Table of Contents

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, 2020

OR

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

For the transition period from _____ to _____

OR

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

Date of event requiring this shell company report _____

Commission file number 001-38097

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

The Netherlands
(Jurisdiction of incorporation or organization)

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

Tim Van Hauwermeiren
argenx BV
Industriepark Zwijnaarde 7,
Building C
9052 Zwijnaarde (Ghent)
Belgium
+32 9 310 34 00
TVanHauwermeiren@argenx.com
(Name, telephone, e-mail and/or facsimile number and address of company contact person)

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

Title of each class:	Trading Symbol:	Name of each exchange on which registered:
American Depositary Shares, each representing one ordinary share with a nominal value of €0.10 per share	ARGX	Nasdaq Global Select Market
Ordinary shares with a nominal value of €0.10 per share *		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, 2020 47,571,283 ordinary shares were outstanding, including ordinary shares represented by American Depositary Shares.

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

Yes X No ☐

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

Yes ☐ No X

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

Yes X No ☐

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

Yes X No ☐

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

Large accelerated filer X | Accelerated filer ☐ | Non-accelerated filer ☐ | Emerging growth company ☐

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. 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 ☐ | International Financial Reporting Standards as issued by the International Accounting Standards Board X | Other ☐

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

Item 17 ☐ Item 18 ☐

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

Yes ☐ No X

TABLE OF CONTENTS

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 timing of the market authorizations of our products (if any);
- the anticipated pricing and reimbursement of our product candidates, if approved;
- the timing or likelihood of regulatory filings and approvals for any product candidates;
- our ability to establish sales, marketing and distribution capabilities for any of our product candidates that achieve regulatory approval;
- our regulatory strategy and our ability to establish and maintain manufacturing arrangements for our product candidates;
- the scope and duration of protection we are able to establish and maintain for intellectual property rights covering our product candidates, platform and technology;
- our estimates regarding expenses, future revenues, capital requirements and our needs for additional financing;
- the rate and degree of market acceptance of our product candidates, if approved;
- the potential benefits of our current collaborations;
- our plans and ability to enter into collaborations for additional programs or product candidates;
- the effect of COVID-19 on our business; 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. Such risks and uncertainties may be amplified by the COVID-19 pandemic and its potential impact on our business and the global economy. 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.

In addition, statements that include "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus supplement, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to unduly rely upon these statements.

Summary of Risk Factors

Our ability to implement our business strategy is subject to numerous risks that you should be aware of before making an investment decision. These risks are described more fully below. These risks include, among others:

- We have incurred significant losses since our inception and expect to incur losses for the foreseeable future. We may never achieve or maintain profitability.
- All of our product candidates are either in preclinical, early-stage clinical or clinical development or market approval has been requested for them, but has not (yet) been granted. Our trials may fail and even if they succeed we may be unable to commercialize any or all of our product candidates due to a lack of, or delay in, regulatory approval or for other reasons.
- We will face significant challenges in successfully commercializing our products.
- 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.
- 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 rely on patents and other intellectual property rights to protect our product candidates and platform technologies. Failure to enforce or protect these rights adequately could harm our ability to compete and impair our business.
- Our future growth and ability to compete depends on retaining our key personnel and recruiting additional qualified personnel.

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 and for the years ended December 31, 2020, 2019 and 2018 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 and for the year ended December 31, 2017 and 2016 have been extracted from our consolidated audited financial statements, which are not included herein. This data should be read together with, and is qualified in its entirety by reference to, "Item 5 —Operating and Financial Review and Prospects" as well as our financial statements and notes thereto appearing elsewhere in this report. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

	Year ended December 31,				
	2020	2019	2018	2017	2016
	(In thousands, except share and per share data)				
Consolidated statement of profit and loss and other comprehensive income:					
Revenue	€ 36,425	€ 69,783	€ 21,482	€ 36,415	€ 14,713
Other operating income	18,109	12,801	7,749	4,841	2,439
Total operating income	**54,534**	**82,584**	**29,232**	**41,257**	**17,152**
Research and development expenses	(325,479)	(197,665)	(83,609)	(51,740)	(31,557)
Selling, general and administrative expenses	(149,367)	(64,569)	(27,471)	(12,448)	(7,011)
Total operating expenses	**(474,846)**	**(262,234)**	**(111,080)**	**(64,188)**	**(38,568)**
Change in fair value on non-current financial assets	2,544	1,096	—	—	—
Operating loss	**(417,769)**	**(178,554)**	**(81,849)**	**(22,932)**	**(21,416)**
Financial income/(expenses)	(1,414)	14,275	3,694	1,250	73
Exchange gains/(losses)	(106,956)	6,066	12,308	(5,797)	(31)
Loss before taxes	**(526,139)**	**(158,213)**	**(65,847)**	**(27,479)**	**(21,374)**
Income tax expense	(2,784)	(4,752)	(794)	(597)	—
Loss for the year and total comprehensive loss	**€ (528,923)**	**€ (162,965)**	**€ (66,641)**	**€ (28,076)**	**€ (21,374)**
Weighted average number of shares outstanding	45,410,442	38,619,121	33,419,356	24,609,536	18,820,612
Basic and diluted loss per share (in €)	€ (11.65)	€ (4.22)	€ (1.99)	€ (1.14)	€ (1.14)

