution and maintenance costs. 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. 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 ARGX-110, 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 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 grant to us would cease 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 ARGX-110 and ARGX-111 for clinical trial 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 ARGX-110 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 POTELLIGENT® CHOK1SV, namely the target CD70 in the case of ARGX-110 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 POTELLIGENT® 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 POTELLIGENT® CHOK1SV.

Upon commercialization of our products developed using POTELLIGENT® 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 POTELLIGENT® agreement or the POTELLIGENT® 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 license maintenance payments to BioWa which cease with commencement of payment of the BioWa royalty, 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 and royalties to BioWa under only one license—either the POTELLIGENT® agreement or the POTELLIGENT® CHOK1SV agreement, but not both. Payments related to the development and commercialization of ARGX-110 and ARGX-111 are foreseen under their respective POTELLIGENT® 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, 2017, we have paid BioWa an aggregate amount of \$1.4 million, which includes target reservation fees and annual research license fees under our POTELLIGENT® agreement and commercial license fees and milestone payments under our POTELLIGENT® CHOK1SV agreement. Through December 31, 2017, we have paid Lonza an aggregate amount of £0.2 million, which includes milestone payments under our POTELLIGENT® agreement.

Under the terms of both 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.

We may terminate the agreement at any time by sending BioWa and Lonza 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 grant to us would cease but BioWa and Lonza would grant our sublicensees a direct license following such termination. In the event the agreement is terminated other than for our failure to make milestone or royalty payments, we would retain the right to sell 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 (GARP)***

In January 2013, we entered into a collaboration and exclusive product license agreement with Université Catholique de Louvain, or UCL, and Sopartec S.A., or Sopartec, to discover and develop novel human therapeutic antibodies against GARP. Under the terms of the collaboration, 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. Upon the expiration of the agreement, this license became 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 have the right to grant sublicenses to third parties, subject to certain restrictions. If we receive any income in connection with such sublicenses, we must pay Sopartec a percentage of that income varying from mid-single digit to lower teen digit depending on the stage of development of the licensed products at the time the sublicense was entered into. In the event that we have not granted a sublicense, we are required to pay a percentage of net sales as a royalty. This royalty varies with net sales volume, but does not exceed 1% in all tiers, and the royalty is subject to customary reductions. This royalty obligation expires on a product-by-product and country-by-country basis when there are no valid claims covering such product. In the event that we have not granted a sublicense, we have certain development and commercial milestone payment obligations of up to approximately €0.9 million in the aggregate. In the event we have granted a sublicense, we are obligated to pay Sopartec a percentage of sublicense revenue received. We also have certain diligence obligations with respect to development and commercialization of products. Through December 31, 2017, we have an aggregate amount of €3.2 million payable to Sopartec, of which €2.7 million has been paid and the remainder is kept in escrow, which includes option fees and payments related to sublicense revenue we received.

### **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 March 16, 2018, our patent estate (which includes both owned and in-licensed patent rights) included 17 issued U.S. patents, 15 pending U.S. patent applications, 60 issued foreign patents (including five granted European patents that have been validated into 42 national patents) and 85 pending foreign patent applications (including 10 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 ARGX-110 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 ARGX-113 product candidate, ARGX-113 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 ARGX-110 product candidate, we have three issued U.S. patents, one with composition of matter claims directed to the ARGX-110 antibody, one with claims directed to the epitope ARGX-110 binds to, and one with claims directed to a polynucleotide that encodes antibodies that bind to the epitope ARGX-110 binds to and one U.S. patent application with method of use claims directed to the treatment of cancer with the ARGX-110 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, ARGX-110 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 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- $\beta$  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- $\beta$  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 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, 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, until all outstanding concerns have been adequately addressed and the FDA has notified the company that investigation may proceed. 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. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA.

#### *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.

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.

### *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.

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. 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, 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. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in FDASIA. 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 European Medicines Authority, or EMA, 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 apply by 2019 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.

#### ***Marketing Authorization***

To obtain a marketing authorization for a product under the European Union regulatory system, an applicant must submit an MAA, either under a centralized procedure administered by the EMA or one of the procedures administered by competent authorities in European Union Member States (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. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, 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.

#### *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.

### ***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. In the United States and markets in other countries, 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 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. 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, a company 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 a company’s ability to generate revenue.

The containment of healthcare costs also has become a priority of federal, state and foreign 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 a company’s revenue from the sale of any approved products. 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 products for which a company or its collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

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 cost effectiveness of any product candidates we may develop to other available therapies. The conduct of such a clinical trial could be expensive 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.

### ***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 the Health Information Technology for Economic and Clinical Health Act of 2009, 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 preempted 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***

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. There have been a number of federal and state proposals during the last few years to reduce the cost of care through changes in the healthcare system, including limits on the pricing, coverage and reimbursement of pharmaceutical and biopharmaceutical products, especially under government-funded health care programs, and increased governmental control of drug pricing.

By way of example, in March 2010, the United States Congress enacted the ACA, which, among other things, includes changes to the coverage and payment for products under governmental and private insurance plans. Among the provisions of the ACA of importance to our potential product candidates are:

- 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" 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;
- creation of the Independent Payment Advisory Board, which, if impaneled, would have authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription products; and
- establishment of the Center for Medicare and Medicaid Innovation within 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 Center for Medicare and Medicaid Innovation through 2019).

There have been legal and political challenges to certain aspects of the ACA. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. 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, the future of the ACA remains uncertain. We continue to evaluate how the ACA and recent efforts to repeal and replace or limit the implementation of the ACA will impact our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, in August 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 up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through

2024 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several 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.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. Such reforms could have an adverse effect on anticipated revenues from product candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop product candidates.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. 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.

## C. ORGANIZATIONAL STRUCTURE

As of December 31, 2017, 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 pharmaceutical 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. We believe our current facility is sufficient to meet our needs for the foreseeable future. We also lease an office in Breda, the Netherlands.

We lease additional office space in Boston, Massachusetts. The lease runs on a yearly basis, and we believe this Boston facility is sufficient for us to initiate U.S. activities in line with our business plan.

We have a total of three facilities worldwide owned or leased as of December 31, 2017, as set forth in the following table:

| Facility location               | Use                             | Approx. size (m <sup>2</sup> ) | Lease expiry                      |
|---------------------------------|---------------------------------|--------------------------------|-----------------------------------|
| Zwijnaarde, Belgium (leased)    | Operations and Laboratory Space | 1,500                          | April 1 <sup>st</sup> , 2026      |
| Breda, the Netherlands (leased) | Headquarters                    | 12                             | July 31 <sup>st</sup> , 2018      |
| Boston, Massachusetts (leased)  | Office Space                    | 163                            | September 30 <sup>th</sup> , 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 seven product candidates. Two of our product candidates are in clinical proof-of-concept trials for three indications, one of which has achieved clinical proof-of-concept and is being prepared for Phase 3 clinical development.

We recently completed a Phase 2 clinical trial for ARGX-113, our most advanced product candidate, for the treatment of the rare autoimmune disease myasthenia gravis, or MG, and we reported topline data from this trial in December 2017. ARGX-113 demonstrated strong clinical improvement and statistically significant benefit over placebo. ARGX-113 treatment resulted in a strong clinical improvement over placebo during the entire duration of the study as measured by all four predefined clinical efficacy scales. In addition, ARGX-113 was observed to have a favorable tolerability profile consistent with that observed in our Phase 1 clinical trial. In March 2017, we initiated a Phase 2 clinical trial of ARGX-113 for the treatment of another rare autoimmune disease, primary immune thrombocytopenia, or ITP. In September 2017, we initiated a Phase 2 clinical trial of ARGX-113 for the treatment of a third rare autoimmune disease, pemphigus vulgaris, or PV. We are currently developing our second lead product candidate, ARGX-110, for rare and aggressive hematological cancers, initially for T-cell lymphoma, or TCL, and acute myeloid leukemia, or AML, as well as high-risk myelodysplastic syndrome, or MDS. In December 2016, we commenced a Phase 1/2 clinical trial of ARGX-110 in combination with azacitidine for the treatment of newly diagnosed AML or high-risk MDS patients, and in April 2017, we initiated the Phase 2 part of a Phase 1/2 clinical trial of ARGX-110 for the treatment of cutaneous TCL, or CTCL. We reported interim data for both clinical trials in December 2017.

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 AbbVie S.A.R.L., or AbbVie, for ARGX-115, a cancer immunotherapy-focused product candidate, against the novel target glycoprotein A repetitions predominant. We received a \$40.0 million (€35.1 million based on the exchange rate in effect as of the date the payment was received) upfront payment and a \$10.0 million (€8.9 million based on the exchange rate in effect as of the date the payment was received) preclinical milestone payment in connection with this collaboration.



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 four internally developed product candidates into clinical development—ARGX-113, ARGX-110, ARGX-111 and ARGX-109—three into the preclinical stage—ARGX-115, ARGX-112 and ARGX-116—and currently have multiple programs in the discovery stages. Through December 31, 2017, we have raised an aggregate gross proceeds of €474.7 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 and (v) \$265.5 million from our second U.S. public offering on the Nasdaq Global Select Market in December 2017. In addition, as of December 31, 2017, we have received upfront payments, milestone payments and research and development service fees from our collaborators totaling €77.3 million and have received €13.2 million in grants and incentives from governmental bodies. As of December 31, 2017, we had cash, cash equivalents and current financial assets of €359.8 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, 2016 and 2017, we incurred total comprehensive losses of €21.4 million and €28.1 million, respectively. As of December 31, 2017, we had accumulated losses of €100.6 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 incur additional 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 one or more Phase 3 clinical trials of ARGX-113 in MG and, potentially, ITP and PV;
- complete the Phase 2 clinical trials of ARGX-113 in ITP and PV and ARGX-110 in CTCL and AML / high-risk MDS;
- develop a subcutaneous formulation of ARGX-113, including a Phase 1 clinical trial in healthy volunteers to explore additional indications;
- 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.

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 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.

### 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.

**AbbVie.** In April 2016, we entered into a collaboration agreement with AbbVie to develop and commercialize ARGX-115. Under the terms of the collaboration agreement, we will be responsible for conducting and funding all ARGX-115 research and development activities up to completion of investigational new drug, or 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 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, 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 near-term preclinical milestone of \$10.0 million. We are also eligible, if AbbVie exercises its option, 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. In addition to the ARGX-115 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.

If AbbVie does not exercise its option to license ARGX-115, we have the right to pursue development and commercialization of ARGX-115 by ourselves or with another partner.

**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. We received a non-refundable, non-creditable upfront payment from LEO Pharma of €3.0 million in cash. In February 2016 and June 2017, we achieved preclinical milestones under this collaboration for which we received milestone payments. We are also eligible to receive 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. Under the terms of the collaboration, LEO Pharma will fund more than half of all product development costs up to approval of a Clinical Trial Authorization Application, or CTA, in Europe for a first product in a Phase 1 clinical trial, with our share of such costs capped. 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.

**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. In May 2014, we expanded the collaboration agreement to accommodate research and development on several novel targets implicated in multiple disease areas. In February 2017, Shire extended the collaboration term for a further year until May 30, 2018.

Through December 31, 2017, Shire has paid us an aggregate total of (i) €3.4 million in upfront payments, (ii) €0.3 million in milestone payments and (iii) \$12.0 million in research and development fees. In addition, Shire purchased €12.0 million of our ordinary shares in July 2014 by participating in our initial public offering on Euronext Brussels.

Shire has the option to license antibodies discovered under the agreement for further development and commercialization worldwide, in return for milestone payments and single-digit percentage royalties on product sales.

**Bayer.** In May 2014, we entered into a research collaboration and exclusive product license option agreement with Bayer AG, focused on the creation of novel human therapeutic antibodies against complex targets in various therapeutic indications using our SIMPLE Antibody technology. We received technology access fees and research funding totaling €3.3 million. We concluded all research under this collaboration in 2016 and we have no further commitment pursuant to this agreement.

## **Basis of Presentation**

### **Revenue**

To date, our revenue has consisted principally of collaboration revenue consisting of (i) upfront payments, including upfront licensing fees, (ii) milestone payments based on achievement of research and development goals and (iii) research and development service fees related to charges for full time equivalents, or FTEs, at contracted rates and reimbursement of research and development expenses. We currently have no products approved for sale. Other than the sources of revenue described above, we do not expect to receive any revenue from any product candidates that we develop, including ARGX-113, ARGX-110 and our preclinical product candidates, until we obtain regulatory approval and commercialize such products, or until we potentially enter into collaborative agreements with third parties for the development and commercialization of such candidates and when we have obtained regulatory approval.

Collaborations typically contain license fees, non-refundable upfront fees, research and development service fees and milestone payments and may involve multiple elements. We evaluate whether the elements under these arrangements have value to our collaboration partner on a standalone basis. If we determine that multiple deliverables exist, the consideration is allocated to one or more units of accounting based upon the best estimate of the selling price of each deliverable. Deliverables that do not meet these criteria are not evaluated separately for the purpose of revenue recognition.

## ***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.

The table below shows our research and development expenses for the past three fiscal years:

|   | Year ended December 31, |                        |          |
|---|-------------------------|------------------------|----------|
|   | 2017                    | 2016<br>(in thousands) | 2015     |
| Total research and development expenses | € 51,740                | € 31,557               | € 20,635 |

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 Bayer, 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.

We typically utilize our employee, consultant and infrastructure resources across all of our development programs. We separately track external development costs with respect to ARGX-113 and ARGX-110, our most advanced product candidates.

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 ARGX-113 and ARGX-110 and the preclinical development of ARGX-115 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, 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 ARGX-113, ARGX-110 or any other product candidate that we may develop in the future, if approved.

Any of these variables with respect to the development of ARGX-113, ARGX-110, ARGX-115 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, notably with the opening of our U.S. office and with preparatory marketing and pricing activities with respect to the potential future commercialization of one or more of our product candidates, if approved. We also expect to incur increased costs for directors' and officers' liability insurance and an enhanced investor relations function.

***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 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 the section of this annual report titled "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 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:

## **Revenue Recognition**

Evaluating the criteria for revenue recognition with respect to our collaboration agreements requires management's judgment to ensure that all criteria have been fulfilled prior to recognizing any amount of revenue in accordance to International Accounting Standard 18. In particular, such judgments are made with respect to determination of the nature of transactions, whether simultaneous transactions shall be considered as one or more revenue-generating transactions, allocation of the contractual price (upfront and milestone payments in connection with a collaboration agreement) to several elements included in an agreement. All of our revenue-generating transactions have been subject to such evaluation by management.

We generate revenue under our collaboration agreements and recognize this revenue as follows:

### ***Upfront Payments***

Upfront payments for which there are subsequent deliverables are initially reported as deferred income and are recognized as revenue when earned over the period of the development collaboration or the manufacturing obligation. Upfront payments also include license fees received upfront.

Deferred revenue reflects the part of upfront payments that has not been recognized as revenue immediately on receipt of payment and which relates to agreements with multiple components that cannot be separated. Deferred revenue is measured at nominal value.

### ***Milestone Payments***

Revenue associated with performance milestones is recognized based upon the achievement of the milestone event if the event is substantive, objectively determinable and represents an important point in the development life cycle of the product candidate.

### ***Research and Development Services Fees***

Research and development service fees are recognized as revenue over the life of the research agreement as the required services are provided and costs are incurred. These services are usually in the form of a defined number of FTEs at a specified rate per FTE.

Commercial collaborations resulting in a reimbursement of research and development costs are recognized as revenue as the related costs are incurred. The corresponding research and development expenses are included in research and development expenses in the consolidated financial statements.

With respect to the allocation of value to the separate elements, we use the stand alone selling prices or management's best estimates of selling prices to estimate the fair value of the elements and account for them separately allocated to each deliverable based on the fair value of each individual element and is recognized when the revenue recognition criteria described above are met. Upfront fees under collaboration or licensing agreements are recognized over the expected duration of the performance obligations, unless there is no continuous involvement required. Management estimates this period at the start of the collaboration and validates the remaining estimated collaboration term at each closing date. The recognition of revenue is linked (i) to the period during which we are continuously involved in the development of the product candidates subject to the collaboration and (ii) in relation to the expenses incurred over the period, which defines a percentage of achievement compared to the original budget.

### ***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. Once calculated, the fair value



of the stock options granted is recognized as an expense in our 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.

No other conditions are attached to the stock options.

On December 31, 2017, the total number of stock options outstanding was 2,862,216, compared to 2,293,636 on December 31, 2016. For the year ended December 31, 2017, no stock options had expired, a total of 203,412 stock options had been exercised and 2,369 stock options had been forfeited.

The expected volatility used in the Black Scholes model is based, for the periods before 2016, on the historical volatility of peer companies. The peer companies are publicly traded entities active in the business of developing antibody-based therapeutics, treatments and drugs and are selected taking into consideration the availability of meaningful trading data history and market capitalization.

For grants beginning in 2016, we only considered the historical volatility of our stock price calculated since our initial public offering on Euronext Brussels. The selection of a relevant peer group requires significant judgments and refers to multiple factors which may vary over the time. For instance, we realized that one of the companies included in the initial peer group had experienced a clinical failure in 2016, which had a significant impact on its volatility over the considered period. In 2016, we looked at our own historical volatility and compared it to (i) the 2016 volatility of the initial peer group, (ii) the volatility of a selection of Belgian biotechnology companies and (iii) a new peer group combining some of the initial peer group companies and a selection of Belgian biotechnology companies. The conclusions were that some of the entities in the initial peer group were no longer deemed representative to estimate our expected volatility. Such entities were replaced in the peer group by selected Belgian biotechnology companies that were deemed more representative of our profile. The inclusion of such Belgian biotechnology companies in the new peer group decreased the average of the volatility of the peer group. We then calculated the impact of the various alternatives on the total fair value of the options granted in 2016 and concluded that the impact of using our own historical volatility would not be significantly different than using the other alternatives over the total vesting period of the stock options and in 2016. Therefore, we believe that excluding peer data as from 2016 is appropriate. We will continue to evaluate the need to use peer data in future 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                     | 36.60 %                  | 36.14 %       |
| Average expected option life (in years) | 10                       | 10            |
| Risk-free interest rate                 | 0.61 %                   | 0.53 %        |
| Expected dividends                      | — %                      | — %           |

|   | Stock options granted in |           |               |
|---|--------------------------|-----------|---------------|
|   | May 2016                 | June 2016 | December 2016 |
| Number of options granted               | 288,950                  | 60,000    | 363,226       |
| Average fair value of options           | € 5.32                   | € 5.46    | € 7.25        |
| Share price                             | € 11.10                  | € 11.36   | € 14.96       |
| Exercise price                          | € 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 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 10 years as there is no history of exercising stock options.
- 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 €4.3 million for the year ended December 31, 2017 and €2.8 million for the year ended December 31, 2016.

#### **Recognition of Deferred Tax Assets and Liabilities**

We are subject to income taxes in the Netherlands and in Belgium and expect to be subject to income taxes in the United States with the formation of our U.S. subsidiary and expansion of U.S. activities. Significant judgment is required in determining the use of net operating 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.

No tax charge or income was recognized during the reporting periods since we are in a loss-making position and have a history of losses. We had consolidated tax loss carry forwards of €113.6 million as of December 31, 2017.

In the year ended December 31, 2017, a business restructuring was implemented, resulting in a taxable amount for our Dutch entity, argenx SE, of €2.4 million subject to a Dutch corporate income tax rate of 25%, or a tax amount of €0.6 million.

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, 2017 and 2016

|   | Year ended<br>December 31, |                   |              |
|---|----------------------------|-------------------|--------------|
|   | 2017                       | 2016              | % Change     |
|   | (In thousands)             |                   |              |
| Revenue   | € 36,415                   | € 14,713          | 148 %        |
| Other operating income                                  | 4,841                      | 2,439             | 98 %         |
| <b>Total operating income</b>                           | <b>41,256</b>              | <b>17,152</b>     | <b>141 %</b> |
| Research and development expenses                       | (51,740)                   | (31,557)          | 64 %         |
| Selling, general and administrative expenses            | (12,448)                   | (7,011)           | 78 %         |
| <b>Operating loss</b>                                   | <b>(22,932)</b>            | <b>(21,416)</b>   | <b>7 %</b>   |
| Financial income  | 1,250                      | 73                | 1,612 %      |
| Financial expenses                                      | —                          | —                 | %            |
| Exchange gains (losses)                                 | (5,797)                    | (31)              | 18,600 %     |
| <b>Loss before taxes</b>                                | <b>€ (27,479)</b>          | <b>€ (21,374)</b> | <b>29 %</b>  |
| Income tax expense                                      | (597)                      | —                 | %            |
| <b>Loss for the period and total comprehensive loss</b> | <b>€ (28,076)</b>          | <b>€ (21,374)</b> | <b>31 %</b>  |
| 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<br>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 %         |
| <b>Total</b>                          | <b>€ 36,415</b>            | <b>€ 14,713</b> | <b>148 %</b> |

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<br>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<br>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<br>December 31, |                        |          |
|----------------|----------------------------|------------------------|----------|
|                | 2017                       | 2016<br>(In thousands) | % Change |
| ARGX-113       | € 12,382                   | € 8,988                | 38 %     |
| ARGX-110       | 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 ARGX-113 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 ARGX-113 corresponded to increased manufacturing and clinical development activities in relation with (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 ARGX-110 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<br>December 31, |                        |          |
|-------------------|----------------------------|------------------------|----------|
|                   | 2017                       | 2016<br>(In thousands) | % Change |
| 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.

#### *Comparison of Years Ended December 31, 2016 and 2015*

|   | Year ended<br>December 31, |                   |             |
|---|----------------------------|-------------------|-------------|
|   | 2016                       | 2015              | % Change    |
|   | (In thousands)             |                   |             |
| Revenue   | € 14,713                   | € 6,854           | 115 %       |
| Other operating income                                  | 2,439                      | 3,101             | (21)%       |
| <b>Total operating income</b>                           | <b>17,152</b>              | <b>9,955</b>      | <b>72 %</b> |
| Research and development expenses                       | (31,557)                   | (20,635)          | 53 %        |
| General and administrative expenses                     | (7,011)                    | (4,925)           | 42 %        |
| <b>Operating loss</b>                                   | <b>(21,416)</b>            | <b>(15,605)</b>   | <b>37 %</b> |
| Financial income  | 73                         | 112               | (35)%       |
| Financial expenses                                      | —                          | —                 | %           |
| Exchange gains (losses)                                 | (31)                       | 181               | (117)%      |
| <b>Loss before taxes</b>                                | <b>€ (21,374)</b>          | <b>€ (15,312)</b> | <b>40 %</b> |
| Income tax income/(expense)                             | —                          | —                 | %           |
| <b>Loss for the period and total comprehensive loss</b> | <b>€ (21,374)</b>          | <b>€ (15,312)</b> | <b>40 %</b> |
| Weighted average number of shares outstanding           | 18,820,612                 | 15,734,007        |             |
| Basic and diluted loss per share (in €)                 | (1.14)                     | (0.97)            |             |

#### *Revenue*

|                                       | Year ended<br>December 31, |                |              |
|---------------------------------------|----------------------------|----------------|--------------|
|                                       | 2016                       | 2015           | % Change     |
|                                       | (In thousands)             |                |              |
| Upfront payments                      | € 9,103                    | € 2,194        | 315 %        |
| Milestone payments                    | 500                        | 343            | 46 %         |
| Research and development service fees | 5,110                      | 4,317          | 18 %         |
| <b>Total</b>                          | <b>€ 14,713</b>            | <b>€ 6,854</b> | <b>115 %</b> |

Our revenue increased by €7.8 million for the year ended December 31, 2016 to €14.7 million, compared to €6.9 million for the year ended December 31, 2015.

The increase of €6.9 million in upfront payments for the year ended December 31, 2016 compared to the year ended December 31, 2015 corresponds 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, 2016 related to a payment received under the LEO Pharma collaboration. The milestone payments recognized for the year ended December 31, 2015 related to a €0.2 million payment received from the Leukemia and Lymphoma Society under a partnership agreement relating to ARGX-110 and a €0.1 million milestone payment received from Bird Rock Bio following the announcement in September 2015 of the first human dosing of ARGX-109 for the treatment of autoimmune disorders including rheumatoid arthritis.

The increase of €0.8 million in research and development service fees for the year ended December 31, 2016 compared to the year ended December 31, 2015 related to payments under the collaboration agreements with LEO Pharma and Shire.

#### *Other Operating Income*

|                                     | Year ended<br>December 31, |         |          |
|-------------------------------------|----------------------------|---------|----------|
|                                     | 2016                       | 2015    | % Change |
|                                     | (In thousands)             |         |          |
| Government grants                   | € 779                      | € 1,598 | (51)%    |
| Research and development incentives | 641                        | 608     | 5 %      |
| Payroll tax rebates                 | 1,019                      | 895     | 14 %     |
| Total                               | € 2,439                    | € 3,101 | (21)%    |

Other operating income decreased by €0.7 million for the year ended December 31, 2016 to €2.4 million, compared to €3.1 million for the year ended December 31, 2015, as a result of a decrease in grants received from the Flemish government. For the years ended December 31, 2016 and 2015, we accrued research and development incentives income of €0.6 million, 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 received €1 million of payroll tax rebates for the year ended December 31, 2016, compared to €0.9 million for the year ended December 31, 2015, for employing certain research and development personnel.

#### *Research and Development Expenses*

|  | Year ended<br>December 31, |          |          |
|--|----------------------------|----------|----------|
|  | 2016                       | 2015     | % Change |
|  | (In thousands)             |          |          |
| Personnel expense                          | € 9,844                    | € 6,665  | 48 %     |
| External research and development expenses | 17,562                     | 11,653   | 51 %     |
| Materials and consumables                  | 1,180                      | 1,050    | 12 %     |
| Depreciation and amortization              | 335                        | 196      | 71 %     |
| Other expenses                             | 2,636                      | 1,071    | 146 %    |
| Total                                      | € 31,557                   | € 20,635 | 53 %     |

Our research and development expenses totaled €31.6 million and €20.6 million for the years ended December 31, 2016 and 2015, respectively. The decrease of €1.8 million in personnel expense for the year ended December 31, 2016 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. We employed 48 employees in our research and development function on December 31, 2016, compared to 35 employees on December 31, 2015.

Our external research and development expenses for the year ended December 31, 2016 totaled €17.6 million, compared to €11.7 million for the year ended December 31, 2015, reflecting higher clinical trial costs related to the development of our product candidate portfolio but lower manufacturing expenses compared to the same period in 2015. The increase of €1.6 million in other expenses for the year ended December 31, 2016 corresponded to (i) patent expenses of €0.3 million related to the growth of our product portfolio, (ii) license fees of €0.7 million we paid to one of our licensors as a result of the signing of the AbbVie agreement, and (iii) €0.6 million of expenses corresponding principally to travel expenses, clinical trial insurance premiums and recruitment for research and development employees. The table below provides additional detail on our external research and development expenses by program:

|                | Year ended<br>December 31, |          |          |
|----------------|----------------------------|----------|----------|
|                | 2016                       | 2015     | % Change |
|                | (In thousands)             |          |          |
| ARGX-113       | € 8,988                    | € 4,148  | 117 %    |
| ARGX-110       | 2,914                      | 3,816    | (24)%    |
| Other programs | 5,660                      | 3,689    | 53 %     |
| Total          | € 17,562                   | € 11,653 | 51 %     |

External research and development expenses for our lead product candidate ARGX-113 totaled €9.0 million for the year ended December 31, 2016, compared to €4.1 million for the year ended December 31, 2015. The increase of €4.8 million of external research and development expenses for the year ended December 31, 2016 for ARGX-113 corresponded to increased manufacturing and clinical development activities linked with the preparation of the Phase 2 clinical trials for MG and ITP. External research and development expenses for ARGX-110 decreased by €0.9 million to €2.9 million during the year ended on December 31, 2016 compared to €3.8 million for the year ended December 31, 2015. For the year ended December 31, 2016, we increased clinical development expenses in connection with the preparation of the TCL and AML clinical trials, offset by a reduction in expenses on drug material compared to the year ended December 31, 2015. External research and development expenses on other programs increased by €2.0 million to €5.7 million for the year ended December 31, 2016, compared to €3.7 million for the year ended December 31, 2015. This increase was primarily due to external research and development expenses incurred under our collaboration agreements with LEO Pharma and AbbVie.

#### *General and Administrative Expenses*

|                   | Year ended<br>December 31, |         |          |
|-------------------|----------------------------|---------|----------|
|                   | 2016                       | 2015    | % Change |
|                   | (In thousands)             |         |          |
| Personnel expense | € 3,256                    | € 1,607 | 103 %    |
| Consulting fees   | 2,563                      | 2,395   | 7 %      |
| Supervisory board | 446                        | 165     | 170 %    |
| Office costs      | 746                        | 758     | (2)%     |
| Total             | € 7,011                    | € 4,925 | 42 %     |

Our general and administrative expenses totaled €7.0 million and €4.9 million for the years ended December 31, 2016 and 2015, respectively. The increase in our general and administrative expenses for the year ended December 31, 2016 was principally due to (i) an increase of €1.6 million of personnel expenses related to employees recruited to strengthen our general and administrative activities, including the share based compensation expenses related to the grant of stock options to our general and administrative employees, (ii) an increase of €0.2 million of consulting fees related to investor relations, business development, IT, legal and audit activities and (iii) an increase of €0.3 million of supervisory board expenses due to the reclassification of share based compensation expenses related to the grant of stock options to board members from personnel expenses to supervisory board expenses and to increases in

the remuneration and travel expenses of the non-executive members of our board of directors. On December 31, 2016, we employed 10 employees in our general and administration function, compared to six employees on December 31, 2015.

#### *Financial Income (Expense)*

For the year ended December 31, 2016, financial income amounted to €0.07 million compared to €0.1 million for the year ended December 31, 2015.

#### *Exchange Gains (Losses)*

The exchange losses of €0.03 million for the year ended December 31, 2016 and the exchange gains of €0.2 million recorded for the year ended December 31, 2015 were both realized by converting foreign currencies into euros.

## **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, 2017, we have raised gross proceeds of €474.7 million from private and public offerings of equity securities, received aggregate gross proceeds of €77.3 million from our collaborators, and received €13.2 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, 2017, we had cash, cash equivalents and current financial assets of €359.8 million.

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 appended to this annual report.

## Cash Flows

### 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<br>December 31, |                  |
|--|------------------|----------------------------|------------------|
|  | 2017             | 2016                       | Variance         |
|  |                  | (In thousands)             |                  |
| <b>Cash and cash equivalents at beginning of the period</b>      | <b>€ 89,897</b>  | <b>€ 35,514</b>            | <b>€ 54,383</b>  |
| 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)          |
| <b>Cash and cash equivalents at end of the period</b>            | <b>€ 190,867</b> | <b>€ 89,897</b>            | <b>€ 100,970</b> |

#### Net Cash (Used in) Provided by 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 ARGX-113 and ARGX-110 and the advancement of other preclinical and discovery-stage product candidate (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 Provided by (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 from 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 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.

## Comparison for the Years Ended December 31, 2016 and 2015

The table below summarizes our cash flows for the years ended December 31, 2016 and 2015

|  | Year ended<br>December 31, |                 |                 |
|--|----------------------------|-----------------|-----------------|
|  | 2016                       | 2015            | Variance        |
|  | (In thousands)             |                 |                 |
| <b>Cash and cash equivalents at beginning of the period</b>      | <b>€ 35,514</b>            | <b>€ 32,180</b> | <b>€ 3,334</b>  |
| Net cash flows (used in) / from operating activities             | 10,599                     | (13,897)        | 24,496          |
| Net cash flows (used in) / from investing activities             | (806)                      | 16,812          | (17,618)        |
| Net cash flows (used in) / from financing activities             | 44,621                     | 238             | 44,383          |
| Effect of exchange rate differences on cash and cash equivalents | (31)                       | 181             | (212)           |
| <b>Cash and cash equivalents at end of the period</b>            | <b>€ 89,897</b>            | <b>€ 35,514</b> | <b>€ 54,383</b> |

### Net Cash (Used in) Provided by Operating Activities

Cash provided by operating activities for the year ended December 31, 2016 was a net inflow of €10.6 million. Cash used by operating activities for the year ended December 31, 2015 was a net outflow of €13.9 million. The net cash inflow for the year ended December 31, 2016 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. The net cash outflow for the year ended December 31, 2015 related to increased operating losses due to increased clinical trial and product candidate manufacturing activities in 2015.

### Net Cash Provided by (Used in) Investing Activities

Investing activities consist primarily of purchase of laboratory equipment and interest received from the placements of our cash and cash equivalents and current financial assets. Cash flow from investing activities represented a net outflow of €0.8 million for the year ended December 31, 2016, compared to a net inflow of €16.8 million for the year ended December 31, 2015. 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 IT equipment. The net inflow for the year ended December 31, 2015 corresponded to the sale of a money market fund previously classified as 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 €44.6 million for the year ended December 31, 2016, compared to €0.2 million for the year ended December 31, 2015. 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, 2017, we had accumulated losses of €100.6 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.

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. We have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development of ARGX-113, ARGX-110 and our other product candidates and discovery stage programs and because the extent to which we may enter into collaborations with third parties for 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 ARGX-113, ARGX-110 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, 2017 to December 31, 2017 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, 2017.

|                             | Payments due by period |                     |                             |           |                      |
|-----------------------------|------------------------|---------------------|-----------------------------|-----------|----------------------|
|                             | Total                  | Less than<br>1 year | 1–3 years<br>(In thousands) | 3–5 years | More than<br>5 years |
| Operating lease commitments | € 1,526                | € 1,028             | € 465                       | € 33      | € —                  |
| Purchase obligation         | € 13,277               | € 8,363             | € 4,915                     | € —       | € —                  |

We signed a lease agreement effective April 2016 for new 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.

In July 2017, we signed a letter of intent with our drug substance manufacturing contractor, Lonza Sales AG, or Lonza, related to the biologics license application for ARGX-113. The total commitment under this letter of intent amounts to a minimum spend of £5.0 million before the end of calendar year 2018, of which we paid £1.0 million upon signature. In December 2017, we amended one of our manufacturing agreements with Lonza. This amendment expands the scope of Lonza's services with additional services for ARGX-113 to be performed at the Lonza facility in Tuas, Singapore. These services relate to the start-up of Lonza Singapore as a potential future commercial manufacturing site. Pursuant to this amendment, we have additional contractual obligations in the aggregate amounts of approximately \$9.3 million, with payments beginning in January 2018. In addition to the obligations for ARGX-113, we have contractual obligations for ARGX-110 for approximately £0.9 million, with payments beginning by the third quarter of 2018.

## 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 executive directors who are 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, 2017:

| Name                 | Age | Position                                     | Nationality | Date of appointment | Term expiration |
|----------------------|-----|--|-------------|---------------------|-----------------|
| Tim Van Hauwermeiren | 45  | Executive Director (Chief Executive Officer) | BE          | July 9, 2014        | 2018            |
| Peter K.M. Verhaeghe | 59  | Non-Executive Director (chairperson)         | BE          | July 9, 2014        | 2018            |
| David L. Lacey       | 65  | Non-Executive Director                       | U.S.        | July 9, 2014        | 2018            |
| Werner Lanthaler     | 49  | Non-Executive Director (vice chairperson)    | AT          | July 9, 2014        | 2018            |
| J. Donald deBethizy  | 67  | Non-Executive Director                       | U.S.        | May 13, 2015        | 2019            |
| Pamela Klein         | 56  | Non-Executive Director                       | U.S.        | April 28, 2016      | 2020            |
| A.A. Rosenberg       | 64  | Non-Executive Director                       | U.K.        | April 26, 2017      | 2021            |

The address for our directors is our registered office, Willemstraat 5, 4811 AH, Breda, the Netherlands.

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 LLM 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 Biozell 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 Idenix Pharmaceuticals, Radius Health Inc., TriNetX, Inc., Clinical Ink, Inc. and iOmx Therapeutics AG and Cullinan Oncology Inc. 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 Daly** is up for nomination to be appointed as a member of our board of directors at our annual General Meeting in May 2018. Mr. Daly served as Executive Vice President and Chief Commercial Officer at Incyte Corporation from 2012 to 2015. Prior to joining Incyte, Mr. Daly worked for Amgen, Inc. for ten years, holding multiple leadership positions. In his last role, Mr. Daly served as Senior Vice President, North America Commercial Operations, Global Marketing and Commercial Development. Previously, he served as Vice President and General Manager of Amgen's Oncology Business Unit. His teams at Amgen were responsible for the successful launch of many products, including Aranesp®, Neulasta®, Vectibix®, Nplate®, Xgeva® and Prolia®. Previously, Mr. Daly spent over 16 years with Glaxo Wellcome/GlaxoSmithKline where he held roles of increasing responsibility, including Senior Vice President, General Manager, Respiratory and Anti-Infective Business Unit, and led the U.S. launch of Advair®. He currently serves on the

Board of Directors of Chimerix Inc. Mr. Daly earned his B.S. in Pharmacy and M.B.A. from the University at Buffalo, The State University of New York.

## 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, 2017:

| Name                 | Age | Position                                       | Nationality | Date of appointment |
|----------------------|-----|--|-------------|---------------------|
| Tim Van Hauwermeiren | 45  | Chief Executive Officer and Executive Director | BE          | July 15, 2008       |
| Eric Castaldi        | 53  | Chief Financial Officer                        | F           | April 1, 2014       |
| Nicolas Leupin       | 44  | Chief Medical Officer                          | CH          | February 1, 2016    |
| Hans de Haard        | 58  | Chief Scientific Officer                       | NL          | July 1, 2008        |
| Torsten Dreier       | 53  | Chief Development Officer                      | G           | May 1, 2008         |
| Debbie Allen         | 58  | Senior VP Business Development                 | UK          | November 1, 2010    |
| Dirk Beusaert        | 53  | 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.

**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 50th percentile of the compensation offered by the European peer group identified by the independent consulting firm used in this analysis. In line with the amended remuneration policy discussed above, our board of directors has amended the current contracts between us and our executive directors to be brought in line with the new remuneration policy.

*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. On September 3, 2015, the maximum percentage for this purpose was set at 40% of base salary of the chief executive officer, and at 35% of base salary of the other 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, 2017:

**Tim Van Hauwermeiren**

|   | Compensation<br>(€) |
|---|---------------------|
| Base salary   | 303,941             |
| Option awards(1)                                    | 2,968,195           |
| Employer social security contribution stock options | —                   |
| Non-equity incentive plan compensation              | 301,635             |
| Pension contributions                               | 14,315              |
| Social security costs                               | 9,459               |
| Other(2)  | 9,601               |
| Total   | 3,607,146           |

- (1) Amount shown represents the expenses recorded with respect to the option awards granted in 2017 to Mr. Van Hauwermeiren measured using the Black Scholes formula. For a description of the assumptions used in valuing these awards, see note 4.12 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) Consists of €9,184 attributable to the lease of a company car and €417 in employer-paid medical insurance premiums.

The following table sets forth information regarding compensation paid by us for Eric Castaldi during the year ended December 31, 2017:

**Eric Castaldi(1)**

|  | Compensation<br>(€) |
|--|---------------------|
| Base salary  | 271,344             |
| Option awards(2)                                       | 1,602,825           |
| Employer social security contribution stock options(3) | 2,486,384           |
| Non-equity incentive plan compensation                 | 173,284             |
| Pension contributions                                  | 62,335              |
| Social security costs                                  | 254,732             |
| Other(4)   | 14,979              |
| Total  | 4,865,883           |

- (1) Mr. Eric Castaldi resigned from our board of directors effective April 26, 2017, but his employment agreement with us as our chief financial officer will continue to have full effect.
- (2) Amount shown represents the expenses recorded with respect to the option awards granted in 2017 to Mr. Castaldi measured using the Black Scholes formula. For a description of the assumptions used in valuing these awards, see note 4.12 to our financial statements included elsewhere in this annual report. These amounts do not reflect the actual economic value realized by Mr. Castaldi.
- (3) The Group incurs employer social security costs with respect to the option awards granted to Mr. Eric Castaldi. 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 Group makes a calculation of the exposure.
- (4) Consists of €12,590 attributable to the lease of a company car and €2,389 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 (including Eric Castaldi, but excluding Tim Van Hauwermeiren) during the year ended December 31, 2017:

|  | Compensation<br>(€) |
|--|---------------------|
| Base salary  | 1,338,964           |
| Option awards(1)                                       | 9,072,838           |
| Employer social security contribution stock options(2) | 3,073,491           |
| Non-equity incentive plan compensation                 | 709,932             |
| Pension contributions                                  | 100,540             |
| Social security costs                                  | 393,481             |
| Other(3)   | 58,783              |
| <b>TOTAL</b>   | <b>14,748,029</b>   |

- (1) Amount shown represents the expenses recorded with respect to the option awards granted in 2017 to Mr. Eric Castaldi, 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 4.12 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 Group 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 Group makes a calculation of the exposure.
- (3) Consists of €51,235 attributable to the leases of company cars and €7,548 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, 2017:

| Name                 | Stock options | Expiration date | Exercise price |
|----------------------|---------------|-----------------|----------------|
| Tim Van Hauwermeiren | 80,000        | 12/14/2027      | € 21.17        |
| Eric Castaldi        | 43,200        | 12/14/2027      | € 21.17        |
| Nicolas Leupin       | 43,200        | 12/14/2027      | € 21.17        |
| Hans de Haard        | 14,353        | 6/26/2027       | € 18.41        |
| Hans de Haard        | 43,200        | 12/14/2027      | € 21.17        |
| Torsten Dreier       | 9,568         | 6/26/2027       | € 18.41        |
| Torsten Dreier       | 43,200        | 12/14/2027      | € 21.17        |
| Debbie Allen         | 43,200        | 12/14/2027      | € 21.17        |
| Dirk Beeusaert       | 39,682        | 6/26/2027       | € 18.41        |
| Dirk Beeusaert       | 15,000        | 12/14/2027      | € 21.17        |