	As of December 31,				
	2020	2019	2018	2017	2016
	(In thousands)				
Condensed consolidated statement of financial position:					
Cash and cash equivalents and current financial assets	€ 1,626,968	€ 1,335,821	€ 564,569	€ 359,775	€ 96,728
Total assets	1,857,693	1,433,339	578,458	370,908	105,772
Deferred revenue — current and non-current	257,002	290,370	2,161	10,070	30,206
Total liabilities	492,110	382,593	40,063	25,977	42,398
Share capital	4,757	4,276	3,597	3,217	2,012
Share premium	2,058,123	1,308,539	673,454	430,518	126,358
Total equity	1,364,373	1,050,746	538,395	344,931	63,374

	As of December 31,				
	2020	2019	2018	2017	2016
	(In thousands)				
Condensed consolidated statement of cash flows:					
Cash and cash equivalents at beginning of the period	**€ 331,282**	**€ 281,040**	**€ 190,867**	**€ 89,897**	**€ 35,514**
Net cash flows (used in) / from operating activities	(346,349)	134,584	(53,839)	(36,546)	10,599
Net cash flows (used in) / from investing activities	310,250	(744,338)	(107,542)	(162,052)	(806)
Net cash flows (used in) / from financing activities	747,897	659,359	244,671	305,365	44,621
Effect of exchange rate differences on cash and cash equivalents	(51,471)	637	6,883	(5,797)	(31)
Cash and cash equivalents at end of the period	**€ 991,609**	**€ 331,282**	**€ 281,040**	**€ 190,867**	**€ 89,897**

B. CAPITALIZATION AND INDEBTEDNESS

Not applicable.

C. REASONS FOR THE OFFER AND USE OF PROCEEDS

Not applicable.

D. RISK FACTORS

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

Summary of Risk Factors

Our ability to implement our business strategy is subject to numerous risks that you should be aware of before making an investment decision. These risks are described more fully below. These risks include, among others:

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

- All of our product candidates are either in preclinical, early-stage clinical or clinical development or market approval has been requested for them, but has not (yet) been granted. Our trials may fail and even if they succeed we may be unable to commercialize any or all of our product candidates due to a lack of, or delay in, regulatory approval or for other reasons.
- We will face significant challenges in successfully commercializing our products.
- 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.
- 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 rely on patents and other intellectual property rights to protect our product candidates and platform technologies. Failure to enforce or protect these rights adequately could harm our ability to compete and impair our business.
- Our future growth and ability to compete depends on retaining our key personnel and recruiting additional qualified personnel.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since our inception and expect to incur losses for the foreseeable future. We may never achieve or maintain profitability.

We are a clinical-stage biopharmaceutical company with a limited operating history. We do not currently have any approved products and have never generated any revenue from product sales. Since our inception, we have incurred significant operating losses, totaling €758.5 million of cumulative losses over the financial years 2018, 2019 and 2020. 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, pre-commercial activities and from general and administrative costs associated with our operations. In addition, we expect to continue to incur significant costs associated with our listings in the United States and in Europe. In the future, we intend to continue to conduct research and development, preclinical testing, clinical trials and regulatory compliance activities and we intend to continue our efforts to establish a sales, marketing and distribution infrastructure. These expenses, together with anticipated general and administrative expenses, will result in incurring further significant losses for at least the next several years. We anticipate that our expenses will increase substantially if and as we execute our business plan as further set out in “Item 4.B. — Business Overview – Our Strategy” and “Item 5.A. — Operating Results — Overview” and as we experience delays or encounter issues relating thereto, including failed studies, ambiguous trial results, safety issues or other regulatory challenges. If our losses become greater than expected, we may require additional financing than anticipated and such financing may not be available to us on acceptable terms or at all.

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 may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability. For instance, even if we receive approval of and commercialize efgartigimod for the treatment of MG in the United States, we can provide no assurances that we will be able to achieve profitability based on sales in that indication alone or that we will be able to receive approval of and commercialize efgartigimod in other indications or in other countries.

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 achieve or sustain profitability could impair our ability to raise capital,

expand our business, diversify our product offerings or continue our operations and as such could have a material adverse impact on our business, financial condition and results of operations.