The table below shows the stock options held at the start of the year ended December 31, 2017 and the stock options granted to our executive management which have vested during the year ended December 31, 2017, as well as the stock options to vest in the years ending December 31, 2018, December 31, 2019 and December 31, 2020 (in number of stock options), and the respective exercise price of such stock options:

| Name                 | Total options held on January 1, 2017 | Options granted in 2017 | Options exercised in 2017 | Total options held on December 31, 2017 | Options vested until 2016 | Exercise price | Options vested in 2017 | Exercise price | Options to vest in 2018 | Exercise price | Options to vest in 2019 | Exercise price | Options to vest in 2020 | Exercise price |
|----------------------|---------------------------------------|-------------------------|---------------------------|---|---------------------------|----------------|------------------------|----------------|-------------------------|----------------|-------------------------|----------------|-------------------------|----------------|
| Tim Van Hauwermeiren | 281,580                               | 80,000                  | (65,380)                  | 296,200                                 | 70,000                    | € 7.17         | 10,200                 | € 9.47         | 10,200                  | € 9.47         | 6,944                   | € 11.47        | 26,667                  | € 21.17        |
|                      |                                       |                         |                           |   | 10,200                    | € 9.47         | 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        |
| Eric Castaldi        | 230,607                               | 43,200                  | —                         | 273,807                                 | 72,007                    | € 2.44         | 9,000                  | € 2.44         |                         |                |                         |                |                         |                |
|                      |                                       |                         |                           |   | 43,333                    | € 7.17         | 21,667                 | € 7.17         |                         |                |                         |                |                         |                |
|                      |                                       |                         |                           |   | 9,400                     | € 9.47         | 9,400                  | € 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        |
| Nicolas Leupin       | 84,600                                | 43,200                  | —                         | 127,800                                 | 9,400                     | € 9.47         | 9,400                  | € 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        | 394,172                               | 57,553                  | (55,750)                  | 395,975                                 | 144,822                   | € 2.44         | 36,333                 | € 7.17         |                         |                |                         |                |                         |                |
|                      |                                       |                         |                           |   | 72,667                    | € 7.17         | 9,400                  | € 9.47         | 9,400                   | € 9.47         | 3,917                   | € 11.47        |                         |                |
|                      |                                       |                         |                           |   | 9,400                     | € 9.47         | 9,400                  | € 9.47         | 9,400                   | € 9.47         | 9,400                   | € 14.13        |                         |                |
|                      |                                       |                         |                           |   |                           |                | 14,883                 | € 11.47        | 9,400                   | € 11.47        | 9,400                   | € 14.13        |                         |                |
|                      |                                       |                         |                           |   |                           |                | 9,400                  | € 14.13        | 9,400                   | € 14.13        | 9,400                   | € 14.13        |                         |                |
|                      |                                       |                         |                           |   |                           |                | 7,177                  | € 18.41        | 4,784                   | € 18.41        | 2,392                   | € 18.41        |                         |                |
|                      |                                       |                         |                           |   |                           |                | 14,400                 | € 21.17        | 14,400                  | € 21.17        | 14,400                  | € 21.17        | 14,400                  | € 21.17        |
| Torsten Dreier       | 380,272                               | 52,768                  | (53,092)                  | 379,948                                 | 137,580                   | € 2.44         | 35,000                 | € 7.17         |                         |                |                         |                |                         |                |
|                      |                                       |                         |                           |   | 70,000                    | € 7.17         | 9,400                  | € 9.47         | 9,400                   | € 9.47         | 3,917                   | € 11.47        |                         |                |
|                      |                                       |                         |                           |   | 9,400                     | € 9.47         | 14,883                 | € 11.47        | 9,400                   | € 11.47        | 9,400                   | € 14.13        |                         |                |
|                      |                                       |                         |                           |   |                           |                | 9,400                  | € 14.13        | 9,400                   | € 14.13        | 9,400                   | € 14.13        |                         |                |
|                      |                                       |                         |                           |   |                           |                | 4,784                  | € 18.41        | 3,189                   | € 18.41        | 1,595                   | € 18.41        |                         |                |
|                      |                                       |                         |                           |   |                           |                | 14,400                 | € 21.17        | 14,400                  | € 21.17        | 14,400                  | € 21.17        | 14,400                  | € 21.17        |
| Debbie Allen         | 177,911                               | 43,200                  | —                         | 221,111                                 | 39,195                    | € 2.44         |                        |                |                         |                |                         |                |                         |                |
|                      |                                       |                         |                           |   | 10,616                    | € 3.95         | 14,500                 | € 7.17         |                         |                |                         |                |                         |                |
|                      |                                       |                         |                           |   | 29,000                    | € 7.17         | 9,400                  | € 9.47         | 9,400                   | € 9.47         | 3,917                   | € 11.47        |                         |                |
|                      |                                       |                         |                           |   | 9,400                     | € 9.47         | 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        |
| Dirk Beesaert        | —                                     | 54,682                  | —                         | 54,682                                  | —                         | € 18.41        | —                      | € 18.41        | 19,841                  | € 18.41        | 13,227                  | € 18.41        | 6,614                   | € 18.41        |
|                      |                                       |                         |                           |   | —                         | € 21.17        | —                      | € 21.17        | 5,000                   | € 21.17        | 5,000                   | € 21.17        | 5,000                   | € 21.17        |



The table below shows the remaining term of the stock options held by our executive management during the year ended December 31, 2017.

| Name                 | Number of stock options | Remaining term on December 31, 2017 (rounded up) |
|----------------------|-------------------------|--|
| Tim Van Hauwermeiren | 105,000                 | 7.0 years  |
|                      | 30,600                  | 8.0 years  |
|                      | 50,000                  | 8.5 years  |
|                      | 30,600                  | 9.0 years  |
|                      | 80,000                  | 10.0 years                                       |
| Eric Castaldi        | 60,970                  | 6.5 years  |
|                      | 85,037                  | 7.0 years  |
|                      | 28,200                  | 8.0 years  |
|                      | 28,200                  | 8.5 years  |
|                      | 28,200                  | 9.0 years  |
|                      | 43,200                  | 10.0 years                                       |
| Nicolas Leupin       | 28,200                  | 8.0 years  |
|                      | 28,200                  | 8.5 years  |
|                      | 28,200                  | 9.0 years  |
|                      | 43,200                  | 10.0 years                                       |
| Hans De Haard        | 69,360                  | 5.5 years  |
|                      | 39,636                  | 6.0 years  |
|                      | 144,826                 | 7.0 years  |
|                      | 28,200                  | 8.0 years  |
|                      | 28,200                  | 8.5 years  |
|                      | 28,200                  | 9.0 years  |
|                      | 14,353                  | 9.5 years  |
|                      | 43,200                  | 10.0 years                                       |
| Torsten Dreier       | 65,890                  | 5.5 years  |
|                      | 37,654                  | 6.0 years  |
|                      | 139,036                 | 7.0 years  |
|                      | 28,200                  | 8.0 years  |
|                      | 28,200                  | 8.5 years  |
|                      | 28,200                  | 9.0 years  |
|                      | 9,568                   | 9.5 years  |
|                      | 43,200                  | 10.0 years                                       |
| Debbie Allen         | 7,180                   | 2.5 years  |
|                      | 810                     | 3.0 years  |
|                      | 18,770                  | 5.5 years  |
|                      | 10,727                  | 6.0 years  |
|                      | 55,824                  | 7.0 years  |
|                      | 28,200                  | 8.0 years  |
|                      | 28,200                  | 8.5 years  |
|                      | 28,200                  | 9.0 years  |
|                      | 43,200                  | 10.0 years                                       |
| Dirk Beeusaert       | 39,682                  | 9.5 years  |
|                      | 15,000                  | 10.0 years                                       |

The table below shows the stock options exercised by our executive management during the year ended December 31, 2017 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 | 65,380                  | € 2.44         |
| Hans De Haard        | 55,750                  | € 3.95         |
| Torsten Dreier       | 53,092                  | € 3.95         |
| Total                | 174,222                 |                |

### **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.

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 (retroactively to January 1, 2017, an increase from €20,000), additional remuneration for the chairperson of the audit committee and the research and development committee of the board of directors at €15,000 (retroactively to January 1, 2017, an increase from €10,000) and additional remuneration for the chairperson of the remuneration and nomination committee of the board of directors at €10,000 (retroactively to January 1, 2017, an increase from €8,000). 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, 2017:

| Name                    | Fees earned or paid in cash (€) | Option awards (€)(1) | Total    |
|-------------------------|---------------------------------|----------------------|----------|
| Peter K.M. Verhaeghe    | 77,500                          | —                    | € 77,500 |
| John Paul de Koning (2) | —                               | —                    | —        |
| David L. Lacey          | 50,000                          | 556,537              | 606,537  |
| Werner Lanthaler        | 55,000                          | —                    | 55,000   |
| Pamela Klein            | 42,500                          | —                    | 42,500   |
| J. Donald deBethizy     | 52,500                          | —                    | 52,500   |
| A.A. Rosenberg          | 42,500                          | —                    | 42,500   |

- (1) Amount shown represents the expenses recorded with respect to the option awards granted in 2017 to the non-executive directors measured using the Black Scholes formula. For a description of the assumptions used in valuing these awards, see note 4.12 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.
- (2) Dr. de Koning is affiliated with Life Sciences Partners, one of our shareholders, and accordingly, did not receive any compensation for his service as a non-executive director. Dr. de Koning resigned from our board of directors effective April 26, 2017.
- (3) Dr. Rosenberg was appointed to the board on April 26, 2017, and therefore the amounts shown reflect the pro rata portion of Dr. Rosenberg's fixed fee earned during 2017.

The table below shows the stock options held at the start of the year ended December 31, 2017 and the stock options granted to the non-executive directors which have vested during the year ended December 31, 2017, as well as the stock options to vest in the years ending December 31, 2018, December 31, 2019 and December 31, 2020 (in number of stock options), and the respective exercise price of such stock options:

| Name                | Total options held on January 1, 2017 | Options granted in 2017 | Total options held on December 31, 2017 | Options vested until 2016 | Exercise price | Options vested in 2017 | Exercise price | Options to vest in 2018 | Exercise price | Options to vest in 2019 | Exercise price | Options to vest in 2020 | Exercise price |
|---------------------|---------------------------------------|-------------------------|---|---------------------------|----------------|------------------------|----------------|-------------------------|----------------|-------------------------|----------------|-------------------------|----------------|
| Peter Verhaeghe     | 34,585                                | —                       | 34,585                                  | 11,626                    | € 2.44         | —                      | —              | —                       | —              | —                       | —              | —                       | —              |
|                     |                                       |                         |   | 7,959                     | € 3.95         | —                      | —              | —                       | —              | —                       | —              | —                       | —              |
|                     |                                       |                         |   | 3,333                     | € 7.17         | 1,667                  | € 7.17         | 3,333                   | € 11.38        | 1,667                   | € 11.38        | —                       | —              |
| David L. Lacey      | 29,443                                | 15,000                  | 44,443                                  | 6,643                     | € 2.44         | 4,267                  | € 7.17         | 3,333                   | € 11.38        | 1,667                   | € 11.38        | —                       | —              |
|                     |                                       |                         |   | 8,533                     | € 7.17         | 5,000                  | € 11.38        | 5,000                   | € 21.17        | 5,000                   | € 21.17        | 5,000                   | € 21.17        |
| Werner Lanthaler    | 29,416                                | —                       | 29,416                                  | 12,814                    | € 2.44         | 1,602                  | € 2.44         | —                       | —              | —                       | —              | —                       | —              |
|                     |                                       |                         |   | 3,333                     | € 7.17         | 1,667                  | € 7.17         | 3,333                   | € 11.38        | 1,667                   | € 11.38        | —                       | —              |
| J. Donald deBethizy | 25,000                                | —                       | 25,000                                  | 7,500                     | € 11.44        | 5,000                  | € 11.44        | 2,500                   | € 11.44        | —                       | —              | —                       | —              |
|                     |                                       |                         |   | —                         | —              | 5,000                  | € 11.38        | 3,333                   | € 11.38        | 1,667                   | € 11.38        | —                       | —              |
| Pamela Klein        | 25,000                                | —                       | 25,000                                  | 7,500                     | € 11.44        | 5,000                  | € 11.44        | 2,500                   | € 11.44        | —                       | —              | —                       | —              |
|                     |                                       |                         |   | —                         | —              | 5,000                  | € 11.38        | 3,333                   | € 11.38        | 1,667                   | € 11.38        | —                       | —              |
| A.A. Rosenberg      | 15,000                                | —                       | 15,000                                  | —                         | € 14.13        | 5,000                  | € 14.13        | 5,000                   | € 14.13        | 5,000                   | € 14.13        | —                       | —              |

The table below shows the remaining term of the stock options held by the non-executive directors during the year ended December 31, 2017.

| Name                 | Number of stock options | Remaining term on December 31, 2017 (rounded up) |
|----------------------|-------------------------|--|
| Peter K.M. Verhaeghe | 3,650                   | 2.5 years  |
|                      | 2,340                   | 3.0 years  |
|                      | 5,560                   | 5.5 years  |
|                      | 3,181                   | 6.0 years  |
|                      | 9,854                   | 7.0 years  |
|                      | 10,000                  | 8.5 years  |
| David L. Lacey       | 3,180                   | 5.5 years  |
|                      | 1,818                   | 6.0 years  |
|                      | 14,445                  | 7.0 years  |
|                      | 10,000                  | 8.5 years  |
|                      | 15,000                  | 10.0 years                                       |
| Werner Lanthaler     | 10,850                  | 6.0 years  |
|                      | 8,566                   | 7.0 years  |
|                      | 10,000                  | 8.5 years  |
| J. Donald deBethizy  | 15,000                  | 7.5 years  |
|                      | 10,000                  | 8.5 years  |
| Pamela Klein         | 15,000                  | 7.5 years  |
|                      | 10,000                  | 8.5 years  |
| A.A. Rosenberg       | 15,000                  | 9.0 years  |

No stock options were exercised by non-executive directors during the year ended December 31, 2017, and no corresponding shares were issued in relation thereto.

### 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.

On April 26, 2017, the shareholders at the General Meeting designated our board of directors as the corporate body competent to issue shares under the Option Plan and to limit or exclude preemption rights of shareholders for such shares and option rights to subscribe for shares with the prior consent of the majority of the non-executive directors for a period of 18 months.

As of March 16, 2018, there were 2,626,184 options outstanding which represent approximately 8.1% 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, 2017, 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          | 5/11/2010  | 3.95               | 103,370                   | 78,530                              | —                        | 24,840                              | 5/11/2013        | 5/11/2020   |
| SOP A          | 11/30/2010 | 3.95               | 62,460                    | 50,340                              | —                        | 12,120                              | 11/30/2013       | 11/30/2020  |
| SOP A          | 2/1/2011   | 3.95               | 3,800                     | 950                                 | —                        | 2,850                               | 2/1/2014         | 2/1/2021    |
| SOP B          | 5/23/2013  | 2.44               | 305,740                   | 105,560                             | —                        | 200,180                             | 5/23/2016        | 5/23/2023   |
| SOP B          | 12/4/2013  | 2.44               | 174,747                   | 60,334                              | —                        | 114,413                             | 12/4/2016        | 12/4/2023   |
| SOP B          | 6/30/2014  | 2.44               | 109,820                   | 26,000                              | —                        | 83,820                              | 6/30/2017        | 6/30/2024   |
| Reshuffling A  | 9/30/2014  | 3.95               | 55,746                    | 40,054                              | —                        | 15,692                              | 9/30/2017        | 9/30/2024   |
| Reshuffling B1 | 9/30/2014  | 2.44               | 174,362                   | 49,646                              | —                        | 124,716                             | 9/30/2017        | 9/30/2024   |
| Reshuffling B2 | 9/30/2014  | 2.44               | 19,719                    | 8,545                               | —                        | 11,174                              | 9/30/2017        | 9/30/2024   |
| SOP 2014.12.18 | 12/18/2014 | 7.17               | 585,250                   | 21,400                              | 47,750                   | 516,100                             | 12/18/2017       | 12/18/2024  |
| SOP 2015.06.18 | 6/18/2015  | 11.44              | 56,500                    | —                                   | 17,500                   | 39,000                              | 6/18/2018        | 6/18/2025   |
| SOP 2015.09.03 | 9/3/2015   | 10.34              | 3,000                     | —                                   | —                        | 3,000                               | 9/3/2018         | 9/3/2025    |
| SOP 2015.12.15 | 12/15/2015 | 9.47               | 243,400                   | —                                   | 7,886                    | 235,514                             | 12/15/2018       | 12/15/2025  |
| SOP 2016.05.25 | 5/25/2016  | 11.47              | 288,950                   | —                                   | 6,640                    | 282,310                             | 5/25/2019        | 5/25/2026   |
| SOP 2016.06.18 | 6/18/2016  | 11.38              | 60,000                    | —                                   | —                        | 60,000                              | 6/18/2019        | 6/18/2026   |
| SOP 2016.12.13 | 12/13/2016 | 14.13              | 363,226                   | —                                   | 1,100                    | 362,126                             | 12/13/2019       | 12/13/2026  |
| SOP 2017.06.26 | 6/26/2017  | 18.41              | 120,536                   | —                                   | —                        | 120,536                             | 6/26/2020        | 6/26/2027   |
| SOP 2017.12.14 | 12/14/2017 | 21.17              | 653,825                   | —                                   | —                        | 653,825                             | 12/14/2020       | 12/14/2027  |
| <b>Total</b>   |            |                    | <b>3,384,451</b>          | <b>441,359</b>                      | <b>80,876</b>            | <b>2,862,216</b>                    |                  |             |

## 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;
- 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;



- 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, 2017, we had 73 employees. At each date shown below, we had the following number of employees, broken out by department and geography:

|                                     | At December 31, |      |      |
|-------------------------------------|-----------------|------|------|
|                                     | 2017            | 2016 | 2015 |
| <b>Function:</b>                    |                 |      |      |
| Research and development            | 58              | 48   | 35   |
| Selling, general and administrative | 15              | 10   | 6    |
| Total                               | 73              | 58   | 41   |
| <b>Geography:</b>                   |                 |      |      |
| Zwijnaarde, Belgium                 | 73              | 58   | 41   |
| Breda, the Netherlands              | —               | —    | —    |
| Total                               | 73              | 58   | 41   |

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 16, 2018 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 16, 2018. The percentage ownership information shown in the table is based upon 32,403,133 ordinary shares outstanding as of March 16, 2018.

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 16, 2018. 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 |
| <b>3% or Greater Shareholders:</b>                                 |                           |            |
| FMR LLC(1)(2)  | 3,217,079                 | 9.93 %     |
| Federated Equity Management Company of Pennsylvania(1)(3)          | 2,891,897                 | 8.92 %     |
| RTW Investments(1)(4)  | 1,436,705                 | 4.43 %     |
| Shire plc(1)(5)  | 1,411,764                 | 4.36 %     |
| LSP IV Management B.V.(1)(6)                                       | 1,400,215                 | 4.32 %     |
| Entities affiliated with Baker Bros. Advisors LLC(1)(7)            | 1,190,197                 | 3.67 %     |
| Perceptive Advisors LLC(1)(8)                                      | 1,124,478                 | 3.47 %     |
| T. Rowe Price Group, Inc. (1)(9)                                   | 986,110                   | 3.04 %     |
| <b>Directors and Executive Management:</b>                         |                           |            |
| Tim Van Hauwermeiren(10)   | 219,724                   | *          |
| Peter Verhaeghe(11)  | 30,696                    | *          |
| David Lacey(12)  | 25,554                    | *          |
| Werner Lanthaler(13)   | 26,527                    | *          |
| Donald deBethizy(14)   | 20,278                    | *          |
| Pamela Klein(15)   | 20,278                    | *          |
| A.A. Rosenberg(16)   | 6,667                     | *          |
| Eric Castaldi(17)  | 138,490                   | *          |
| Nicolas Leupin(18)   | 52,483                    | *          |
| Hans de Haard(19)  | 404,965                   | 1.24 %     |
| Torsten Dreier(20)   | 400,065                   | 1.22 %     |
| Debbie Allen(21)   | 145,794                   | *          |
| Dirk Beeusaert   | —                         | —          |
| All directors and executive management as a group (13 persons)(22) | 1,491,521                 | 4.44 %     |

\* 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 3,217,079 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) 2,487,414 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 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 250 West 55<sup>th</sup> Street, 16<sup>th</sup> Floor, Suite A, New York, NY 10019.
- (5) Consists of 1,411,764 ordinary shares beneficially held. The address for Shire plc is Zählerweg 10, 6300 Zug, Switzerland.
- (6) Consists of 1,400,215 shares beneficially held. The address for LSP IV Management B.V. is Johannes Vermeerplein 9, 1071DV, Amsterdam, the Netherlands.
- (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) The address for Perceptive Advisors, LLC is 51 Astor Place, 10<sup>th</sup> Floor, New York, NY 10003.
- (9) Consists of 986,110 ADSs held by T. Rowe Price Associates, Inc. The address for T. Rowe Price Associates, Inc is 100 East Pratt Street, Baltimore, MD 21202.
- (10) Consists of (i) 65,380 shares and (ii) 154,344 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 16, 2018. Next to this, 23,823 shares are being held by a Stichting Administratiekantoor for which Tim Van Hauwermeiren is a director.
- (11) Consists of 30,696 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 16, 2018.
- (12) Consists of 25,554 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 16, 2018.
- (13) Consists of (i) 25,972 shares and (ii) 555 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 16, 2018.

- (14) Consists of 20,278 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 16, 2018.
- (15) Consists of 20,278 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 16, 2018.
- (16) Consists of 6,667 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 16, 2018.
- (17) Consists of 138,490 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 16, 2018.
- (18) Consists of 52,483 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 16, 2018.
- (19) Consists of (i) 98,660 shares and (ii) 306,305 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 16, 2018.
- (20) Consists of (i) 105,002 shares and (ii) 295,063 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 16, 2018.
- (21) Consists of 145,794 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 16, 2018.
- (22) Consists of (i) 295,014 shares and (ii) 1,196,507 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 16, 2018.

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 16, 2018, 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 53.4% of the 32,403,133 ordinary shares outstanding as of March 16, 2018. 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 16, 2018, assuming that all of our ordinary shares represented by ADSs are held by residents of the United States, we estimate that approximately 83% of our outstanding ordinary shares were held in the United States by approximately 67 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 American 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.

## 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. We have also entered into an employment agreement with Eric Castaldi, our Chief Financial Officer. Mr. Castaldi served as an executive director until April 26, 2017. The key terms of these agreements, reflecting updates approved by the board of directors on September 12, 2107, are as follows:

|                          | Tim Van Hauwermeiren |  | Eric Castaldi |  |
|--------------------------|----------------------|--|---------------|--|
| Base salary              | €                    | 303,941  | €             | 271,344  |
| Cash bonus               |                      | maximum 50% of base salary based on previously determined bonus targets established by the non-executive directors |               | maximum 35% of base salary based on previously determined bonus targets established by the non-executive directors |
| Pension contributions(1) | €                    | 11,929   | €             | 84,972   |
| Duration                 |                      | Indefinite   |               | Indefinite   |

(1) Amounts shown represent pension contributions paid during the year-ended December 31, 2017.

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. In the case of Mr. Castaldi, if we terminate his employment without taking into account the statutory notice period (other than a termination for serious cause), or Mr. Castaldi terminates his employment with us in circumstances in which it cannot reasonably be expected for him to continue employment with us (and provided we have failed to remedy the condition after a period of 14 days from being given notice of such condition) then Mr. Castaldi shall be entitled to receive the higher of (i) 12 months’ gross annual salary or (ii) salary and benefits as defined under Belgian law for the statutory notice period (or, if the termination took into account all or part of the statutory notice period, for the remainder of the statutory notice period). In each such case (other than a termination for serious cause), there will be a full acceleration of the vesting of any outstanding stock options held by Mr. Castaldi. Mr. Van Hauwermeiren may be dismissed immediately as an executive director.

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, we sold this entire shareholding in FairJourney Biologics LDA, and thus FairJourney Biologics LDA is no longer a related company. Throughout the 2017 fiscal year, even though we held the shares in FairJourney Biologics LDA as stated above, FairJourney Biologics LDA was not a related party in accordance with IAS 24—Related Party Disclosures, since neither we nor any of our key management personnel controlled the company nor had significant influence over it.

#### ***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 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 March 16, 2018, we were awarded a €2.5 million grant from Flanders Innovation and Entrepreneurship, or VLAIO, to identify novel therapeutic antibodies. This grant will be used to fund research of novel targets involved in the regulation of locally-released TGF- $\beta$ , a protein active in immunosuppression.

On March 22, 2018, we announced the expansion of our pipeline with the addition of complement-targeted ARGX-117 for treatment of severe autoimmune diseases. ARGX-117 has the potential to have a synergistic effect with the lead autoimmune compound ARGX-113.

## 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.

The following tables set forth for the periods indicated the reported high and low sale prices per ADS in U.S. dollars and per ordinary share on Euronext Brussels in euros.

#### Nasdaq

| Period                                       | High     | Low      |
|--|----------|----------|
| <b>Annual:</b>                               |          |          |
| 2017 (beginning May 18, 2017)                | \$ 69.27 | \$ 17.33 |
| <b>Quarterly:</b>                            |          |          |
| Second Quarter 2017 (beginning May 18, 2017) | \$ 25.00 | \$ 17.33 |
| Third Quarter 2017                           | \$ 22.61 | \$ 19.36 |
| Fourth Quarter 2017                          | \$ 69.27 | \$ 22.21 |
| First Quarter 2018 (through March 20, 2018)  | \$ 87.00 | \$ 55.50 |
| <b>Month ended:</b>                          |          |          |
| September 2017                               | \$ 22.61 | \$ 20.52 |
| October 2017                                 | \$ 27.25 | \$ 22.27 |
| November 2017                                | \$ 35.71 | \$ 22.21 |
| December 2017                                | \$ 69.27 | \$ 28.84 |
| January 2018                                 | \$ 85.31 | \$ 55.50 |
| February 2018                                | \$ 87.00 | \$ 69.97 |
| March 2018 (through March 20, 2018)          | \$ 86.08 | \$ 75.49 |

## Euronext Brussels

| Period                                      | High |       | Low |       |
|---|------|-------|-----|-------|
| <b>Annual:</b>                              |      |       |     |       |
| 2014 (beginning July 10, 2014)              | €    | 8.75  | €   | 6.23  |
| 2015  | €    | 14.27 | €   | 7.40  |
| 2016  | €    | 15.99 | €   | 9.23  |
| 2017  | €    | 57.48 | €   | 14.75 |
| <b>Quarterly:</b>                           |      |       |     |       |
| First Quarter 2015                          | €    | 10.15 | €   | 7.40  |
| Second Quarter 2015                         | €    | 14.27 | €   | 8.60  |
| Third Quarter 2015                          | €    | 11.75 | €   | 8.46  |
| Fourth Quarter 2015                         | €    | 11.35 | €   | 8.71  |
| First Quarter 2016                          | €    | 11.58 | €   | 9.23  |
| Second Quarter 2016                         | €    | 12.34 | €   | 10.15 |
| Third Quarter 2016                          | €    | 15.38 | €   | 11.56 |
| Fourth Quarter 2016                         | €    | 15.99 | €   | 12.50 |
| First Quarter 2017                          | €    | 16.80 | €   | 14.75 |
| Second Quarter 2017                         | €    | 19.85 | €   | 15.15 |
| Third Quarter 2017                          | €    | 18.88 | €   | 16.75 |
| Fourth Quarter 2017                         | €    | 57.48 | €   | 18.50 |
| First Quarter 2018 (through March 20, 2018) | €    | 70.50 | €   | 48.80 |
| <b>Month ended:</b>                         |      |       |     |       |
| September 2017                              | €    | 18.88 | €   | 17.01 |
| October 2017                                | €    | 22.30 | €   | 18.50 |
| November 2017                               | €    | 25.44 | €   | 19.55 |
| December 2017                               | €    | 57.48 | €   | 24.35 |
| January 2018                                | €    | 66.00 | €   | 48.80 |
| February 2018                               | €    | 70.50 | €   | 55.80 |
| March 2018 (through March 20, 2018)         | €    | 69.80 | €   | 62.00 |

On March 20, 2018, the last reported sale price of the ADSs on the Nasdaq Global Select Market was \$80.49 per ADS, and the last reported sale price of the ordinary shares on Euronext Brussels was €65.60 per share.

### 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**

A summary of our articles of association was included under the caption “Description of Share Capital” in our final prospectus dated December 13, 2017 that we filed with the SEC pursuant to Rule 424(b) on December 14, 2017 (File No. 333-221984) and is incorporated by reference herein.

### **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 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 acquisition, 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 are initial purchasers of ADSs and that will 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 the U.S. federal estate, gift, or alternative minimum tax considerations, or any U.S. state, local, or non-U.S. tax considerations of the acquisition, 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 acquisition, 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.

The U.S. Treasury has expressed concerns that parties to whom ADSs are released before shares are delivered to the depositary (“pre-release”), or intermediaries in the chain of ownership between holders and the issuer of the security underlying the ADSs, may be taking actions that are inconsistent with the claiming of foreign tax credits by

holders of ADSs. These actions would also be inconsistent with the claiming of the reduced rate of tax, described below, applicable to dividends received by certain non-corporate holders. Accordingly, the creditability of Dutch or Belgian taxes, and the availability of the reduced tax rate for dividends received by certain non-corporate U.S. holders, each described below, could be affected by actions taken by such parties or intermediaries.

As indicated below, this discussion is subject to U.S. federal income tax rules applicable to a “passive foreign investment company,” or a PFIC.

**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 acquisition, 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 applied to list our ordinary shares on the Nasdaq Global Select Market, which is an established securities market in the United States, and we expect the ADSs to be readily tradable on Nasdaq. 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 a 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 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. Based on the foregoing, we do not anticipate that we will be a PFIC for the current 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 acquisition, 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 acquisition, 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 acquisition, 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 Prior to Our Redomiciliation**

The following summary outlines certain material Dutch tax consequences in connection with the acquisition, ownership and disposal of the ADSs, prior to our proposed redomiciliation. 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, or (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). A legislative proposal is currently pending before the Lower House of the Dutch Parliament which, inter alia, aims to expand the (domestic) dividend withholding tax exemption for profits distributions made by Dutch resident companies to shareholders resident in a country with which the Netherlands has concluded a tax treaty that includes an article on dividends and that hold an interest of at least 5% in the Dutch company. The expanded exemption will be subject to new anti-abuse rules that are similar to the current anti-abuse rules included in the Netherlands corporate income tax act for foreign taxpayers that hold a substantial interest in a Netherlands resident 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 Redomiciliation**

The following summary outlines certain material Dutch tax consequences in connection with the acquisition, ownership and disposal of the ADSs, if and when our 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 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 Prior to Our Redomiciliation**

The paragraphs below present a summary of certain material Belgian federal income tax consequences of the ownership and disposal of ADSs by an investor that purchases such ADSs prior to the completion of our proposed redomiciliation. 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, pursuant to a recently introduced new imputation mechanism, it is no longer possible to fully impute a repayment of capital to fiscal capital if the company has reserves. Under this new imputation rule, 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.

The Belgian government has recently announced its intention to propose a new imputation mechanism under which it would no longer be possible to fully impute a repayment of capital to fiscal capital. Under the new imputation rule, a reimbursement of capital would proratedly be 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 certain priority rule). The part imputed on the reserves would be treated as a dividend distribution subject to applicable tax rules. With respect to reimbursements of fiscal capital carried out by non-resident companies, the Belgian government also intends to apply the same rule and clarify that such transactions will have to be carried out in

accordance with the corporate law provisions of the country of residence of the distributing companies. These new tax measures would, if adopted, be effective as of 2018. No official text has, however, been published yet.

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 the newly introduced tax exemption with respect to ordinary dividends in an amount of up to €640 (amount applicable in income year 2018) 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. The Belgian government has announced that the said maximum amount would increase to €800 as of income year 2019.

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 at the time the dividends are paid or attributed 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 33.99% (including the 3% crisis surcharge), unless the reduced corporate income tax rates applicable to qualifying companies with limited profits apply. The Belgian government recently announced its intention to gradually reduce the standard corporate income tax rate from 33% to 29% in 2018 and 25% in 2020. The 3% surcharge applicable to this corporate income tax rate (which currently results in an aggregate tax rate of 33.99%) would be decreased to 2% in 2018 and abolished in 2020. To prevent companies from shifting profits to taxable periods which would be subject to a lower corporate income tax rate, new anti-avoidance measures would be introduced. Moreover, the reduced (progressive) tax rates applicable to certain qualifying companies with limited profits would be replaced by a reduced rate (of 20.4% (including the 2% crisis surcharge as mentioned above) in 2018 and 2019 and 20% thereafter) on the first €100,000 of taxable profits for certain qualifying companies. No official text has, however, been published yet.

Belgian resident companies can generally (although subject to certain limitations) deduct up to 95% 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 ITC Taxation Condition, are met, or together, the Conditions for the application of the Dividend Received Deduction regime. The Belgian government recently announced its intention to increase the deduction relating to the Dividend Received Deduction regime from 95% to 100% of the gross dividend received. This new tax measure would, if adopted, be effective as of 2018.

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 at the time the dividends are paid or attributed 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 Belgian 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, the dividend income is generally tax-exempt. Although there is no specific exemption from Belgian dividend withholding tax at source for dividends paid or attributed to OFPs, subject to certain limitations, the Belgian dividend withholding tax can be credited against the OFPs' corporate income tax and is reimbursable to the extent it exceeds the corporate income tax due.

### *Other Taxable Legal Entities*

For taxpayers subject to the Belgium 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 at the time the dividends are paid or attributed 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 up to 95% 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. As specified above, the Belgian government recently announced its intention to increase the deduction relating to the Dividend Received Deduction regime from 95% to 100% of the gross dividend received. This new tax measure would, if adopted, be effective as of 2018.

### ***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 (other than Belgian resident companies which qualify as a small company within the meaning of Article 15, §1-6 of the Belgian Companies Code, or SMEs) are subject to Belgian capital gains taxation at a flat rate of 0.412% on gains realized upon the disposal of the ADSs provided that: (i) the Article 203 ITC Taxation Condition is satisfied and (ii) the ADSs have been held in full legal ownership for an uninterrupted period of at least one year. The 0.412% flat capital gains tax rate cannot be off-set by any tax assets (such as tax losses) or tax credits. The Belgian government recently announced its intention to abolish such a separate capital gain tax of 0.412%. The said changes would, if adopted, be effective as of 2018. No official text has, however, been published yet.

Belgian resident companies qualifying as SMEs are normally not subject to Belgian capital gains taxation on gains realized upon the disposal of the ADSs provided that (i) the Article 203 ITC Taxation Condition is satisfied and (ii) 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 ordinary shares by a Belgian resident company (non-SME or SME) are taxable at a flat corporate income tax rate of, currently, 25.75% (including the 3% crisis surcharge). Under the recently announced corporate tax reform (as discussed above), the tax rate in this case would be 25.5% (including the 2% crisis surcharge) in 2018 and 2019 and equal to the 25% standard tax rate thereafter (unless the reduced tax rates apply).

The Belgian government recently announced that the requirement relating to the holding of a participation representing at least 10% of the company's share capital or a participation in the company with an acquisition value of at least €2,500,000 (as applicable under the Belgian dividend received deduction) would also become applicable to the capital gains tax exemption on shares (irrespective of whether the shareholder is an SME). If this participation condition is not met, the capital gains would be taxable at the standard corporate tax rate (being 29% plus a 2% surcharge as of 2018 and 25% as of 2020, according to the announced government proposals), unless the reduced corporate income tax rate applies. The said changes would, if adopted, be effective as of 2018. No official text has, however, been published yet.

Capital losses on the ADSs incurred by resident companies (both non-SMEs and SMEs) are as a general rule not tax deductible.

The 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 33.99% (including the 3% crisis surcharge), which are announced to be reduced as of 2018, as discussed above, and the 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 ADS 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 0.27% of the purchase price, capped at €1,600 per transaction and per party. The Belgian government has recently announced its intention to increase the rate of the tax on stock exchange transactions from 0.27% to 0.35%. The nominal caps as applicable per transaction and per party should however remain unchanged. This change would be effective as of 2018. No official text has, however, been published yet.

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%, 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. However, the first reference period starts on March 10, 2018 and ends on September 30, 2018 ("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 Tax Consequences Upon Completion of Our Redomiciliation**

The summary below presents certain material Belgian federal income tax consequences of the ownership and disposal of ADSs by an investor that purchases such ADSs, if and when our proposed 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. The Belgian government recently announced its intention to propose a new imputation mechanism under which it would no longer be possible to fully impute a repayment of capital to fiscal capital if the company has reserves. Under the new imputation rule, a reimbursement of capital would proratedly be 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. These new tax measures would, if adopted, be effective as of 2018.

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 the newly introduced tax exemption with respect to ordinary dividends in an amount of up to €640 (amount applicable in income year 2018) 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. The Belgian government has announced that the said maximum amount would increase to €800 as of income year 2019.

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 at the time the dividends are paid or attributed, 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 33.99% (including at 3% crisis surcharge), unless the reduced corporate income tax rates applicable to qualifying companies with limited profits apply. The Belgian government recently announced its intention to gradually reduce the standard corporate income tax rate from 33% to 29% in 2018 and 25% in 2020. The 3% surcharge applicable to said corporate income tax rate (which currently results in an aggregate tax rate of 33.99%) would be decreased to 2% in 2018 and abolished in 2020. Moreover, the reduced (progressive) tax rates applicable to certain qualifying companies with limited profits would be replaced by a reduced rate (of 20.4% (including the 2% crisis surcharge as mentioned above) in 2018 and 2019 and 20% thereafter) on the first €100,000 of taxable profits for certain qualifying companies. To prevent companies from shifting profits to taxable periods which would be subject to a lower corporate income tax rate, new anti-avoidance measures would be introduced. No official text has, however, been published yet.



Belgian resident companies can generally (although subject to certain limitations) deduct up to 95% 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 Belgian 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 Belgian government announced its intention to increase the deduction relating to the Dividend Received Deduction regime from 95% to 100% of the gross dividend received. This new tax measure would, if adopted, be effective as of 2018.

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 at the time the dividends are paid or attributed 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. Although there is no specific exemption from dividend withholding tax at source for dividends paid or attributed to OFPs, subject to certain limitations, the 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.

### *Other Taxable Legal Entities*

For taxpayers subject to the Belgium 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 at the time the dividends are paid or attributed 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 PE can deduct up to 95% (which would become 100% after adoption of the announced tax law changes, as discussed above) 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 the newly introduced tax exemption with respect to ordinary dividends in an amount of up to €640 (amount applicable in income year 2018) 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. The Belgian government has announced that the said maximum amount would increase to €800 as of income year 2019.

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. 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 subject to a reduced Belgian withholding tax of 1.6995%, or the Reduced 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. The Reduced Withholding Tax only applies if and to the extent that the ordinary Belgian withholding tax is, in principle, neither creditable nor reimbursable in the hands of the non-resident company. The Belgian government also announced its intention to replace this Reduced Withholding Tax by a full exemption. This new tax measure would, if adopted, be applicable to dividends paid or attributed as of 2018. No official text has, however, been published yet.

In order to benefit from the Reduced Withholding Tax (or, after adoption of the above-mentioned tax law change, the 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 participation with an acquisition value of at least €2,500,000 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).

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 (other than SMEs) are subject to Belgian capital gains taxation at a flat rate of 0.412% on gains realized upon the disposal of the ADSs provided that: (i) the Article 203 ITC Taxation Condition is satisfied and (ii) the ADSs have been held in full legal ownership for an uninterrupted period of at least one year. The 0.412% flat capital gains tax rate cannot be off-set by any tax assets (such as tax losses) or tax credits. The Belgian government recently announced its intention to abolish such a separate capital gain tax of 0.412% as of 2018. No official text has, however, been published yet.

Belgian resident companies qualifying as SMEs are normally not subject to Belgian capital gains taxation on gains realized upon the disposal of the ADSs provided that (i) the Article 203 ITC Taxation Condition is satisfied and (ii) 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 the ADSs by a Belgian resident company (non-SME or SME) are taxable at a flat corporate income tax rate of, currently, 25.75% (including the 3% crisis surcharge). Under the recently announced corporate tax reform (see above), the tax rate in this case would be 25.5% (including the 2% crisis surcharge) in 2018 and 2019 and equal to the standard tax rate of 25% thereafter (unless the reduced tax rates apply).

The Belgian government recently announced that the requirement relating to the holding of a participation representing at least 10% of the company's share capital or a participation in the company with an acquisition value of at least €2,500,000 (as applicable under the Belgian dividend received deduction) would also become applicable to the capital gains tax exemption on shares (irrespective of whether the shareholder is an SME). If this participation condition is not met, the capital gains would be taxable at the standard corporate tax rate (being 29% plus a 2% surcharge as of 2018 and 25% as of 2020, according to the announced government proposals), unless the reduced corporate income tax rate applies. The said changes would, if adopted, be effective as of 2018. No official text has, however, been published yet.

Capital losses on the ADSs incurred by resident companies (both non-SMEs and SMEs) are as a general rule not tax deductible.

The 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 33.99% (including the 3% crisis surcharge), which are announced to be reduced as of 2018 (as discussed above), and the 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 ordinary shares 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. 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 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. The Belgian government recently orally announced its intention to increase the rate of the tax on stock exchange transactions from 0.27% to 0.35%. The nominal caps as applicable per transaction and per party should however remain unchanged. This change would be effective as of 2018. No official text has, however, been published yet.

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. Pursuant to this law, Belgian resident and non-resident individuals are taxed at a rate of 0.15%, 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. However, the first reference period starts on March 10, 2018 and ends on September 30, 2018 ("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](http://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](http://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 variable interest-bearing financial assets are cash at banks and our investments in money market funds. 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, 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, notably with the opening of our U.S. office in October 2017, 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, 2017. 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, 2017, 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), (i) are effective at that level of reasonable assurance in ensuring that information required to be disclosed in the reports that are filed or submitted under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms, and (ii) are effective at that level of reasonable assurance in ensuring that information to be disclosed in the reports that are filed or submitted under the Exchange Act is accumulated and communicated to the management of our company, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure.

## Management’s Annual Report on Internal Control Over Financial Reporting

This annual report does not include a report of the management’s assessment regarding internal control over financial reporting due to a transition period established by rules of the SEC for newly public companies.

## Attestation Report of the Registered Public Accounting Firm

This annual report does not include an attestation report of the company’s registered public accounting firm due to a transition period established by rules of the SEC.

## Changes in Internal Control Over Financial Reporting

This annual report does not disclose any changes in internal control over financial reports given that there has been no assessment by management regarding internal control over financial reporting for the reasons disclosed above.