Substantial additional funding may be required in order to complete the development and commercialization of our product candidates but may not be available to us on acceptable terms or at all.

Notwithstanding our significant position of cash and cash equivalents and current financial assets as of December 31, 2021, we expect to require additional funding in the future to sufficiently finance our operations, to advance development of our product candidates and to continue our business activities relating to research and development and the commercialization of our products. Our future capital requirements for efgartigimod or our preclinical programs will depend on many factors, including those set out in "Item 5.B — Liquidity and Capital Resources".

We expect our cash burn to increase significantly in 2021. The increased spend will support our transition to an integrated immunology company, including the build-out of global commercial infrastructure and drug product inventory ahead of the expected launch of efgartigimod in MG, the advancement of our clinical-stage pipeline, including seven clinical trials of efgartigimod, and continued investment in our immunology innovation program. Any failure by us to keep the cash burn under control by applying our funds effectively and managing our cash and investments appropriately could result in financial losses that could have a material adverse effect on our business.

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. 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. Adequate additional financing may not be available to us on acceptable terms, or at all. The inability for us to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy and as a result we may be forced to delay, reduce or terminate the development or commercialization of all or part of our research programs or product candidates, 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 or we may be unable to take advantage of future business opportunities, all of which may have a material adverse impact on our business, financial condition and results of operations.

The investment of our cash and cash equivalents may be subject to risks which may cause losses and affect the liquidity of these investments.

As of December 31, 2020, we had cash and cash equivalents and current financial assets of €1,627.0 million. We historically have invested substantially all of our available cash and cash equivalents and current financial assets in either current accounts, savings accounts, term accounts or highly liquid money market funds, pending their use in our business. Any future investments may include term deposits, corporate bonds, commercial paper, certificate of deposit, government securities and money market funds in accordance with our cash management policy. These investments may be subject to general credit, liquidity, and market and interest rate risks. For example, we may realize losses in the fair value of these investments or a complete loss of these investments, which would have a negative effect on our financial condition. In addition, should our investments cease paying or reduce the amount of interest paid to us, our interest income would suffer. The market risks associated with our investment portfolio may have an adverse effect on our results of operations, liquidity and financial condition.

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

All of our product candidates are either in preclinical, early-stage clinical or clinical development or market approval has been requested for them, but has not (yet) been granted. Our trials may fail and even if they succeed we may be unable to commercialize any or all of our product candidates due to a lack of, or delay in, regulatory approval or for other reasons.

For our clinical trials to succeed and in order to obtain the requisite regulatory approvals to market and sell any of our product candidates, we or our collaborators for such candidates must successfully 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. 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, operating results and financial condition.

We may experience delays in our ongoing clinical trials, including as a result of COVID-19, 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 large variety of reasons outside our control, including delays of approval from regulatory authorities, institutional review boards or ethics committees, delays or failure to recruit or retain patients, failures of third parties to comply with regulatory or contractual requirements or issues relating to the quantity, quality or stability of the product candidate.

We could encounter delays, for example if a clinical trial is suspended or terminated by us, by the institutional review boards, or 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, 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, 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 product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. We could also experience operational challenges as we undertake an increasing number of clinical trials. 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, results of operations and financial condition.

Clinical trials must be conducted in accordance with the EMA, FDA, PMDA 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 contract research organizations or 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 EMA, FDA or other regulatory authorities, and apply different standards of diagnosis, screening and medical care.

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 applications, or INDs, in the United States or Japan, or a Clinical Trial Authorization Applications, or CTAs, in Europe, or a comparable application in other jurisdictions. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the EMA, FDA or other regulatory authorities 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 or comparable applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or CTAs or comparable applications will result in the EMA, FDA or other regulatory authorities allowing clinical trials to begin.

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.

Any of these occurrences may harm our business, results of operations and financial condition 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.

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. We have limited experience in submitting and supporting the applications necessary to seek regulatory approvals and expect to rely on third-party CROs to assist us in this process. Securing regulatory approval requires the submission of extensive nonclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities.

If we are unable to obtain regulatory approval of our product candidates on a timely basis or at all, our business will be materially impacted. For instance, we have incurred significant time and expense related to preparation for the build-out of our global commercial infrastructure and drug product inventory ahead of the expected launch of efgartigimod in MG in the United States. If efgartigimod is not approved in the United States, or if such approval is significantly delayed, it could have a material adverse effect on our business and cause the price of the ordinary shares to decline.

Business interruptions resulting from the COVID-19 pandemic could cause a disruption of the development of our product candidates and adversely impact our business.

Public health crises such as pandemics or similar outbreaks could adversely impact our business, such as the COVID-19 pandemic. The COVID-19 pandemic is evolving, and to date has led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures.