## 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](http://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 2016 and 2017. Our accountants billed the following fees to us for professional services in each of those fiscal years:

| Fees               | Year Ended December 31, |                |
|--------------------|-------------------------|----------------|
|                    | 2017                    | 2016           |
|                    | in thousands of €       |                |
| Audit Fees         | € 205.0                 | € 85.0         |
| Audit-Related Fees | 698.0                   | 65.0           |
| Tax Fees           | —                       | 2.0            |
| All Other Fees     | —                       | —              |
| <b>Total</b>       | <b>€ 903.0</b>          | <b>€ 152.0</b> |

“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, “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, 2017 and 2016.

#### **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-46 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/<br>Form | Incorporated by Reference |         | File Date<br>(mm/dd/yyyy) |
|---------|---|-------------------|---------------------------|---------|---------------------------|
|         |   |                   | File Number               | Exhibit |                           |
| 1.1     | <a href="#">Articles of Association (English translation), as amended</a>   | Form F-1/A        | 333-217417                | 3.1     | 05/04/2017                |
| 1.2     | <a href="#">Rules for the Board of Directors</a>  | Form F-1          | 333-217417                | 3.2     | 04/21/2017                |
| 2.1     | <a href="#">Form of Deposit Agreement</a>   | Form F-1/A        | 333-217417                | 4.1     | 05/16/2017                |
| 2.2     | <a href="#">Form of American Depositary Receipt (included in Exhibit 2.1)</a>   |                   |                           |         |                           |
| 4.1     | <a href="#">Leases dated April 1, 2016 between argenx BVBA and Bio-Incubator Gent 2 NV</a>  | Form F-1          | 333-217417                | 10.1    | 04/21/2017                |
| 4.2**   | <a href="#">Patent License Agreement, dated February 15, 2012, between the registrant and The Board of Regents of the University of Texas System, as amended</a>  | Form F-1          | 333-217417                | 10.2    | 04/21/2017                |
| 4.3†    | <a href="#">Form of Indemnification Agreement between the registrant and each of its executive officers and directors</a>   | Form F-1          | 333-217417                | 10.3    | 04/21/2017                |
| 4.4     | <a href="#">argenx option plan and form of option agreement and notice of option grant thereunder</a>   | Form F-1          | 333-221984                | 10.4    | 12/11/2017                |
| 8.1     | <a href="#">List of subsidiaries of the registrant</a>  | Form F-1          | 333-221984                | 21.1    | 12/11/2017                |
| 12.1#   | <a href="#">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</a> |                   |                           |         |                           |
| 12.2#   | <a href="#">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</a> |                   |                           |         |                           |

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](#)

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, 2018

### 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, 2017, 2016 and 2015**

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| <a href="#">Consolidated Statements of Financial Position</a>                             | F-3 |
| <a href="#">Consolidated Statements of Profit and Loss and Other Comprehensive Income</a> | F-4 |
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## **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 ("the Company") as of December 31, 2017 and 2016, the related consolidated statements of profit and loss and other comprehensive income, changes in equity and cash flows for each of the three years in the period ended December 31, 2017 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, 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, 2017, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

### **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 Public Company Accounting Oversight Board (United States) (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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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.

March 26, 2018

Rotterdam, Netherlands

We have served as the Company's auditor since 2015.

ARGENX SE

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

| (in thousands of €)                            |      | As of<br>December 31, |                  |                 |
|--|------|-----------------------|------------------|-----------------|
|  | Note | 2017                  | 2016             | 2015            |
| <b>ASSETS</b>                                  |      |                       |                  |                 |
| <b>Current assets</b>                          |      |                       |                  |                 |
| Cash and cash equivalents                      | 4.10 | € 190,867             | € 89,897         | € 35,514        |
| Restricted cash                                | 4.6  | 1,692                 | 786              | —               |
| Research and development incentive receivables | 4.5  | 158                   | 163              | —               |
| Financial assets                               | 4.9  | 168,907               | 6,831            | 6,813           |
| Prepaid expenses                               | 4.8  | 2,338                 | 2,146            | 454             |
| Trade and other receivables                    | 4.7  | 2,842                 | 1,970            | 1,356           |
| <b>Total current assets</b>                    |      | <b>366,804</b>        | <b>101,793</b>   | <b>44,137</b>   |
| <b>Non-current assets</b>                      |      |                       |                  |                 |
| Restricted cash                                | 4.6  | 256                   | 1,149            | —               |
| Research and development incentive receivables | 4.5  | 3,033                 | 2,046            | 1,568           |
| Other non-current assets                       | 4.4  | 125                   | —                | —               |
| Financial assets                               | 4.3  | 1                     | 1                | 1               |
| Property, plant and equipment                  | 4.2  | 676                   | 766              | 249             |
| Intangible assets                              | 4.1  | 13                    | 17               | 7               |
| <b>Total non-current assets</b>                |      | <b>4,104</b>          | <b>3,979</b>     | <b>1,825</b>    |
| <b>TOTAL ASSETS</b>                            |      | <b>€ 370,908</b>      | <b>€ 105,772</b> | <b>€ 45,962</b> |

| (in thousands of €)                         | Note | As of<br>December 31, |                  |                 |
|---|------|-----------------------|------------------|-----------------|
|   |      | 2017                  | 2016             | 2015            |
| <b>EQUITY AND LIABILITIES</b>               |      |                       |                  |                 |
| <b>Equity</b>                               | 4.11 |                       |                  |                 |
| Equity attributable to owners of the parent |      |                       |                  |                 |
| Share capital                               |      | € 3,217               | € 2,012          | € 1,580         |
| Share premium                               |      | 430,518               | 126,358          | 82,169          |
| Accumulated losses                          |      | (100,568)             | (72,492)         | (51,118)        |
| Other reserves                              |      | 11,764                | 7,496            | 4,647           |
| <b>Total equity</b>                         |      | <b>€ 344,931</b>      | <b>€ 63,374</b>  | <b>€ 37,278</b> |
| <b>Non-current liabilities</b>              |      | 25                    | 1                | —               |
| Provisions for employee benefits            | 4.13 | 25                    | 1                | —               |
| <b>Current liabilities</b>                  |      | 25,952                | 42,397           | 8,684           |
| Trade and other payables                    | 4.14 | 15,285                | 12,191           | 4,543           |
| Current tax liabilities                     | 4.15 | 597                   | —                | —               |
| Deferred revenue                            | 4.16 | 10,070                | 30,206           | 4,141           |
| <b>Total liabilities</b>                    |      | <b>€ 25,977</b>       | <b>€ 42,398</b>  | <b>€ 8,684</b>  |
| <b>TOTAL EQUITY AND LIABILITIES</b>         |      | <b>€ 370,908</b>      | <b>€ 105,772</b> | <b>€ 45,962</b> |

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<br>December 31, |                   |                   |
|---|------|----------------------------|-------------------|-------------------|
|   |      | 2017                       | 2016              | 2015              |
| Revenue   | 5.1  | € 36,415                   | € 14,713          | € 6,854           |
| Other operating income                                | 5.2  | 4,841                      | 2,439             | 3,101             |
| <b>Total operating income</b>                         |      | <b>41,256</b>              | <b>17,152</b>     | <b>9,955</b>      |
| Research and development expenses                     | 5.4  | (51,740)                   | (31,557)          | (20,635)          |
| Selling, general and administrative expenses          | 5.5  | (12,448)                   | (7,011)           | (4,925)           |
| <b>Operating loss</b>                                 |      | <b>€ (22,932)</b>          | <b>€ (21,416)</b> | <b>€ (15,605)</b> |
| Financial income                                      | 5.8  | 1,250                      | 73                | 112               |
| Financial expenses                                    | 5.8  | —                          | —                 | —                 |
| Exchange gains/(losses)                               | 5.8  | (5,797)                    | (31)              | 181               |
| <b>Loss before taxes</b>                              |      | <b>€ (27,479)</b>          | <b>€ (21,374)</b> | <b>€ (15,312)</b> |
| Income tax expense                                    | 5.9  | € (597)                    | € —               | € —               |
| <b>Loss for the year and total comprehensive loss</b> |      | <b>€ (28,076)</b>          | <b>€ (21,374)</b> | <b>€ (15,312)</b> |
| Weighted average number of shares outstanding         |      | 24,609,536                 | 18,820,612        | 15,734,007        |
| Basic and diluted loss per share (in €)               | 5.10 | (1.14)                     | (1.14)            | (0.97)            |

The notes are an integral part of these consolidated financial statements.

**ARGENX SE**

**CONSOLIDATED STATEMENT OF CASH FLOWS**

| (in thousands of €)   | Note | Year Ended<br>December 31, |                 |                 |
|---|------|----------------------------|-----------------|-----------------|
|   |      | 2017                       | 2016            | 2015            |
| <b>CASH FLOWS (USED IN) / FROM OPERATING ACTIVITIES</b>         |      |                            |                 |                 |
| <b>Operating result</b>   |      | € (22,932)                 | € (21,416)      | € (15,605)      |
| Adjustments for non-cash items                                  |      |                            |                 |                 |
| Amortization of intangible assets                               |      | 10                         | 11              | 5               |
| Depreciation of property, plant and equipment                   |      | 425                        | 323             | 191             |
| Loss on disposal of fixed assets                                |      | 11                         | —               | —               |
| Provisions for employee benefits                                |      | 24                         | 1               | —               |
| Expense recognized in respect of share-based payments           |      | 4,268                      | 2,849           | 2,270           |
|   |      | <b>(18,195)</b>            | <b>(18,232)</b> | <b>(13,139)</b> |
| Movements in current assets/liabilities                         |      |                            |                 |                 |
| (Increase)/decrease in trade and other receivables              | 4.7  | (122)                      | (614)           | (651)           |
| (Increase)/decrease in other current assets                     |      | (1,093)                    | (2,641)         | (362)           |
| Increase/(decrease) in trade and other payables                 | 4.14 | 3,094                      | 7,648           | (434)           |
| Increase/(decrease) in deferred revenue                         | 4.16 | (20,136)                   | 26,065          | 689             |
| (Increase)/decrease in other non-current assets                 |      | (94)                       | (1,627)         | —               |
| <b>NET CASH FLOWS (USED IN) / FROM OPERATING ACTIVITIES</b>     |      | € (36,546)                 | 10,599          | (13,897)        |
| <b>CASH FLOWS (USED IN) / FROM INVESTING ACTIVITIES</b>         |      |                            |                 |                 |
| Purchase of intangible assets                                   | 4.1  | (6)                        | (21)            | (5)             |
| Purchase of property, plant and equipment                       | 4.2  | (345)                      | (840)           | (274)           |
| (Increase)/decrease in current financial assets                 | 4.9  | (162,076)                  | (18)            | 16,979          |
| Interest received   |      | 375                        | 73              | 112             |
| <b>NET CASH FLOWS (USED IN) / FROM INVESTING ACTIVITIES</b>     |      | € (162,052)                | € (806)         | € 16,812        |
| <b>CASH FLOWS (USED IN) / FROM FINANCING ACTIVITIES</b>         |      |                            |                 |                 |
| Proceeds from issue of shares (1)                               | 4.11 | 305,365                    | 44,621          | 238             |
| <b>NET CASH FLOWS (USED IN) / FROM FINANCING ACTIVITIES</b>     |      | € 305,365                  | € 44,621        | € 238           |
| <b>NET INCREASE (DECREASE) IN CASH &amp; CASH EQUIVALENTS</b>   |      | € 106,767                  | € 54,414        | € 3,153         |
| <b>Cash and cash equivalents at the beginning of the period</b> |      | € 89,897                   | € 35,514        | € 32,180        |
| Exchange gains/(losses) on cash & cash equivalents              | 5.8  | € (5,797)                  | € (31)          | € 181           |
| <b>Cash and cash equivalents at the end of the period</b>       |      | <b>190,867</b>             | <b>89,897</b>   | <b>35,514</b>   |

(1) The gross cash flow from the issue of shares amounts to €308.7 million. The Company paid €3.4 million with respect to issuance costs.

The notes are an integral part of these consolidated financial statements.

ARGENX SE

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

| (in thousands of €)                         | Attributable to owners of the parent |                  |                    |   |   | Total equity     |
|---|--------------------------------------|------------------|--------------------|---|---|------------------|
|   | Share capital                        | Share premium    | Accumulated losses | Other reserves<br>Equity-settled<br>share-based<br>payment<br>reserve | Total equity<br>attributable<br>to owners<br>of the<br>parent |                  |
| <b>Balance at January 1, 2015</b>           | <b>€ 1,571</b>                       | <b>€ 81,940</b>  | <b>€ (35,806)</b>  | <b>€ 2,377</b>  | <b>€ 50,082</b>   | <b>€ 50,082</b>  |
| Total comprehensive loss of the period      | €                                    | €                | € (15,312)         | €   | € (15,312)  | € (15,312)       |
| Issue of share capital                      | 9                                    | 229              |                    |   | 238   | 238              |
| Transaction costs for equity issue          |                                      |                  |                    |   | —   | —                |
| Share-based payment                         |                                      |                  |                    | 2,270   | 2,270   | 2,270            |
| <b>Balance year ended December 31, 2015</b> | <b>€ 1,580</b>                       | <b>€ 82,169</b>  | <b>€ (51,118)</b>  | <b>€ 4,647</b>  | <b>€ 37,278</b>   | <b>€ 37,278</b>  |
| Total comprehensive loss of the period      | €                                    | €                | € (21,374)         | €   | € (21,374)  | € (21,374)       |
| Issue of share capital                      | 432                                  | 46,038           |                    |   | 46,470  | 46,470           |
| Transaction costs for equity issue          |                                      | (1,849)          |                    |   | (1,849)   | (1,849)          |
| Share-based payment                         |                                      |                  |                    | 2,849   | 2,849   | 2,849            |
| <b>Balance year ended December 31, 2016</b> | <b>€ 2,012</b>                       | <b>€ 126,358</b> | <b>€ (72,492)</b>  | <b>€ 7,496</b>  | <b>€ 63,374</b>   | <b>€ 63,374</b>  |
| Total comprehensive loss of the period      | €                                    | €                | € (28,076)         | €   | € (28,076)  | € (28,076)       |
| Issue of share capital                      | 1,205                                | 327,175          |                    |   | 328,380   | 328,380          |
| Transaction costs for equity issue          |                                      | (23,015)         |                    |   | (23,015)  | (23,015)         |
| Share-based payment                         |                                      |                  |                    | 4,268   | 4,268   | 4,268            |
| <b>Balance year ended December 31, 2017</b> | <b>€ 3,217</b>                       | <b>€ 430,518</b> | <b>€ (100,568)</b> | <b>€ 11,764</b>   | <b>€ 344,931</b>  | <b>€ 344,931</b> |

Please refer to note 4.11 for more information on the share capital and movement in number of shares. See also note 4.12 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 (the Company) 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 Group) 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 principal Group 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 Group’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, 2017 and for the comparative information as of and for the years ended December 31, 2016 and 2015.

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 Group’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 principal accounting policies applied in the preparation of the above 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 February 27, 2018.

**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 financial statements are presented in euro (€), which is the Group'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**

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. Where a reasonable and consistent basis of allocation can be identified, corporate assets are also allocated to individual cash-generating units, or otherwise they are allocated to the smallest group of cash-generating units for which a reasonable and consistent allocation basis can be identified.

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 assets**

Financial assets are 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 depends on the nature and purpose of the financial assets and is determined at the time of initial recognition. Management determines the classification at the time of the purchase and re-evaluates such designation at each subsequent balance sheet date.

Purchase and sale of financial assets are recognized on the settlement date, which is the date an asset is delivered to or by the Group. The cost of financial assets includes transaction costs.

The carrying amounts of all financial assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount is impaired. If objective evidence exists that a financial asset or group of financial assets is impaired, the amount of the impairment loss is 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 is immediately recognized in net finance costs.

An impairment loss on financial assets is reversed if, in a subsequent period, the amount of the impairment loss decreased and this decrease can be related objectively to an event occurring after the impairment loss was recognized. Such reversal is immediately recognized in net finance costs.

## **2.9 Trade and other receivables**

Trade and other receivables are initially recognized at fair value and are subsequently carried at amortized cost using the effective interest method. A provision for impairment of trade and other receivables is 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 various research and development incentives from certain governmental agencies. These research and development incentives generally aim to partly reimburse approved expenditures incurred in research and development efforts of the Company and are credited to the consolidated statement of profit and loss and other comprehensive income, in other operating income, when there is reasonable assurance that the research and development incentives are receivable.

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.

Where the Company purchases treasury shares, the consideration paid, including any directly attributable incremental costs (net of income taxes), is deducted from equity attributable to the Company’s equity holders until the shares are cancelled, reissued or disposed of. Where such shares are subsequently sold or reissued, any consideration received, net of any directly attributable incremental transaction costs and the related income tax effects is included in equity attributable to the Company’s equity holders.

The Company has never distributed any dividends to its shareholders. As of 31 December 2017, no profits were available for distribution.

### **2.13 Trade 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 Financial liabilities**

Debt and equity instruments issued by the Company are classified as either financial liabilities or as equity in accordance with the substance of the contractual arrangements and the definitions of a financial liability and an equity instrument.

Financial liabilities are classified as either “financial liabilities at fair value through profit or loss” or “other financial liabilities”.

### **2.15 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.

### **2.16 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 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.

#### **2.17 Short-term employee benefits**

Short-term employee benefits include salaries and social security taxes, paid vacation and bonuses. They are recognized as expenses for the period in which employees perform the corresponding services. Outstanding payments at the end of the period are shown as other current liabilities.

#### **2.18 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 4.12.

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 Group's estimate of equity instruments that will eventually vest, with a corresponding increase in equity. At the end of each reporting period, the Group 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.

#### **2.19 Deferred revenue**

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.

Government grants whose primary condition is that the Company should purchase, construct or otherwise acquire non-current assets are also recognized as deferred revenue in the statement of financial position.

#### **2.20 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 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.

## **2.21 Revenue and other operating income recognition**

The Group generates revenue from collaborations and strategic alliances.

Revenue is recognized when it is probable that future economic benefits will flow to the group and these benefits can be measured reliably. Further, revenue recognition requires that all significant risks and rewards of ownership of the goods included in the transaction have been transferred to the buyer or when the related services are performed and specific criteria have been met for each of the Group's activities as described below.

### ***Collaborations***

Collaborations typically include upfront payments, milestone payments, research and development service fees and may involve multiple elements. The Group evaluates whether the elements under these arrangements have value to its collaboration partner or client on a stand-alone basis. If the Group determines that multiple deliverables exist, the consideration is allocated to one or more units of accounting based upon the best estimate of the selling price of each deliverable. Deliverables that do not meet these criteria are not evaluated separately for the purpose of revenue recognition.

The Group receives upfront, milestone and other similar payments related to the sale of services or out-licensing of products from these collaborations and strategic alliances.

The revenue recognition policies can be summarized as follows:

#### **Upfront payments**

Upfront payments, for which there are subsequent deliverables, are initially reported as deferred revenue and are recognized as revenue when earned over the period of the development collaboration or the manufacturing obligation. Upfront payments also include license fees received upfront.

Deferred revenue reflects the part of revenue that has not been recognized as income immediately upon receipt of payment and which relates to agreements with multiple components which cannot be separated. Deferred revenue is measured at nominal value.

#### **Milestone payments**

Revenue associated with performance milestones is recognized based upon the achievement of the milestone event if the event is substantive, objectively determinable and represents an important point in the development life cycle of the product.

## Research and development services fees

Research and development service fees are recognized as revenue over the life of the research agreement as the required services are provided and costs are incurred. These services are usually in the form of a defined number of full-time equivalents (FTE) at a specified rate per FTE.

Commercial collaborations resulting in a reimbursement of research and development costs are recognized as revenue as the related costs are incurred. The corresponding research and development expenses are included in research and development expenses in the consolidated financial statements.

### ***Grants, research and development incentives and payroll tax rebates***

Because it carries out extensive research and development activities, the Group 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 Group 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.

## **2.22 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.

## **2.23 Fair value measurements**

Historical cost is generally based on the fair value of the consideration given in exchange for assets.

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either in the principal market for the asset or liability or in the absence of a principal market, in the most advantageous market for the asset or liability. The principal or the most advantageous market must be accessible by the Company. The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

All assets and liabilities for which fair value is measured or disclosed in the financial statements are categorized within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

- Level 1— Quoted (unadjusted) market prices in active markets for identical assets or liabilities
- Level 2— Valuation techniques for which the lowest level input that is significant to the fair value measurement is directly or indirectly observable
- Level 3— Valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable

## 2.24 Adoption of new and revised standards

### New accounting policies and disclosures for 2017

The following new standards and amendments to standards are mandatory for the first time for the financial year beginning January 1, 2017:

- Amendments to IAS 12, 'Income taxes' on Recognition of deferred tax assets for unrealized losses. These amendments on the recognition of deferred tax assets for unrealized losses clarify how to account for deferred tax assets related to debt instruments measured at fair value.
- Annual improvements 2014-2016 applicable to three standards of which changes on IFRS 1 and IAS 28 are applicable as of 1 January 2018 and changes on IFRS 12 are applicable as of 1 January 2017. These set of amendments impacts 3 standards: IFRS 1, 'First-time adoption of IFRS', regarding the deletion of short-term exemptions for first-time adopters regarding IFRS 7, IAS 19, and IFRS 10; IFRS 12, 'Disclosure of interests in other entities' regarding clarification of the scope of the standard (these amendments should be applied retrospectively for annual periods beginning on or after 1 January 2017) and IAS 28, 'Investments in associates and joint ventures' regarding measuring an associate or joint venture at fair value.

### New accounting policies and disclosures effective in 2018 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 1 January 2017 and have been endorsed by the European Union.

- IFRS 9 'Financial instruments' and subsequent amendments, effective for annual periods beginning on or after 1 January 2018. The standard addresses the classification, measurement, derecognition of financial assets and financial liabilities and general hedge accounting.

We performed a preliminary assessment evaluating the guidance to determine the potential impact on the consolidated financial statements.

Financial assets and liabilities are recognized on our statement of financial position when we become a party to the contractual provisions of the instrument. Hedging and derivatives have never been used: we do not use currency derivatives to hedge planned future cash flows, nor do we make use of forward foreign exchange contracts.

Our assessment is that the coming new standards on IFRS 9 "Financial instruments" and subsequent amendments (applicable for annual periods beginning on or after January 1, 2018) should not have a material impact on our consolidated financial statements. We plan to adopt IFRS 9 on the effective date.

- IFRS 15 'Revenue from contracts with customers' and subsequent amendments. The standard will improve comparability of the top line in financial statements globally. Companies using IFRS will be required to apply the revenue standard for annual periods beginning on or after 1 January 2018.

In 2017, the Company made an impact analysis in view of the application of IFRS 15 Revenue from Contracts with Customers, applicable for annual periods beginning on or after 1 January 2018. In accordance with IFRS 15 companies need to apply 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

An inventory of the contracts with customers was completed. The substance of our current arrangements is that the Group 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

We have assessed that there is one single combined performance obligation for certain arrangements in our material ongoing license and collaboration arrangements under the new standards of IFRS 15, 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 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. As prescribed under IFRS 15 transaction price needs to be re-assessed at each reporting period.

## 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 combined 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 combined performance obligation.

## 5. Recognize revenue

Revenue from certain arrangements is recognized as the Group satisfies a combined performance obligation.

The Company recognizes upfront payments and milestone payments, allocated to a combined performance obligation over the estimated service period based on a pattern that reflects the transfer of the services. The revenues recognized would reflect the level of service each period. In this case, the Group would use an output 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 (% of completion method).

Research and development service fees are recognized as revenues 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.

## Assessment of the impact of IFRS 15

The Company plans to adopt IFRS 15 on January 1, 2018 using a modified retrospective approach. Based on the company's assessment of all contracts, potential performance obligations, and potential allocation of the revenue, the Group estimates the impact of IFRS 15 on its consolidated financial statements as follows:

- there is no impact on the pattern and timing of revenue recognition for upfront payments and research and development service fees,



- the pattern and timing of revenue recognition of milestone payments is different: milestone payments were previously recognized based on upon the achievement of the milestone event, whereas under IFRS 15, the milestone payment is linked to a combined performance obligation over the estimated service period,
- as a result, the accumulated losses and deferred revenue will increase by €2.7 million at the opening balance sheet date of January 1, 2018.

■ IFRS 16 'Leases' (effective 1 January 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 recognize 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 know that this new coming standard will have an impact on our consolidated financial statements in 2019 and we are currently evaluating the guidance to determine this impact. We plan to adopt IFRS 16 on the effective date.

■ Amendments to IFRS 2: Share-based payments (effective 1 January 2018): The amendment clarifies the measurement basis for cash-settled payments and the accounting for modifications that change an award from cash settled to equity settled. It also introduces an exception to the principles in IFRS 2 that will require an award to be treated as if it was wholly equity-settled, where an employer is obliged to withhold an amount for the employee's tax obligation associated with a share-based payment and pay the amount to the tax authorities.

These amendments will not have any material impact on our consolidated financial statements.

■ IFRIC 22, 'Foreign currency transactions and advance consideration (effective 1 January 2018): 'This IFRIC addresses foreign currency transactions or parts of transactions where there is consideration that is denominated or priced in a foreign currency. The interpretation provides guidance for when a single payment/receipt is made as well as for situations where multiple payments/receipts are made. The guidance aims to reduce diversity in practice.

This standard will not have any material impact on our consolidated financial statements.

■ IFRIC 23, 'Uncertainty over income tax treatments' (effective 1 January 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.

We are currently evaluating the guidance to determine the impact on our consolidated financial statements in 2019. We plan to adopt IFRIC 23 on the effective date.

## **2.25 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 Group manages its activities and operates as one business unit which is reflected in its organizational structure and internal reporting. The Group 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:

#### ***Going concern***

The Group has incurred net losses since its inception and for the year ended December 31, 2017, 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 February 27, 2018, the Board has reviewed and approved the consolidated financial statements and accounting standards. Taking into account the cash and cash equivalents and current financial asset position of €359.8 million on December 31, 2017, the Board is of the opinion that the Group is a going concern basis.

Whilst the current cash position is sufficient for the Group'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.

#### ***Revenue recognition***

For revenue recognition, the significant estimates relate to allocation of value to the separate elements in multiple element arrangements. With respect to the allocation of value to the separate elements, the Company is using the stand-alone selling prices or management's best estimates of selling prices to estimate the fair value of the elements and account for them separately. Revenue is allocated to each deliverable based on the fair value of each individual element and is recognized when the revenue recognition criteria described above are met.

Upfront fees under collaboration or licensing agreements are recognized over the expected duration of the performance obligations, unless there is no continuous involvement required. Management estimates this period at the start of the collaboration and validates the remaining estimated collaboration term at each closing date.

#### ***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 4.12.

#### ***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 Group has reported losses, and consequently, the Group 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, 2017.

#### 4. Notes relating to the consolidated statement of financial position

##### 4.1 Intangible assets

(in thousands of €)

|  |             |
|--|-------------|
| <b>Opening balance as on January 1, 2015</b>   |             |
| Cost   | € 67        |
| Accumulated amortization                       | (60)        |
| <b>Book value at the beginning of the year</b> | <b>7</b>    |
| <b>Movements</b>                               |             |
| Additions                                      | 5           |
| Amortization                                   | (5)         |
| <b>Balance as on December 31, 2015</b>         |             |
| Cost   | 72          |
| Accumulated amortization                       | (65)        |
| <b>Book value at year end</b>                  | <b>7</b>    |
| <b>Movements</b>                               |             |
| Additions                                      | 21          |
| Amortization                                   | (11)        |
| <b>Balance as on December 31, 2016</b>         |             |
| Cost   | 93          |
| Accumulated amortization                       | (76)        |
| <b>Book value at year end</b>                  | <b>17</b>   |
| <b>Movements</b>                               |             |
| Additions                                      | 6           |
| Amortization                                   | (10)        |
| <b>Balance as on December 31, 2017</b>         |             |
| Cost   | 99          |
| Accumulated amortization                       | (86)        |
| <b>Book value at year end</b>                  | <b>€ 13</b> |

The intangible assets correspond to software. 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 | Total   |
|--|--------------|--------------------------|---------|
| <b>Opening balance as on January 1, 2015</b>   |              |                          |         |
| Cost   | € 63         | € 935                    | € 998   |
| Accumulated depreciation                       | (48)         | (784)                    | (832)   |
| <b>Book value at the beginning of the year</b> | 15           | 151                      | 166     |
| <b>Movements</b>                               |              |                          |         |
| Additions                                      | 30           | 244                      | 274     |
| Depreciation                                   | (18)         | (173)                    | (191)   |
| <b>Closing balance as on December 31, 2015</b> |              |                          |         |
| Cost   | 93           | 1,179                    | 1,272   |
| Accumulated depreciation                       | (66)         | (957)                    | (1,023) |
| <b>Book value at year end</b>                  | 27           | 222                      | 249     |
| <b>Movements</b>                               |              |                          |         |
| Additions                                      | 115          | 725                      | 840     |
| Depreciation                                   | (38)         | (285)                    | (323)   |
| <b>Closing balance as on December 31, 2016</b> |              |                          |         |
| Cost   | 208          | 1,904                    | 2,112   |
| Accumulated depreciation                       | (104)        | (1,242)                  | (1,346) |
| <b>Book value at year end</b>                  | 104          | 662                      | 766     |
| <b>Movements</b>                               |              |                          |         |
| Additions                                      | 25           | 321                      | 346     |
| Cost of disposals                              | —            | (69)                     | (69)    |
| Depreciation                                   | (53)         | (372)                    | (425)   |
| Accumulated depreciation on disposals          | —            | 58                       | 58      |
| <b>Closing balance as on December 31, 2017</b> |              |                          |         |
| Cost   | 233          | 2,156                    | 2,389   |
| Accumulated depreciation                       | (157)        | (1,556)                  | (1,713) |
| <b>Book value at year end</b>                  | € 76         | € 600                    | € 676   |

There are no commitments to acquire property, plant and equipment. Furthermore, no items of property, plant and equipment are pledged.

## 4.3 Non-current financial assets

Non-current financial assets consist of a minority participation in Bird Rock Bio, Inc. (formerly RuiYi, Inc.) (Bird Rock Bio). The Company has no significant influence over these investments. This investment is classified as “available for sale”—investment and if no reliable fair value measurements are available, valued at cost. At the end of 2017, this investment was recorded at cost as no reliable fair value information was available.

In December 2017, the Company sold the minority participation in FairJourney Biologics LDA, recorded at cost at the end of 2016 as no reliable fair value information was available at that time, and realized a gain of €0.9 million. This gain is reported in the income statement as financial income.

## 4.4 Other non-current assets

On December 31, 2017, the Group had a total receivable of €0.9 million in relation with the sale of its minority participation in FairJourney Biologics LDA in December 2017. The amount of any services to be rendered by FairJourney Biologics LDA invoiced until December 31, 2019, will be considered as a payment in-kind to be off-set against the receivable generated by the sale of the minority participation. €0.1 million of this receivable has a long term maturity (more than 12 months) and has been recorded as “Other non-current assets”. The balance of €0.8 million has a short term maturity and has been recorded as “Trade and other receivables”, see note 4.7.

#### 4.5 Research and development incentive receivables

| (in thousands of €)  | Year Ended<br>December 31, |                |                |
|--|----------------------------|----------------|----------------|
|  | 2017                       | 2016           | 2015           |
| Research and development incentive receivables—current     | € 158                      | € 163          | € —            |
| Research and development incentive receivables—non-current | 3,033                      | 2,046          | 1,568          |
|  | <b>€ 3,191</b>             | <b>€ 2,209</b> | <b>€ 1,568</b> |

On December 31, 2017, the Group has recorded a tax receivable of €3.2 million compared to €2.2 million on December 31, 2016, in relation with 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 2018 onwards.

#### 4.6 Restricted cash

| (in thousands of €)                | Year Ended<br>December 31, |                |            |
|------------------------------------|----------------------------|----------------|------------|
|                                    | 2017                       | 2016           | 2015       |
| <b>Non-current restricted cash</b> |                            |                |            |
| Rental guarantees                  | € 256                      | € 244          | € —        |
| Escrow account > 1 year            | —                          | 905            | —          |
| <b>Total non-current</b>           | <b>€ 256</b>               | <b>€ 1,149</b> | <b>€ —</b> |
| <b>Current restricted cash</b>     |                            |                |            |
| Escrow account < 1 year            | 1,692                      | 786            | —          |
| <b>Total restricted cash</b>       | <b>€ 1,948</b>             | <b>€ 1,935</b> | <b>€ —</b> |

On December 31, 2017, the Group 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 €0.25 million with a long term maturity (more than 12 months) and 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 €1.69 million with a short maturity and 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 Group or to the third party under certain conditions after the completion of the work plan of the related collaboration agreement with AbbVie.

#### 4.7 Trade and other receivables

The trade and other receivables are composed of receivables which are detailed below:

| (in thousands of €)    | Year Ended<br>December 31, |                |                |
|------------------------|----------------------------|----------------|----------------|
|                        | 2017                       | 2016           | 2015           |
| VAT receivable         | € 317                      | € 278          | € 175          |
| Trade receivables      | 845                        | 1,118          | 719            |
| Other receivables      | 750                        | —              | —              |
| Interest receivable    | —                          | 6              | 17             |
| VLAIO grant receivable | 930                        | 568            | 445            |
|                        | <b>€ 2,842</b>             | <b>€ 1,970</b> | <b>€ 1,356</b> |

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 2018.

Trade receivables correspond to amounts invoiced to the collaborators or strategic allies of the Group. No bad debt allowance was recorded nor were any trade receivables impaired on December 31, 2017 and December 31, 2016. The amount of €0.8 million in “Other receivables” relates to the short-term part of the receivable with FairJourney Biologics LDA described in note 4.4. 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.

#### 4.8 Prepaid expenses

The prepaid expenses on December 31, 2017 amounted to €2.3 million compared to €2.1 million on December 31, 2016. On December 31, 2017, the prepaid expenses related to (i) a €1.0 million upfront reservation fee paid in 2017 to a third-party drug product manufacturer, (ii) a €0.5 million license fee paid to a third party involved in the license agreement signed with AbbVie in April 2016, this amount being recognized as expense in the statement of profit and loss over the period of the agreement, and (iii) a €0.9 million to insurance prepayments and prepayments for other invoices for which the services will be rendered in future periods.

#### 4.9 Current financial assets

On December 31, 2017, the current financial assets amounted to €168.9 million compared to €6.8 million on December 31, 2016. 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.
- A USD term account with a maturity of 6 months.

Please also refer to note 6.1 for more information on the financial instruments.

#### 4.10 Cash and cash equivalents

| (in thousands of €)    | Year Ended<br>December 31, |          |          |
|------------------------|----------------------------|----------|----------|
|                        | 2017                       | 2016     | 2015     |
| Cash equivalents       | € 25,000                   | € 54,500 | € 11,006 |
| Cash and bank balances | 165,867                    | 35,397   | 24,508   |
|                        | € 190,867                  | € 89,897 | € 35,514 |

On December 31, 2017, cash and cash equivalents amounted to €190.9 million compared to €89.9 million on December 31, 2016 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, or in highly rated money market funds. Policies are in place that limit the amount of credit exposure to any one financial institution (see also note 6.4).

#### 4.11 Shareholders' capital

Roll forward of number of shares outstanding:

|  |                   |
|--|-------------------|
| <b>Number of shares outstanding on January 1, 2015</b>               | <b>15,705,112</b> |
| Exercise of Options on September 1, 2015                             | 97,655            |
| <b>Number of shares outstanding on December 31, 2015</b>             | <b>15,802,767</b> |
| Private placement (Federated Investment) on January 20, 2016         | 1,480,420         |
| Exercise of Options on February 15, 2016                             | 2,200             |
| Exercise of Options on March 16, 2016                                | 10,000            |
| Exercise of Options on April 21, 2016                                | 10,000            |
| Exercise of Options on May 27, 2016                                  | 33,092            |
| Private placement (Sunflower) on June 1, 2016                        | 2,703,000         |
| Exercise of Options on September 26, 2016                            | 70,000            |
| Exercise of Options on October 17, 2016                              | 15,000            |
| <b>Number of shares outstanding on December 31, 2016</b>             | <b>20,126,479</b> |
| 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 on August 24, 2017                               | 5,000             |
| Exercise of Options on September 1, 2017                             | 15,000            |
| Exercise of Options on October 2, 2017                               | 1,400             |
| Exercise of Options on November 7, 2017                              | 950               |
| Exercise of Options on November 14, 2017                             | 4,260             |
| Exercise of Options on November 15, 2017                             | 40,750            |
| Exercise of Options on November 21, 2017                             | 53,092            |
| Exercise of Options on November 22, 2017                             | 7,730             |
| Exercise of Options on December 4, 2017                              | 65,380            |
| 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 on December 18, 2017                             | 9,850             |
| <b>Number of shares outstanding on December 31, 2017</b>             | <b>32,180,641</b> |

##### *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.

#### **4.12 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 Group has granted on June 20, 2017 a total of 120,536 stock options and on December 14, 2017 a total of 653,825 stock options to its employees, Board members and consultants. The total number of stock options outstanding on December 31, 2017 totaled 2,862,216 compared to 2,293,636 on December 31, 2016 and 1,752,926 on December 31, 2015. No stock options were expired in the years ended December 31, 2017, 2016 and 2015. 203,412 stock options have been exercised in the year ended December 31, 2017 compared to 140,292 in the year ended December 31, 2016 and 97,656 in the year ended December 31, 2015. A total of 2,369 stock options have been forfeited in the year ended December 31, 2017 compared to 31,174 in the year ended December 31, 2016 and 47,333 in the year ended December 31, 2015.

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<br>per stock<br>options<br>(in €) | Outstanding<br>stock options on<br>December 31, |                  |                  |
|-------------|--|---|------------------|------------------|
|             |  | 2017  | 2016             | 2015             |
| 2019        | € 3.95   | —   | —                | 103,370          |
| 2020        | 3.95   | 36,960  | 112,738          | 62,460           |
| 2021        | 3.95   | 2,850   | 3,800            | 3,800            |
| 2022        | 2.44   | —   | —                | 686,732          |
| 2023        | 3.95   | —   | —                | 55,747           |
| 2024        | 2.44   | 314,593   | 360,787          | —                |
| 2024        | 2.44   | 135,890   | 169,926          | —                |
| 2024        | 3.95   | 15,692  | 55,746           | —                |
| 2024        | 7.17   | 516,100   | 522,500          | 537,917          |
| 2024        | 2.44   | 83,820  | 83,820           | —                |
| 2025        | 11.44  | 39,000  | 39,000           | 56,500           |
| 2025        | 10.34  | 3,000   | 3,000            | 3,000            |
| 2025        | 9.47   | 235,514   | 235,733          | 243,400          |
| 2026        | 11.38  | 60,000  | 60,000           | —                |
| 2026        | 11.47  | 282,310   | 283,360          | —                |
| 2026        | 14.13  | 362,126   | 363,226          | —                |
| 2027        | 18.41  | 120,536   | —                | —                |
| 2027        | € 21.17  | 653,825   | —                | —                |
|             |  | <b>2,862,216</b>                                | <b>2,293,636</b> | <b>1,752,926</b> |

|                                    | 2017                       |                                    | 2016                       |                                    | 2015                       |                                    |
|------------------------------------|----------------------------|------------------------------------|----------------------------|------------------------------------|----------------------------|------------------------------------|
|                                    | Number of<br>stock options | Weighted average<br>exercise price | Number of<br>stock options | Weighted average<br>exercise price | Number of<br>stock options | Weighted average<br>exercise price |
| <b>Outstanding at January 1</b>    | <b>2,293,636</b>           | € 7.72                             | <b>1,752,926</b>           | € 5.37                             | <b>1,595,015</b>           | € 4.39                             |
| Granted                            | 774,361                    | 20.74                              | 712,176                    | 12.82                              | 302,900                    | 9.84                               |
| Exercised                          | (203,412)                  | 3.46                               | (140,292)                  | 3.52                               | (97,656)                   | 2.44                               |
| Forfeited                          | (2,369)                    | 12.52                              | (31,174)                   | 10.90                              | (47,333)                   | 7.17                               |
| <b>Outstanding at December 31,</b> | <b>2,862,216</b>           | 11.54                              | <b>2,293,636</b>           | 7.72                               | <b>1,752,926</b>           | 5.37                               |
| <b>Exercisable at December 31,</b> | <b>1,598,829</b>           | € 6.80                             | <b>1,257,091</b>           | € 4.68                             | <b>1,366,703</b>           | € 4.41                             |

The weighted average remaining contractual life of the stock options outstanding amounted to 8.03 years on December 31, 2017 (December 31, 2016: 8.09 years). The table below shows the weighted average remaining contractual life for each range of exercise price:

| Exercise price (in €) | Outstanding on<br>December 31, 2017 | Weighted average<br>remaining<br>contractual life<br>(in years) |
|-----------------------|-------------------------------------|---|
| 2.44–3.95             | 589,805                             | 5.81  |
| 7.17–9.47             | 751,614                             | 7.28  |
| 10.33–14.13           | 746,436                             | 8.62  |
| 18.41–21.17           | 774,361                             | 9.88  |

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 Group since its initial public offering.

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 is an overview of the parameters 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                      | — %      | — %       | — %      |

Below in an overview of the parameter used in relation to the grants during 2015:

| Stock options granted in                | June 2015 | Sept 2015 | Dec 2015 |
|---|-----------|-----------|----------|
| Number of options granted               | 56,500    | 3,000     | 243,400  |
| Average fair value of options (in EUR)  | € 7.79    | € 6.79    | € 6.25   |
| Share price (in EUR)                    | € 11.58   | € 10.24   | € 9.85   |
| Exercise price (in EUR)                 | € 11.44   | € 10.34   | € 9.47   |
| Expected volatility                     | 59 %      | 59 %      | 58 %     |
| Average expected option life (in years) | 10        | 10        | 10       |
| Risk-free interest rate                 | 1.21 %    | 1.08 %    | 0.98 %   |
| Expected dividends                      | — %       | — %       | — %      |

The total share-based payment expense recognized in the consolidated statement of comprehensive income totaled €4.3 million for the year ended December 31, 2017 compared to €2.8 million for the year ended December 31, 2016 and €2.3 million for the year ended December 31, 2015.