The extent to which the COVID-19 pandemic impacts our business and operations and those of our collaborators, including clinical development and regulatory efforts, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate geographic spread of the disease, the duration of the outbreak, the duration and effect of business disruptions and the short-term effects and ultimate effectiveness of the travel restrictions, quarantines, social distancing requirements, vaccines, and business closures to contain and treat the disease. Accordingly, we do not yet know the full extent of potential delays or impacts on our business, our clinical and regulatory activities and those of our partners, healthcare systems or the global economy as a whole. However, these impacts could adversely affect our business, financial condition, results of operations and growth prospects. In addition, to the extent the ongoing COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described herein.

Operational impacts of COVID-19

We conduct our clinical trials globally, including in areas impacted by COVID-19 in North America, Europe and Japan. The continued spread of COVID-19 has and could continue to adversely impact our business and operations, including our or our third-party partners' discovery activities, preclinical studies and clinical trials. The COVID-19 pandemic, and measures undertaken to control the spread of the virus, could impair our or our third-party partners' ability to initiate clinical trial sites and recruit and retain patients because principal investigators and site staff, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography or due to prioritization of hospital resources toward the outbreak and restrictions in travel. Furthermore, some patients may be unwilling to enroll in our or our third-party partners' trials or be unable to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services. Patients in our and our third-party partners' trials are at increased risk for COVID-19-related health issues due to a number of factors, including their age, the nature of their disease or stage of their disease. If patients in our or our third-party partners' trials contract COVID-19, it could adversely impact the outcome of the trial, including by limiting the quality, completeness and interpretability of data that we are able to collect. As a result of these restrictions, enrollment in some of the ongoing trials we or our third-party partners are conducting has been or may be delayed, but the extent of the full impact is not quantifiable until the trajectory of the pandemic is better understood. The pandemic may also lead to delayed and missed dosing or delayed and missed disease evaluations for patients that have already been enrolled in ongoing trials. We and our third-party partners will continue to monitor the impact of COVID-19 on all ongoing clinical trials and will implement changes as necessary.

Economic impacts of COVID-19

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our ADSs and/or our ordinary shares.

Impacts of COVID-19 on employees or other stakeholders

COVID-19 may also negatively impact our employees and our other stakeholders. Precautionary measures that we have taken, such as temporarily requiring employees to work remotely, suspending all non-essential travel for our employees and discouraging employee attendance at industry events, may not succeed in minimizing the risk of infection to our employees, and such measures, together with the COVID-19 pandemic, could negatively impact the productivity or emotional health and wellbeing of our employees.

We may face ongoing obligations and additional expenses even if our product candidates are approved, and we may face restrictions, market withdrawal and penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

If the EMA, FDA or a comparable 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 expensive 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 and therefore cannot be sold in the United States if we do not obtain a BLA. 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.

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 revoke, 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.

Our product candidates may have serious adverse, undesirable or unacceptable side effects or even death.

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 EMA, FDA or other comparable regulatory authorities. While our preclinical and clinical studies for our product candidates to date show that our product candidates have generally been well tolerated from a risk-benefit perspective, we have observed adverse events and treatment emergent adverse events in our clinical studies to date, and we may see additional adverse events and treatment emergent adverse events or TEAEs in our ongoing and future trials, which may be more serious than those observed to date, and as a result, our ongoing and future trials may be negatively impacted.

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, results of operation and financial condition significantly. Further, because all of our product candidates and preclinical programs, other than efgartigimod, are based on our SIMPLE Antibody™ platform, any adverse safety or efficacy

findings related to any product candidate or preclinical program may adversely impact the viability of our other product candidates or preclinical programs.

Additionally, if any of our product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products, a number of potentially significant negative consequences could arise, 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. For example, we understand that another company developing an FcRn antagonist recently initiated a voluntary pause of its ongoing clinical trials after an observed signal of elevated total cholesterol and LDL levels in one of its ongoing trials. We have evaluated efgartigimod in over 350 subjects and patients and we are not aware of any elevation of cholesterol markers related to treatment with efgartigimod. However, if we were to observe unexpected adverse events of whatever kind, our trials could be similarly paused and it could have a material adverse effect on our ability to further the advancement of our product candidates.

We face significant competition for our drug discovery and development efforts.

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. A detailed analysis of the intense competition we face in the autoimmune field, the field of leukemia and lymphoma and the monoclonal antibody drug discovery field is set out in “Item 4.B. — Business Overview — Competition”. 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 is likely to have a material adverse effect on our business, financial condition and results of operation.

We depend on enrollment of patients in our clinical trials for our product candidates.

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 available 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; PF; CIDP; 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.

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 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 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 product liability insurance for our product candidates and 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, we may not be able to maintain insurance coverage at a reasonable cost or to 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.

Risks Related to Commercialization of Our Product Candidates

We will face significant challenges in successfully commercializing our products.