#### 4.13 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, 2015, a net liability of €10 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, 2016 and 2017, a net defined benefit obligation of respectively €1 thousand and €25 thousand was recorded.

The amounts recognized in the balance sheet are as follows:

| (in thousands of €)                                | 2017        | 2016       | 2015       |
|--|-------------|------------|------------|
| Defined benefit obligation                         | € 1,007     | € 670      | € 486      |
| Fair value of plan assets                          | 982         | 669        | 486        |
| <b>Deficit / surplus (-) of funded obligations</b> | <b>25</b>   | <b>1</b>   | <b>—</b>   |
| <b>Net liability (asset)</b>                       | <b>€ 25</b> | <b>€ 1</b> | <b>€ —</b> |

The movement in the defined benefit obligation, plan assets, net liability and asset over the year is as follows:

| (in thousands of €)                              | 2017           | 2016         |
|--|----------------|--------------|
| <b>Defined benefit obligation at 1 January</b>   | <b>€ 670</b>   | <b>€ 486</b> |
| Service cost                                     | 352            | 113          |
| Interest expense / income (-)                    | 11             | 6            |
| Contributions by plan participants               | (148)          | (64)         |
| Actuarial gains (-) / losses (+)                 | 124            | 131          |
| Benefits paid / transfers out                    | (2)            | (2)          |
| <b>Defined benefit obligation at 31 December</b> | <b>€ 1,007</b> | <b>€ 670</b> |

| (in thousands of €)                             | 2017         | 2016         |
|---|--------------|--------------|
| <b>Fair value of plan assets at 1 January</b>   | <b>€ 669</b> | <b>€ 486</b> |
| Interest expense / income (-)                   | 10           | 7            |
| Administrative costs & taxes                    | (46)         | (19)         |
| Contributions by company & participants         | 423          | 176          |
| Contributions by plan participants              | (148)        | (64)         |
| Actuarial gains (+) / losses (-)                | 76           | 85           |
| Benefits paid / transfers out                   | (2)          | (2)          |
| <b>Fair value of plan assets at 31 December</b> | <b>€ 982</b> | <b>€ 669</b> |

In the income statement, current service cost and interest expense or income are included in the operating loss.

The Group's estimated employer contributions for 2017 amount to €0.3 million compared to €0.1 million in 2016. Plan assets on December 31, 2016 and 2017 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 | 2017  | 2016  |
|----------------------|-------|-------|
| Discount rate        | 1.3 % | 1.3 % |

The duration of the benefit obligations equals 21 years. Sensitivity analyses show the following effects:

| Sensitivity analysis<br>(in thousands of €) | Change in<br>assumption | Impact on defined-<br>benefit obligation | %       |
|---|-------------------------|--|---------|
| Discount rate                               | -0.25 %                 | Increase by 35.9                         | 3.56 %  |
| Discount rate                               | 0.25 %                  | Decrease by 31.0                         | (3.08)% |

The above analyses were done on a mutually exclusive basis, and holding all other assumptions constant. Through its defined benefit plan, the Group is exposed to a number of risks, the most significant of which are detailed below:

|                               |   |
|-------------------------------|---|
| <b>Asset volatility</b>       | 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.  |
| <b>Changes in bond yields</b> | 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.   |
| <b>Salary risk</b>            | 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. |
| <b>Longevity risk</b>         | 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 46 years on December 31, 2017 compared to 48 years on December 31, 2016.

#### 4.14 Trade and other payables

| (in thousands of €)                  | Year Ended<br>December 31, |                 |                |
|--------------------------------------|----------------------------|-----------------|----------------|
|                                      | 2017                       | 2016            | 2015           |
| Trade payables                       | € 4,395                    | € 4,385         | € 1,886        |
| Accruals for invoices to be received | 4,046                      | 5,444           | 1,239          |
| Short-term employee benefits         | 6,844                      | 2,362           | 1,418          |
|                                      | <b>€ 15,285</b>            | <b>€ 12,191</b> | <b>€ 4,543</b> |

Trade payables correspond primarily to clinical and manufacturing activities. The fair value of trade payables approximates their carrying amount, no trade payables were overdue.

The accruals for invoices to be received amount to €4.0 million for the year ended December 31, 2017 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 organization for expenses incurred in relation with ongoing clinical trials were not yet charged to the Group on December 31, 2017.

Short-term employee benefits include payables and accruals for salaries and bonuses to be paid to the employees of the Group.

#### 4.15 Current tax liability

As part of its business restructuring, the Group 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. The tax consequences of this transaction for argenx SE have been agreed with the Dutch tax authorities on March 23, 2017, and relate to:

- (i) The at arm's length compensation for the Company being fixed at €79.9 million; and
- (ii) the right to offset the full amount of the Company's tax loss carry forward of €77.5 million against this compensation.

Hence, the business restructuring has resulted in a taxable amount for argenx SE of €2.4 million subject to a Dutch corporate income tax rate of 25%, or a tax amount of €0.6 million.

For the same business restructuring, there is also 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 Group 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. Accordingly, no deferred tax asset has been recognized in respect of these tax operating losses.

#### 4.16 Deferred revenue

Deferred revenue relates to cash received from collaboration and strategic alliances prior to completion of the earnings process. On December 31, 2017, deferred revenue amounted to €10.1 million compared to €30.2 million at the same date in 2016, and included €9.8 million related to the upfront payment received from AbbVie in April 2016, and €0.3 million related to the upfront payment received from LEO Pharma in May 2015. These payments are recognized as revenue over the estimated duration of the Group'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<br>December 31, |                 |                |
|---|----------------------------|-----------------|----------------|
|   | 2017                       | 2016            | 2015           |
| Upfront payments                            | € 20,137                   | € 9,103         | € 2,194        |
| Milestone payments                          | 9,677                      | 500             | 343            |
| Research and development service fees (FTE) | 6,601                      | 5,110           | 4,317          |
|   | <b>€ 36,415</b>            | <b>€ 14,713</b> | <b>€ 6,854</b> |

For the years ended December 31, 2017 and 2016, the majority of the revenue was generated under the agreements with Shire, 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, 2017 corresponded principally to the partial recognition in revenue over the period of the upfront payment received following the signatures of a collaboration agreement with AbbVie in April 2016, with LEO Pharma in May 2015, and with Shire in February 2012. These payments are recognized as revenue over the estimated period of the Group's continuing involvement in the research and development activities provided for under the terms of these agreements.

The milestone payment of €9.7 million recognized in the year ended December 31, 2017 related to a payment received under the AbbVie and LEO Pharma collaborations.

The research and development service fees (FTE) for the year ended December 31, 2017 corresponded to FTE payments received under the collaboration agreements of €2.1 million from Shire, €3.9 million from LEO Pharma and €0.6 million from Staten Biotechnology B.V. (Staten).

Below are summaries of the key collaborations.

#### AbbVie

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

The Group has 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 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. The Group received an upfront, non refundable, 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, 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 near-term preclinical milestones of \$10 million. The Group is also eligible, if AbbVie exercises its option, to receive additional 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 Group has the right, on a product-by-product basis to co-promote ARGX-115 based products in the European Economic Area and Switzerland and to combine the product with the Group'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. In addition to the ARGX-115 program, and upon reaching a predetermined preclinical stage milestone, AbbVie will fund further GARP-related research by the Group for an initial period of two years. AbbVie will have the right to license additional therapeutic programs emerging from this research, for which the Group could receive associated milestone and royalty payments.

If AbbVie does not exercise its option to license ARGX-115, the Group has the right to pursue development and commercialization of ARGX-115 by itself or with another partner.

Unless terminated earlier 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 program, upon the earliest of (i) a technical failure of the IND-enabling studies which is outside of the Group's 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 the Group. 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.

### **Shire**

In February 2012 the Group entered into a research collaboration and exclusive product license option agreement with Shire International GmbH (Shire). Pursuant to the agreement the Group is using its SIMPLE Antibody™ Technology to create novel human therapeutic antibodies addressing diverse rare and unmet diseases being pursued by Shire. Shire has the option to license the most promising antibody leads from each collaborative program for further developments and commercialization worldwide, in return for milestone and royalty payments. Under the terms of the license, the Group has already received technology access fees and research funding and is eligible to receive discovery milestone payments. In September 2013, the Group received a first technical success milestone payment from Shire, and in January 2014, the Group received two extra discovery milestone payments from Shire. In January 2013 the scope of the agreement was expanded by the parties with no change to the agreement structure.

On May 30, 2014 the collaboration between Shire and the Group was expanded to include in addition to the use of the Group's entire suite of human antibody discovery technologies for an expanded set of disease targets. Pursuant to the amended agreement (which is in addition to the existing collaboration), the Group shall apply during multiple years these technologies for the generation and development of human mAbs against multiple targets selected by Shire in line with its therapeutic focus.

Shire has the option to license the most promising antibody leads for further developments and commercialization worldwide, in return for fees, clinical, regulatory and sales milestones, as well as single digit royalties on therapeutic product sales. As of the reporting date, this is considered contingent revenue. Shire will be responsible for clinical development and commercialization of products, with the Group having the right to license any programs not pursued by Shire into its own development pipeline. Under the amended agreement, Shire made an upfront cash payment of €3 million. At the same time as expanding the collaboration, Shire made an equity investment during the Group's IPO in July 2014 of €12 million.

The upfront cash payment is recognized based on the principle of percentage of completion of the work plan. Research funding based on an agreed FTE rate, is recognized on a monthly basis in the income statement.

## Leo Pharma

In May 2015 the Group 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 will 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 currently in preclinical development for inflammation related skin diseases. The Group receives pre-IND payments of €4.5 million, including an upfront payment. The companies will co-fund product development costs up to clinical trial application (CTA) filing.

The Group 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.

The access fee related to the existing argenx antibody that has been received is recognized based on the principle of percentage of completion of the work plan. Development and management funding based on an agreed FTE rate, is recognized on a monthly basis in the income statement.

## 5.2 Other operating income

| (in thousands of €)                 | Year Ended<br>December 31, |                |                |
|-------------------------------------|----------------------------|----------------|----------------|
|                                     | 2017                       | 2016           | 2015           |
| Grants                              | € 422                      | € 779          | € 1,598        |
| Research and development incentives | 983                        | 641            | 608            |
| Payroll tax rebates                 | 3,436                      | 1,019          | 895            |
|                                     | <b>€ 4,841</b>             | <b>€ 2,439</b> | <b>€ 3,101</b> |

### Grants

The Flanders Innovation and Entrepreneurship Agency provided the Group with several grants.

On December 31, 2017 the situation of the grants received by the Group reflected the expenses incurred by the Group in the various research and development projects sponsored by Flanders Innovation and Entrepreneurship Agency and was as follows:

#### (Amounts presented in thousands of €)

##### Flanders Innovation & Entrepreneurship—TGO

Grantor: Flanders Innovation & Entrepreneurship Agency

Start date: 01/01/2013

End date: 06/30/2017

Amount granted and approved: € 2,697

Amount recognized: 2,697

##### Flanders Innovation & Entrepreneurship—Baekelandt

Grantor: Flanders Innovation & Entrepreneurship Agency

Start date: 01/01/2014

End date: 12/31/2017

Amount granted and approved: € 277

Amount recognized: 270

#### Flanders Innovation & Entrepreneurship 4

Grantor: Flanders Innovation & Entrepreneurship Agency

Start date: 01/01/2015

End date: 12/31/2017

Amount granted and approved: € 1,568

Amount recognized: 1,568

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 financial statements, except for those described in note 7.2 of this report.

#### Other Incentives

##### Research and development incentives

The Group has accounted for a tax receivable of €1.0 million in the year ended December 31, 2017, compared to €0.6 million in the year ended December 31, 2016, 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 4.5).

##### Payroll tax rebates

The Group accounted for €3.4 million payroll tax rebates in the year ended December 31, 2017, compared to €1.0 million in the year ended December 31, 2016, as a reduction in withholding income taxes for its highly-qualified personnel employed in its research and development department.

### 5.3 Segment reporting

The Group 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. The table below also discloses where the non-current assets from the group are situated.

| (in thousands of €) | Revenue from external customers |                 |                |
|---------------------|---------------------------------|-----------------|----------------|
|                     | Year ended December 31,         |                 |                |
|                     | 2017                            | 2016            | 2015           |
| Netherlands         | € 628                           | € 548           | € 275          |
| Belgium             | —                               | —               | —              |
| Germany             | —                               | 311             | 2,190          |
| Denmark             | 6,240                           | 3,066           | 827            |
| Switzerland         | 2,486                           | 3,315           | 3,127          |
| United States       | 1                               | 47              | 435            |
| Luxembourg          | 27,060                          | 7,426           | —              |
| <b>Total</b>        | <b>€ 36,415</b>                 | <b>€ 14,713</b> | <b>€ 6,854</b> |

Information about major clients:

The Group received €36.4 million of revenue from its external customers in the year ended December 31, 2017 compared to €14.7 million over the same period in 2016, of which €27.1 million came from the Group's largest client, €6.2 million from its second largest client and €2.5 million from its third largest client, compared to respectively €7.4 million, €3.3 million and €3.1 million in the year ended December 31, 2016.



## 5.4 Research and development expenses

| (in thousands of €)                        | Year Ended<br>December 31, |                 |                 |
|--|----------------------------|-----------------|-----------------|
|  | 2017                       | 2016            | 2015            |
| Personnel expense                          | € 16,473                   | € 9,844         | € 6,665         |
| External research and development expenses | 27,893                     | 17,562          | 11,653          |
| Materials and consumables                  | 1,562                      | 1,180           | 1,050           |
| Depreciation and amortization              | 446                        | 335             | 196             |
| Other expenses                             | 5,366                      | 2,636           | 1,071           |
|  | <b>€ 51,740</b>            | <b>€ 31,557</b> | <b>€ 20,635</b> |

## 5.5 Selling, general and administrative expenses

| (in thousands of €) | Year Ended<br>December 31, |                |                |
|---------------------|----------------------------|----------------|----------------|
|                     | 2017                       | 2016           | 2015           |
| Personnel expense   | € 6,745                    | € 3,256        | € 1,607        |
| Consulting fees     | 3,289                      | 2,563          | 2,395          |
| Supervisory board   | 621                        | 446            | 165            |
| Office costs        | 1,793                      | 746            | 758            |
|                     | <b>€ 12,448</b>            | <b>€ 7,011</b> | <b>€ 4,925</b> |

## 5.6 Personnel expenses

The personnel expenses which exclude consultants mentioned above are as follows:

| (in thousands of €)                                  | Year Ended<br>December 31, |                 |                |
|--|----------------------------|-----------------|----------------|
|  | 2017                       | 2016            | 2015           |
| Short-term employee benefits—Salaries                | € 12,149                   | € 8,527         | € 5,192        |
| Short-term employee benefits—Social Security         | 1,504                      | 1,027           | 802            |
| Post-employment benefits                             | 291                        | 175             | 207            |
| Termination benefits                                 | 8                          | 86              | 124            |
| Share-based payment                                  | 3,985                      | 2,849           | 1,945          |
| Employer social security contributions stock options | 5,281                      | 436             | —              |
|  | <b>€ 23,218</b>            | <b>€ 13,100</b> | <b>€ 8,270</b> |

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<br>December 31, |             |             |
|----------------------------|----------------------------|-------------|-------------|
|                            | 2017                       | 2016        | 2015        |
| Research and development   | 56.8                       | 46.9        | 31.4        |
| General and administrative | 14.7                       | 9.9         | 5.8         |
|                            | <b>71.5</b>                | <b>56.8</b> | <b>37.2</b> |

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 €1.2 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) versus €0.9 million for the year ended December 31, 2016 (of which €0.2 million is presented as research and development expenses and €0.7 million is included under selling, general and administrative expenses). The Group's future operating lease commitments are as follows:

| Operating lease commitments (in thousands of €) | Year Ended<br>December 31, |                |                |
|---|----------------------------|----------------|----------------|
|   | 2017                       | 2016           | 2015           |
| Less than 1 year                                | € 1,028                    | € 915          | € 630          |
| 1–3 years                                       | 465                        | 1,159          | 1,130          |
| 3–5 years                                       | 33                         | 24             | 142            |
| More than 5 years                               | —                          | —              | —              |
|   | <b>€ 1,526</b>             | <b>€ 2,098</b> | <b>€ 1,902</b> |

The Group has a lease plan for the company's cars with maturity dates up to four years.

For the laboratory and office space, the Group 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.

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<br>December 31, |             |            |
|---|----------------------------|-------------|------------|
|   | 2017                       | 2016        | 2015       |
| Interest income on bank deposits              | € 165                      | € 61        | € 76       |
| Net gains on investments at FVTPL             | 210                        | 12          | 36         |
| Realized gain on non-current financial assets | 875                        | —           | —          |
| <b>Financial income</b>                       | <b>1 250</b>               | <b>73</b>   | <b>112</b> |
| <b>Exchange gains/(losses)</b>                | <b>(5 797)</b>             | <b>(31)</b> | <b>181</b> |

The exchange losses of €5.8 million for the year ended December 31, 2017 was primarily attributable to unrealized exchange rate losses on our cash and current financial assets position in USD due to the unfavorable 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<br>December 31, |            |            |
|--|----------------------------|------------|------------|
|  | 2017                       | 2016       | 2015       |
| Loss before taxes  | (27,479)                   | (21,374)   | (15,312)   |
| Income tax calculated at 25%   | 6,870                      | 5,344      | 3,828      |
| Effect of expenses that are not deductible in determining taxable results                        | (1,141)                    | (755)      | (568)      |
| Effect of stock issue expenses that are not deductible in determining taxable results            | 5,754                      | 462        | —          |
| Effect of concessions (R&D incentives and grants)  | 453                        | 463        | 759        |
| Effect of tax losses carried forward not recognized (Netherlands)                                | —                          | (5,551)    | (3,601)    |
| Effect of usage of tax losses carried forward not previously recognized (Netherlands)            | 19,378                     | —          | —          |
| Effect of tax losses carried forward not recognized (Belgium)                                    | (27,413)                   | —          | (301)      |
| 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                     | (517)                      | (180)      | (122)      |
| Deferred tax asset other than loss carryforwards not recognized                                  | (4,363)                    | —          | —          |
| Other  | 9                          | 22         | 5          |
| <b>Income tax expense recognized in the consolidated statement of profit and loss</b>            | <b>€ (597)</b>             | <b>€ —</b> | <b>€ —</b> |

The tax rate used for the 2017, 2016 and 2015 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 €28.4 million on December 31, 2017 compared to €21.0 million on December 31, 2016. The reduction of the Belgian corporation tax rate from 33.99% to 29.58% as of 2018 and subsequently to 25% as of 2020 was substantively enacted on December 25, 2017 and will be effective from January 1, 2018. As a result, the relevant unrecognized deferred tax balances have been remeasured. Deferred tax have been measured using the effective rate that will apply in Belgium (25%). The unrecognized deferred tax asset on unused tax credits amounts to €0.01 million on December 31, 2017 compared to €6.6 million on December 31, 2016. The Group has unused tax loss carried forwards for an amount of €113.6 million on December 31, 2017, of which €1.3 million will expire in 2026. This, combined with other temporary differences, resulted in a net deferred tax asset position. Due to the uncertainty surrounding the Group's ability to realize taxable profits in the near future, the Company did not recognize any deferred tax assets.

The Group has transferred the legal ownership of its intellectual property rights from the Dutch argenx SE to its wholly owned Belgian subsidiary, argenx BVBA. The tax consequences of this transaction for argenx SE have been preliminarily agreed with the Dutch tax authorities on March 23, 2017 and relate to:

- (i) the arm's length compensation for the Company being fixed at €79.9 million; and
- (ii) the right to offset the full amount of the Company's tax loss carry forward of €77.5 million against this compensation.

The restructuring is estimated to result in a taxable amount for argenx SE of €2.3 million subject to an exit tax in the Netherlands at a rate of 25%, i.e., an estimated tax payable amount of €0.6 million for the year ended December 31, 2017.

For the same business restructuring, there is also a tax ruling pending in Belgium. If approved as currently proposed, the restructuring is estimated to result in additional tax deductible costs for argenx BVBA for an amount of up to €79.9 million (see note 4.15).