We are in the process of setting up our sales and marketing infrastructure, have no experience in the sale or marketing of pharmaceutical products and may not timely have the appropriate infrastructure in place yet (including, such as information technology, enterprise resource planning and forecasting). 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 plan 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, the United States and Japan. 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. Recruiting and training a sales force is expensive and costs of creating an independent sales and marketing organization and of marketing and promotion could be above those anticipated by us. In addition, recruiting and training a sales force is time consuming and could delay any product launch. In the event that any such launch (*e.g.* the expected launch of efgartigimod in MG in the U.S.) 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.

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, financial condition and results of operations.

The future commercial success of our product candidates will depend on the degree of market acceptance.

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. For instance, our product candidates may not achieve an adequate level of acceptance by physicians because of dosing complexity or from patients because of infusion fatigue. 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. Even if some products achieve market acceptance, the market may prove not to be large enough to allow us to generate significant revenues.

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. See also “Item 4.B. — Business Overview — Government Regulation”.

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

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. A detailed description of the relevant legislative and regulatory initiatives and changes is contained in “Item 4.B. — Business Overview — Government Regulation”. If such legislative and/or regulatory initiatives and changes would lead to increased restrictions on marketing our products, or lead to limiting the funds available for healthcare in jurisdictions relevant to us which may reduce reimbursement levels and is likely to affect the prices we may set, we would be negatively impacted in our ability to successfully and profitably market our product candidates.

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, European, Japanese and Chinese healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute. Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. These laws may impact, among other things, our proposed sales, marketing and education programs and constrain our business and financial arrangements and

relationships with third-party payors, healthcare professionals who participate in our clinical research program, healthcare professionals and others who recommend, purchase, or provide our approved products, and other parties through which we market, sell and distribute our products for which we obtain marketing approval. In addition, we may be subject to patient data privacy and security regulation by both the U.S. federal government and the other states and countries in which we conduct our business. Finally, our current and future operations are subject to additional healthcare-related statutory and regulatory requirements and enforcement by regulatory authorities in jurisdictions in which we conduct our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements. We have no experience in the sale or marketing of pharmaceutical products and, in light of any future approval and commercialization, we will need to continue building an internal program to ensure compliance with the different health care laws and regulations. The establishment of an internal compliance program will involve substantial costs and the program may not be successful in complying with the different reporting requirements. For an overview of some of the laws and regulations which may affect our ability to operate, please refer to “Item 4.B. — Business Overview — Government Regulation”.

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

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time and resource consuming and can divert a company’s attention from the business. For further details and examples, we refer “Item 4.B — Business Overview — Government Regulation”.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. For example, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is generally not permitted in the countries that form part of the European Union. Some European Union Member States have enacted laws explicitly prohibiting the provision of these types of benefits and advantages to induce or reward improper performance generally, and the United Kingdom has enacted such laws through the Bribery Act 2010. Infringements of these laws can result in substantial fines and imprisonment. EU Directive 2001/83/EC, which is the EU Directive governing medicinal products for human use, further provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision has been transposed into the Human Medicines Regulations 2012 and so remains applicable in the UK despite its departure from the EU. 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.

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

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

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

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

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

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

Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the European Union, after a recommendation from the EMA's Committee for Orphan Medicinal Products, or COMP, the European Commission grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition either affecting not more than five in 10,000 persons in the European Union or 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. In each case there must be no satisfactory method of diagnosis, prevention or treatment of such condition, 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. If we fail to obtain or if we lose orphan drug status for one or more of our product candidates, the aforementioned incentives and market exclusivity may not or no longer be available to us, which is likely to increase the overall cost of development and to decrease the competitive position of such product candidate.

We may from time to time seek orphan drug designation in the United States or Europe for certain indications addressed by our product candidates. For example, in September 2017, the FDA granted orphan drug designation for the use of efgartigimod for the treatment of MG, in January 2019 the FDA granted orphan drug designation for the use of efgartigimod for the treatment of Primary Immune Trombocytopenia and for the use of cusatuzumab for the treatment of acute myeloid leukemia. 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.

We may not obtain or maintain adequate coverage or reimbursement status for our product candidates.

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) and other countries, commercial health insurers, and managed care organizations, provide coverage and establish adequate reimbursement levels for such product candidates. Moreover, increasing efforts by governmental and third-party payors in the European Union, the United States, China 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. For instance, access to efgartigimod for the treatment of MG may be restricted by limited payer coverage due to treatment criteria, which may prevent us from realizing its full commercial potential. A detailed analysis of some of the most relevant developments and challenges regarding coverage and reimbursement is set out in "Item 4.B. — Business Overview — Government Regulation".

Limitations on reimbursement and reimbursement levels may diminish or prevent altogether any significant demand for our products and/or may prevent us entirely from entering certain markets, which would prevent us from generating significant revenues or becoming profitable, which would adversely affect our business, financials and results of operations.

We may not be able to successfully achieve support among healthcare providers and third-party payors for our product candidates, and our relationships with such parties are subject to regulations.

Our current and future arrangements with providers, researchers, consultants, third-party payors and customers are subject to broadly applicable national, 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.

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 more information see "Item 4.B — Business Overview — Government Regulation"). Violations of these laws can subject us to criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment and exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm, and the required curtailment or restructuring of our operations. Moreover, we expect that there will continue to be federal and state laws and regulations, proposed and implemented, that could impact our business, financial condition and results of operations.

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 subject to a high level of regulation by the FDA, the EMA, the PMDA and other comparable regulatory authorities and by other national or supra-national regulatory authorities. Applicable regulations impose substantial requirements covering nearly all aspects of our activities and the activities of our partners and licensees, notably on research and development, manufacturing, preclinical tests, clinical trials, labeling, marketing, sales, storage, record keeping, promotion and pricing of our product candidates.

Failure to (timely) comply with regulatory requirements could have far reaching consequences for us, including significant delay in our product development as a result of regulatory authorities recommending non-approval or restrictions on approval of a product candidate. Any failure or delay 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.

Regulations differ substantially per jurisdiction and are subject to constant change. 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 approval. Moreover, clinical studies conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the EMA, the FDA or the PMDA does not ensure approval by the comparable 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 EMA, the FDA or the PMDA.

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 product candidates. Each of the FDA, EMA and other comparable regulatory 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, EMA or one or more other comparable foreign authority. The FDA, EMA or other comparable regulatory 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.

The FDA, EMA and other comparable regulatory authorities have substantial discretion in the approval process and determining when or whether regulatory approval will be obtained for any of our product candidates. Any of the FDA, EMA and other comparable regulatory authorities may disagree with our interpretation of data submitted for their review. 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, EMA or any other regulatory authority. For instance, we announced positive Phase 3 data and submitted a BLA to the FDA in December 2020, for efgartigimod for the treatment of gMG. The FDA must inform us within 60 days of submission if it has accepted our BLA submission and filed it for regulatory review. If the FDA determines that our BLA submission is incomplete or insufficient for filing, the FDA may refuse to file the BLA. Any such refusal by the FDA could require us to expend additional time and resources to revise and resubmit our BLA or harm our business and reputation. We can provide no assurances that our BLA will be approved on the timeline that we expect or at all. Furthermore, the FDA announced plans to resume prioritized domestic inspections in July 2020. We may not be ready for such an inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities in view of the commercial launch of efgartigimod for the treatment of MG.

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.

The time required to obtain approval by the FDA, EMA and comparable regulatory 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. 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, including efgartigimod for the treatment of gMG, which would significantly harm our business, results of operations and prospects.

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.

We may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities.

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.

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 and relevant third parties 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, EMA and other comparable regulatory 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 in other countries; 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, results of operations and financial condition, 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. or international 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. These risks may be particularly heightened given our lack of experience with commercialization and the rapid growth of our sales and marketing function. Furthermore, due to the highly regulated environment in which we operate and our heavy reliance on approval of our products by governmental entities and healthcare providers, reputational risks related to the misconduct or other improper behavior as described above are likely to have a bigger impact on us than on most companies operating in other industries.

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, EMA and other comparable 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.

We may face service, manufacturing or supply chain failures or other failures, business interruptions or other disasters.

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, such as capacity issues, or 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 manufacturing failures or product defects, resulting in lot failures, product recalls, product liability claims and insufficient inventory. Furthermore, our supply chain failures would create a risk of non-compliance toward partners due to shortages, for example, if argenx BV is not able to deliver its product to its partner in China.

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, financial condition and results of operations.

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.

We face the risk of computer system failures, data leaks and cybercrimes.

Despite the implementation of security measures, our internal computer systems and those of our third-party service providers are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failure. Cyber-attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyber-attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. Cyber-attacks also could include phishing attempts or e-mail fraud to cause payments or information to be transmitted to an unintended recipient.

Any system failure, accident or security breach that causes interruptions in our own or in third-party service vendors' operations could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our or our partners' regulatory approval efforts and significantly increase our costs in order to recover or reproduce the lost data. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability, our product development programs and competitive position may be adversely affected and the further development of our product candidates may be delayed. If the integrity of our cybersecurity systems is breached, we may incur significant effects such as remediation expenses, lost revenues, litigation costs and increased insurance premiums and may also experience reputational damage and the erosion of shareholder value. Furthermore, we may incur additional costs to remedy the damage caused by these disruptions or security breaches. Like other companies, we have on occasion experienced, and will continue to experience, threats to our data and systems, including malicious codes and viruses, phishing, business email compromise attacks, or other cyber-attacks. Whereas none of these instances had a material impact so far, the number and complexity of these threats continue to increase over time. If a material breach of our information technology systems or those of our third party service providers occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged.