## 5.10 Loss per share

| (in thousands of €)                            | Year Ended December 31, |                 |                 |
|--|-------------------------|-----------------|-----------------|
|  | 2017                    | 2016            | 2015            |
| Loss of the year                               | € (28,076)              | € (21,374)      | € (15,312)      |
| Weighted average number of shares outstanding  | 24,609,536              | 18,820,612      | 15,734,007      |
| <b>Basic and diluted loss per share (in €)</b> | <b>€ (1.14)</b>         | <b>€ (1.14)</b> | <b>€ (0.97)</b> |

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 Group 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

| (in thousands of €)                            | At December 31, 2017 |                 | At December 31, 2016 |                 | At December 31, 2015 |                |
|--|----------------------|-----------------|----------------------|-----------------|----------------------|----------------|
|  | Carrying amount      | Fair value      | Carrying amount      | Fair value      | Carrying amount      | Fair value     |
| Non-current financial assets                   | € 1                  | € 1             | € 1                  | € 1             | € 1                  | € 1            |
| Current financial assets                       | 168,907              | 168,907         | 6,831                | 6,831           | 6,813                | 6,813          |
| <b>Financial assets</b>                        | <b>168,908</b>       | <b>168,908</b>  | <b>6,832</b>         | <b>6,832</b>    | <b>6,814</b>         | <b>6,814</b>   |
| Other non-current assets                       | 125                  | 125             | —                    | —               | —                    | —              |
| Trade and other receivables                    | 2,842                | 2,842           | 1,970                | 1,970           | 1,356                | 1,356          |
| Cash and cash equivalents                      | 190,867              | 190,867         | 89,897               | 89,897          | 35,514               | 35,514         |
| Non-current restricted cash                    | 256                  | 256             | 1,149                | 1,149           | —                    | —              |
| Current restricted cash                        | 1,692                | 1,692           | 787                  | 787             | —                    | —              |
| <b>Loans and receivables</b>                   | <b>195,782</b>       | <b>195,782</b>  | <b>93,803</b>        | <b>93,803</b>   | <b>36,870</b>        | <b>36,870</b>  |
| <b>Total financial assets</b>                  | <b>364,690</b>       | <b>364,690</b>  | <b>100,635</b>       | <b>100,635</b>  | <b>43,684</b>        | <b>43,684</b>  |
| Provision for employee benefits                | 25                   | 25              | 1                    | 1               | —                    | —              |
| Trade and other payables                       | 15,285               | 15,285          | 12,191               | 12,191          | 4,543                | 4,543          |
| <b>Financial liabilities at amortized cost</b> | <b>15,310</b>        | <b>15,310</b>   | <b>12,192</b>        | <b>12,192</b>   | <b>4,543</b>         | <b>4,543</b>   |
| <b>Total financial liabilities</b>             | <b>€ 15,310</b>      | <b>€ 15,310</b> | <b>€ 12,192</b>      | <b>€ 12,192</b> | <b>€ 4,543</b>       | <b>€ 4,543</b> |

Financial assets:

- non-current financial assets: please refer to note 4.3 for more information (level 3).
- 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 Group's 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; and
  - a USD term account with a maturity of six months. This term account is held at a bank which is independently rated with a minimum rating of 'A'.

#### Loans and receivables:

- other non-current assets: please refer to note 4.3 for more information
- trade and other receivables: please refer to note 4.7 for more information and to note 6.3 below for the credit risk
- cash and cash equivalents: please refer to note 4.10 for more information and to note 6.3 below for the credit risk
- restricted cash: please refer to note 4.6 for more information

#### Financial liabilities:

Due to the current nature of the financial liabilities, the nominal value of all financial liabilities presented above approximates their fair value.

#### Fair value hierarchy:

The Group carried the following assets at fair value on December 31, 2017, 2016 and 2015 respectively:

| (in thousands of €)                 | At December 31, 2017 |            |            |
|-------------------------------------|----------------------|------------|------------|
|                                     | Level 1              | Level 2    | Level 3    |
| Non-current financial assets        | €                    | €          | € 1        |
| Current financial assets            | 168,907              |            |            |
| <b>Assets carried at fair value</b> | <b>€ 168,907</b>     | <b>€ —</b> | <b>€ 1</b> |

| (in thousands of €)                 | At December 31, 2016 |            |            |
|-------------------------------------|----------------------|------------|------------|
|                                     | Level 1              | Level 2    | Level 3    |
| Non-current financial assets        | €                    | €          | € 1        |
| Current financial assets            | 6,831                |            |            |
| <b>Assets carried at fair value</b> | <b>€ 6,831</b>       | <b>€ —</b> | <b>€ 1</b> |

| (in thousands of €)                 | At December 31, 2015 |            |            |
|-------------------------------------|----------------------|------------|------------|
|                                     | Level 1              | Level 2    | Level 3    |
| Non-current financial assets        | €                    | €          | € 1        |
| Current financial assets            | 6,813                |            |            |
| <b>Assets carried at fair value</b> | <b>€ 6,813</b>       | <b>€ —</b> | <b>€ 1</b> |

All assets and liabilities for which fair value was measured or disclosed in the financial statements are categorized within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

- Level 1—Quoted (unadjusted) market prices in active markets for identical assets or liabilities
- Level 2—Valuation techniques for which the lowest level input that is significant to the fair value measurement is directly or indirectly observable
- Level 3—Valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable

During the disclosed calendar year no transfers occurred between the applicable categories. Given the insignificant value of the Group's assets categorized as Level 3, the additional Level 3 disclosures have been omitted.

## 6.2 Capital risk

The Group 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 Group 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, 2017 cash and cash equivalents amounted to €190.9 million and total capital amounted to €433.7 million. The current cash situation and the anticipated cash generation are the most important parameters in assessing the capital structure. The Group'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 Group. The Group 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 Group 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 Group holds its cash and cash equivalents mainly with different banks which are independently rated with a minimum rating of 'A-'.

The Group 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 Group 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 Group 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 Group'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 Group'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 financial statements.

## 6.5 Interest rate risk

The Group 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, 2017, if applicable interest rates would increase/decrease by 25 basis points this would have a positive/negative impact of €0.3 million (compared to €0.1 million for the year ended December 31, 2016 and 2015).

## 6.6 Foreign exchange risk

The Group undertakes transactions denominated in foreign currencies; consequently, exposures to exchange rate fluctuations arise.

The Group is mainly exposed to the US Dollar and GBP.

The net exposure to exchange differences of the monetary assets (being cash and cash equivalents) of the Group at the end of the reporting period are as follows:

| (in thousands of €) | At December 31, |      |      |
|---------------------|-----------------|------|------|
|                     | 2017            | 2016 | 2015 |
| USD                 | 147,169         | 624  | 345  |
| GBP                 | 406             | —    | —    |

On December 31, 2017, if the USD/EUR exchange rate would have increased/decreased by 10%, this would have had a negative/positive impact of €13.38 million (compared to €0.06 million on December 31, 2016). On December 31, 2017, if the GBP/EUR exchange rate would have increased/decreased by 10%, this would have had no significant impact.

10% is the sensitivity rate used when reporting foreign currency risk internally to key management personnel and represents management's assessment of the reasonably possible change in foreign exchange rates. The sensitivity analysis includes only outstanding foreign currency denominated monetary items and adjusts their translation at the period end for a 10% change in foreign currency rates.

## 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 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, |                |                |
|---|-------------------------|----------------|----------------|
|   | 2017                    | 2016           | 2015           |
| Short term employee benefits                            | € 3,126                 | € 1,832        | € 1,482        |
| Post employment benefits                                | 115                     | 125            | 59             |
| Termination benefits                                    | —                       | —              | 124            |
| Share-based payment(1)                                  | 12,041                  | 2,261          | 1,761          |
| Employer social security contributions stock options(2) | 3,073                   | 436            | —              |
|   | <b>€ 18,355</b>         | <b>€ 4,654</b> | <b>€ 3,426</b> |

- (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 Group 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 Group 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, 2017, 2016 and 2015 (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, 2017, 2016 and 2015 and the full bonus was granted in the same year.

| 2015                 | Base salary    | Bonus          | Pension contributions | Social security costs | ESOP (1)       | Other (2)    | Total            |
|----------------------|----------------|----------------|-----------------------|-----------------------|----------------|--------------|------------------|
| Tim Van Hauwermeiren | 217,260        | 103,298        | 8,690                 | 8,760                 | 201,248        | 9,210        | <b>548,466</b>   |
| Eric Castaldi        | 222,159        | 75,075         | 62,097                | 133,621               | 185,464        | —            | <b>678,416</b>   |
| <b>Total</b>         | <b>439,419</b> | <b>178,373</b> | <b>70,787</b>         | <b>142,381</b>        | <b>386,712</b> | <b>9,210</b> | <b>1,226,882</b> |

| 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        | <b>874,015</b>   |
| Eric Castaldi        | 235,952        | 82,583         | 84,972                | 136,124               | 786,035        | —            | <b>1,325,666</b> |
| <b>Total</b>         | <b>489,236</b> | <b>183,897</b> | <b>96,901</b>         | <b>146,408</b>        | <b>842,597</b> | <b>9,184</b> | <b>1,768,223</b> |

| 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         | <b>3,607,146</b> |
| Eric Castaldi        | 271,344        | 173,284        | 62,335                | 254,732               | 4,089,209        | 14,979        | <b>4,865,883</b> |
| <b>Total</b>         | <b>575,285</b> | <b>474,919</b> | <b>76,650</b>         | <b>264,191</b>        | <b>7,057,404</b> | <b>24,580</b> | <b>8,473,029</b> |



(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 Group makes a calculation of the exposure.

(2) Consists of 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, 2017, 2016 and 2015 and their exercise price equal to the fair market value upon date of grant, and the stock options exercised during 2017, 2016 and 2015.

| 2015                 | ESOPs         | Term     | Exercise price | Exercised |
|----------------------|---------------|----------|----------------|-----------|
| Tim Van Hauwermeiren | 30,600        | 10 years | 9.47           | —         |
| Eric Castaldi        | 28,200        | 10 years | 9.47           | —         |
| <b>Total</b>         | <b>58,800</b> |          |                | <b>—</b>  |

| 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          |                |
| <b>Total</b>         | <b>137,000</b> |          |                | <b>125,292</b> |

| 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          |               |
| <b>Total</b>         | <b>123,200</b> |          |                | <b>65,380</b> |

The table below shows the stock options held at the start of the year ended December 31, 2017, the stock options granted to executive directors which have vested during the year ended December 31, 2017 and the stock options to vest in the years until 2020.

| Name                 | Total options held on January 1, 2017 | options granted in 2017 | options exercised in 2017 | Total options held on December 31, 2017 | Options vested until 2016 | Exercise price | Options vested in 2017 | Exercise price | Options to vest 2018 | Exercise price | Options to vest 2019 | Exercise price | Options to vest 2020 | Exercise price |
|----------------------|---------------------------------------|-------------------------|---------------------------|---|---------------------------|----------------|------------------------|----------------|----------------------|----------------|----------------------|----------------|----------------------|----------------|
| Tim Van Hauwermeiren | 281,580                               | 80,000                  | (65,380)                  | 296,200                                 | 70,000                    | 7.17           | 35,000                 | 7.17           |                      |                |                      |                |                      |                |
|                      |                                       |                         |                           |   | 10,200                    | 9.47           | 10,200                 | 9.47           | 10,200               | 9.47           |                      |                |                      |                |
|                      |                                       |                         |                           |   |                           |                | 26,389                 | 11.47          | 16,667               | 11.47          | 6,944                | 11.47          |                      |                |
|                      |                                       |                         |                           |   |                           |                | 10,200                 | 14.13          | 10,200               | 14.13          | 10,200               | 14.13          |                      |                |
|                      |                                       |                         |                           |   |                           |                |                        |                | 26,667               | 21.17          | 26,666               | 21.17          | 26,667               | 21.17          |
| Eric Castaldi        | 230,607                               | 43,200                  | —                         | 273,807                                 | 72,007                    | 2.44           | 9,000                  | 2.44           |                      |                |                      |                |                      |                |
|                      |                                       |                         |                           |   | 43,333                    | 7.17           | 21,667                 | 7.17           |                      |                |                      |                |                      |                |
|                      |                                       |                         |                           |   | 9,400                     | 9.47           | 9,400                  | 9.47           | 9,400                | 9.47           |                      |                |                      |                |
|                      |                                       |                         |                           |   |                           |                | 14,883                 | 11.47          | 9,400                | 11.47          | 3,917                | 11.47          |                      |                |
|                      |                                       |                         |                           |   |                           |                | 9,400                  | 14.13          | 9,400                | 14.13          | 9,400                | 14.13          |                      |                |
|                      |                                       |                         |                           |   |                           |                |                        |                | 14,400               | 21.17          | 14,400               | 21.17          | 14,400               | 21.17          |

The table below shows the remaining term of the options held by the executive directors on December 31, 2017.

| Name                 | Number of options | Remaining term at December 31, 2017 (rounded up) |
|----------------------|-------------------|--|
| Tim Van Hauwermeiren | 105,000           | 7.0 years  |
|                      | 30,600            | 8.0 years  |
|                      | 50,000            | 8.5 years  |
|                      | 30,600            | 9.0 years  |
|                      | 80,000            | 10.0 years                                       |
| Eric Castaldi        | 60,970            | 6.5 years  |
|                      | 85,037            | 7.0 years  |
|                      | 28,200            | 8.0 years  |
|                      | 28,200            | 8.5 years  |
|                      | 28,200            | 9.0 years  |
|                      | 43,200            | 10.0 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, 2017, 2016 and 2015:

|                     | 2017             | 2016             | 2015             |
|---------------------|------------------|------------------|------------------|
| Peter Verhaeghe     | € 77,500         | € 55,000         | € 35,000         |
| John Paul de Koning | —                | —                | —                |
| Christina Takke     | NA               | NA               | —                |
| David L Lacey       | 50,000           | 45,930           | 45,651           |
| Werner Lanthaler    | 55,000           | 45,000           | 35,000           |
| Pamela Klein        | 42,500           | 35,000           | NA               |
| Don Debethizy       | 52,500           | 43,000           | 27,617           |
| A.A. Rosenberg      | 42,500           | —                | —                |
| <b>Total</b>        | <b>€ 320,000</b> | <b>€ 223,930</b> | <b>€ 143,268</b> |

The table below shows the number of stock options granted to the non-executive directors during the years ended December 31, 2017, 2016 and 2015 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, 2015 and 2016.

| 2015               | ESOPs         | Term     | Exercise price | Exercised |
|--------------------|---------------|----------|----------------|-----------|
| Don Debethizy      | 15,000        | 10 years | 11.44          | —         |
| <b>Total</b>       | <b>15,000</b> |          |                |           |
| 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          | —         |
| <b>Total</b>       | <b>50,000</b> |          |                |           |

- (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 | 21.17          |           |
| <b>Total</b>   | <b>15,000</b> |          |                | —         |

The table below shows the stock options held at the start of the year ended December 31, 2017 and the stock options granted to the non-executive directors which have vested during the year ended December 31, 2017, as well as the stock options to vest in the years ending December 31, 2018, December 31, 2019 and December 31, 2020 (in number of stock options), and the respective exercise price of such stock options:

| Name                | Total options held on January 1, 2017 | Options granted in 2017 | Total options held on December 31, 2017 | Options vested until 2016 | Exercise price | Options vested in 2017 | Exercise price | Options to vest in 2018 | Exercise price | Options to vest in 2019 | Exercise price | Options to vest in 2020 | Exercise price |
|---------------------|---------------------------------------|-------------------------|---|---------------------------|----------------|------------------------|----------------|-------------------------|----------------|-------------------------|----------------|-------------------------|----------------|
| Peter Verhaeghe     | 34,585                                | —                       | 34,585                                  | 11,626                    | € 2.44         | 7,959                  | € 3.95         |                         |                |                         |                |                         |                |
|                     |                                       |                         |   | 3,333                     | € 7.17         | 1,667                  | € 7.17         | 5,000                   | € 11.38        | 3,333                   | € 11.38        | 1,667                   | € 11.38        |
| David L. Lacey      | 29,443                                | 15,000                  | 44,443                                  | 6,643                     | € 2.44         | 8,533                  | € 7.17         | 4,267                   | € 7.17         | 3,333                   | € 11.38        | 1,667                   | € 11.38        |
|                     |                                       |                         |   |                           |                |                        |                | 5,000                   | € 11.38        | 5,000                   | € 21.17        | 5,000                   | € 21.17        |
| Werner Lanthaler    | 29,416                                | —                       | 29,416                                  | 12,814                    | € 2.44         | 3,333                  | € 7.17         | 1,602                   | € 2.44         |                         |                |                         |                |
|                     |                                       |                         |   |                           |                |                        |                | 5,000                   | € 11.38        | 3,333                   | € 11.38        | 1,667                   | € 11.38        |
| J. Donald deBethizy | 25,000                                | —                       | 25,000                                  | 7,500                     | € 11.44        |                        |                | 5,000                   | € 11.44        | 2,500                   | € 11.44        |                         |                |
|                     |                                       |                         |   |                           |                |                        |                | 5,000                   | € 11.38        | 3,333                   | € 11.38        | 1,667                   | € 11.38        |
| Pamela Klein        | 25,000                                | —                       | 25,000                                  | 7,500                     | € 11.44        |                        |                | 5,000                   | € 11.44        | 2,500                   | € 11.44        |                         |                |
|                     |                                       |                         |   |                           |                |                        |                | 5,000                   | € 11.38        | 3,333                   | € 11.38        | 1,667                   | € 11.38        |
| A.A. Rosenberg      | 15,000                                | —                       | 15,000                                  | —                         | € 14.13        |                        |                | 5,000                   | € 14.13        | 5,000                   | € 14.13        |                         |                |

The table below shows the remaining term of the stock options held by the non-executive directors on December 31, 2017.

| Name                 | Number of stock options | Remaining term on December 31, 2017 (rounded up) |
|----------------------|-------------------------|--|
| Peter K.M. Verhaeghe | 3,650                   | 2.5 years  |
|                      | 2,340                   | 3.0 years  |
|                      | 5,560                   | 5.5 years  |
|                      | 3,181                   | 6.0 years  |
|                      | 9,854                   | 7.0 years  |
|                      | 10,000                  | 8.5 years  |
| David L. Lacey       | 3,180                   | 5.5 years  |
|                      | 1,818                   | 6.0 years  |
|                      | 14,445                  | 7.0 years  |
|                      | 10,000                  | 8.5 years  |
|                      | 15,000                  | 10.0 years                                       |
| Werner Lanthaler     | 10,850                  | 6.0 years  |
|                      | 8,566                   | 7.0 years  |
|                      | 10,000                  | 8.5 years  |
| J. Donald deBethizy  | 15,000                  | 7.5 years  |
|                      | 10,000                  | 8.5 years  |
| Pamela Klein         | 15,000                  | 7.5 years  |
|                      | 10,000                  | 8.5 years  |
| A.A. Rosenberg       | 15,000                  | 9.0 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.

No stock options were exercised by non-executive directors during the year ended December 31, 2017, and no corresponding shares were issued in relation thereto.

## 7.2 Contingencies

The Group is currently not facing any outstanding claims or litigations that may have a significant adverse impact on the Group's financial position.

As described in note 5.2 the Group 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 Group 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 Group deems that the claw back risk is remote in view of the continuous monitoring of the contractual conditions. Currently the Group has fulfilled all the 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.

## 7.3 Commitments

At balance sheet date, there were no commitments signed for the acquisition of property, plant and equipment or intangible assets.

In July 2017, the Group signed a letter of intent with its drug substance manufacturing contractor, Lonza Sales AG, or Lonza, related to the biologics license application for ARGX-113. The total commitment under this letter of intent amounts to a minimum spend of £5.0 million before the end of calendar year 2018, of which the Group paid £1.0 million upon signature. In December 2017, the Group amended one of its manufacturing agreements with Lonza. This amendment expands the scope of Lonza's services with additional services for ARGX-113 to be performed at the Lonza facility in Tuas, Singapore. These services relate to the start-up of Lonza Singapore as a potential future commercial manufacturing site. Pursuant to this amendment, the Group has additional contractual obligations in the aggregate amounts of approximately \$9.3 million, with payments beginning in January 2018. In addition to the obligations for ARGX-113, the Group also has contractual obligations for ARGX-110 for approximately £0.9 million, with payments beginning by the third quarter of 2018.

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, |              |              |
|---------------------------|-------------------------|--------------|--------------|
|                           | 2017                    | 2016         | 2015         |
|                           | in thousands of €       |              |              |
| Audit fees(1)             | € 205                   | € 85         | € 70         |
| Audit-related fees        | 698                     | 65           | 35           |
| Tax and other services(2) | —                       | 2            | 3            |
| <b>Total</b>              | <b>€ 903</b>            | <b>€ 152</b> | <b>€ 108</b> |

(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 Group'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<br>Biotechnical<br>research on drugs<br>and pharma<br>processes |
| argenx BVBA     | 0818292196          | Belgium         | 100.00 %      | Pharmaceuticals<br>and pharmacy<br>supplies merchant<br>wholesalers             |
| argenx US, Inc. | 36-4880497          | USA             | 100.00 %      |   |

## 7.6 Events after the balance sheet date

On March 16, 2018, the Company has been awarded a €2.5 million VLAIO grant to identify novel therapeutic antibodies. This grant will be used to fund research of novel targets involved in regulation of locally-released TGF- $\beta$ , a protein active in immunosuppression.

On March 22, 2018, the Company announced the expansion of its pipeline with addition of complement targeted ARGX-117 for treatment of severe autoimmune diseases. ARGX-117 has the potential to have synergistic effect with the lead autoimmune compound ARGX-113.

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**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, 2018

/s/ Tim Van Hauwermeiren

Name: Tim Van Hauwermeiren

Title: Chief Executive Officer

(Principal Executive Officer)

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**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, 2018

/s/ Eric Castaldi

Name: Eric Castaldi

Title: Chief Financial Officer  
(Principal Financial Officer)

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**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, 2017 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, 2018

/s/ Tim Van Hauwermeiren

Name: Tim Van Hauwermeiren

Title: Chief Executive Officer

(Principal Executive Officer)

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**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, 2017 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, 2018

/s/ Eric Castaldi

Name: Eric Castaldi

Title: Chief Financial Officer

(Principal Financial Officer)

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