We could be required to expend significant amounts of money and other resources to respond to these threats or breaches and to repair or replace information systems or networks, and could suffer financial loss or the loss of valuable confidential information. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely and there can be no assurance that any measures we take will prevent cyber-attacks or security breaches that could adversely affect our business.

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

Risks Related to Our Dependence on Third Parties

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

We have relied upon and plan to continue to rely upon third parties, including licensees, 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 partners, third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, EMA and comparable 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, EMA or comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Upon inspection by a given regulatory authority, such regulatory authority may determine that our clinical trials do not fully 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 results of operations.

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

We are, and expect to continue to be, dependent on partnerships with partners relating to the development and commercialization of our existing and future research programs and product candidates. We currently have collaborative research relationships with various pharmaceutical companies such as Janssen, AbbVie, Shire, Zai Lab 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 termination of the collaboration agreements with all its consequences, disagreement on the interpretation of contractual terms or no adherence or uncertainties as part of the ongoing collaboration.

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. Furthermore, we use Vetter Pharma International GmbH's fill and finish services for our 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, financial condition and results of operation.

We and our third-party suppliers may also be subject to audits by the FDA, EMA or other comparable regulatory 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, pandemic, natural hazards or vandalism at the CMO could significantly interrupt our manufacturing capability. Alternative production plans in place or disaster-recovery facilities available to us may not be sufficient. In case of a disruption, we may have to establish additional alternative manufacturing sources. This would require substantial investment on our part, which we may not be able to obtain on commercially acceptable terms or at all. Additionally, we may experience significant 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 facili-ties. 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. 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.

Accuracy and timing of our financial reporting is partially dependent on information received from third party partners, which we do not control.

We have collaborated, and plan to continue to collaborate, with third parties on product candidates that we believe have promising utility in disease areas or patient populations that are better served by resources of larger biopharmaceutical companies. See “Collaborations” in “Item 4.B.—Business Overview” for a more detailed description of these collaborations. As part of some of these collaborations, our collaboration partners are responsible for providing us with financial information regarding specific projects, including funds spent, liabilities incurred and expected future costs, on which we rely for our own financial reporting. In the event that our collaboration partners fail to provide us with the necessary financial information within the agreed upon timeframes, or if such financial information proves partially inaccurate, this is likely to impact the accuracy of our own financial reporting. Our reliance on financial information received from our collaboration partners may impact our own internal and external financial reporting and any delay in the provision of such financial information to us or any failure by us to identify mistakes in the financial information provided to us may cause our own financial statements to be partially inaccurate. Any inaccuracy in our financial reporting could cause investors to lose confidence in our financial reporting. This in turn may lead to reputational damage and/or affect our ability to, and the terms on which we may, obtain future (equity) financing which may harm our business.

Risks Related to Intellectual Property

We rely on patents and other intellectual property rights to protect our product candidates and platform technologies. 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. Specifically, we are materially dependent on patent and other proprietary protection related to our core platform technologies, described in “Platform Technologies” in “Item 4.B. —Business Overview — Intellectual Property”, and our product candidates, as described in “Product Candidates: Wholly-Owned Programs” in “Item 4.B. —Business Overview — Intellectual Property” and “Product Candidates: Partnered Programs” in “Item 4.B. —Business Overview — Intellectual Property”. 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. The enforcement, defense and maintenance of such patents and other intellectual property rights may be challenging and costly.

We cannot be certain that patents will be issued or granted with respect to applications that are currently pending. As a biopharmaceutical company our patent position is 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 potential. 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 “Licensure and Regulation of Biologics in the United States” in Item 4.B. —Business Overview — Government Regulation 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. Any of the aforementioned situations could cause harm to our ability to protect our intellectual property, which in turn would allow competitors to market comparable products which could materially adversely affect our competitive position and as such our business, financial condition and results of operation.

Issued patents 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 and may harm our competitive position.

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

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

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

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

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

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

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

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

Our involvement in litigation, and in, *e.g.*, any interference, derivation, reexamination, *inter partes* review, opposition or post-grant proceedings or other intellectual property proceedings inside and outside of the European Union or the United States may divert management time from focusing on business operations, could cause us to spend significant amounts of money and may have no guarantee of success. Potential intellectual property litigation could also, amongst other things, force us to stop selling, incorporating, manufacturing or using certain of our products, to obtain a license to sell or use certain technology from a third party asserting its intellectual property rights, to redesign certain products or processes that use any allegedly infringing or misappropriated technology 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, which may result in significant cost and/or delay to us. Moreover, certain licenses 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 and redesigning certain products or processes could be technically infeasible.

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 may negatively impact us. 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.

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.

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 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.

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.

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, results of operations and financial condition 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.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage and changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our products.

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.

Any inability of us to protect our competitive advantage with regard to any of our product candidates may prevent us from successfully monetizing such product candidate and this could materially adversely affect our business, prospects, financial condition and results of operations.

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, as described in detail in “Item 6.A.—Directors and Senior Management”.

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

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

We have grown significantly in number of employees and scope of operations over the recent years and expect to experience significant growth in the number of our employees and the scope of our operations also in the near future, particularly in the areas of drug research, 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 and may dilute our corporate culture, which in turn may

make it more difficult to attract and retain employees. Any inability to manage growth could delay the execution of our business plans or disrupt our operations, which in turn could materially harm our business and prospects.

Public health issues or other catastrophic events could disrupt the supply, delivery or demand of products, which could negatively affect our operations and performance.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. To date, the outbreak of COVID-19 has already resulted in extended shutdowns of certain businesses in many countries all over the world. The spread of COVID-19 has impacted the global economy and may impact our operations, including the potential interruption of our clinical trial activities and our supply chain, and the operations of our key business partners. Global health concerns, such as the recent developments around COVID-19, could also result in social, economic, and labor instability in the countries in which we or the third parties with whom we engage operate. We have also taken temporary precautionary and severely restrictive measures intended to help minimize the risk of COVID-19 to our employees, including temporarily requiring our employees to work remotely, suspending non-essential travel worldwide for our employees and discouraging employee attendance at industry events and in-person work-related meetings. These measures could negatively affect our business. COVID-19 has also caused volatility in the global financial markets and threatened a slowdown in the global economy, which may negatively affect our ability to raise additional capital on attractive terms or at all. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if we or any of the third parties with whom we engage, including the suppliers, contract manufacturers, clinical trial sites, regulators and other third parties with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted. It is also possible that global health concerns such as this one could disproportionately impact the clinical sites in which we conduct any of our clinical trials, which could have a material adverse effect on our business and our results of operation and financial condition.

In addition, a catastrophic event that results in the destruction or disruption of our data centers or our critical business or information technology systems would severely affect our ability to conduct normal business operations and, as a result, our operating results would be adversely affected.

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.

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 and the significant position of cash we need to have available to continue our business activities, our assets, earnings and cash flows are influenced by movements in exchange rates of several currencies. Our net sales and costs will be affected by fluctuations in the rate of exchange particularly between the U.S. dollar, our new functional currency as per January 1, 2021, and the euro, Swiss francs, Japanese Yen and British pounds, which are our main financing and potential revenue currencies beyond the U.S. dollar. The majority of our operating expenses are paid in euros, but we also receive payments and we regularly acquire services, consumables and materials in euros, Swiss francs and British pounds. As a result, our business may be affected by fluctuations in foreign exchange rates between the U.S. dollar and 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.

Recent developments relating to the United Kingdom's withdrawal from the European Union could adversely affect us.

The recent withdrawal of the United Kingdom from its membership in the European Union, often referred to as "Brexit", could lead to legal and regulatory uncertainty in the United Kingdom and may lead to the United Kingdom and European Union adopting divergent laws and regulations, including those related to the pricing of prescription pharmaceuticals, 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 pricing of prescription pharmaceuticals, we could face significant new costs. As a result, Brexit could impair our ability to transact business in the European Union and the United Kingdom.

The United Kingdom. and the EU have signed a EU-UK Trade and Cooperation Agreement, or TCA, which became provisionally applicable on January 1, 2021 and will become formally applicable once ratified by both the United Kingdom and the EU. This agreement provides details on how some aspects of the United Kingdom and EU's relationship will operate going forwards however there are still many uncertainties. The uncertainty concerning the United Kingdom's legal, political and economic relationship with the European Union may be a source of instability in the international markets, create significant currency fluctuations, and/or otherwise adversely affect trading agreements or similar cross-border co-operation arrangements (whether economic, tax, fiscal, legal, regulatory or otherwise).

These developments, or the perception that any of them could occur, have had, and may continue to have, a significant adverse effect on global economic conditions and the stability of global financial markets, and could significantly reduce global market liquidity and limit the ability of key market participants to operate in certain financial markets. In particular, it could also lead to a period of considerable uncertainty in relation to the United Kingdom financial and banking markets, as well as on the regulatory process in Europe. Asset valuations, currency exchange rates and credit ratings may also be subject to increased market volatility.

If other EU Member States pursue withdrawal, barrier-free access among the EEA overall could be diminished or eliminated. The long-term effects of Brexit will depend on how the terms of the TCA take effect in practice and any further agreements (or lack thereof) between the United Kingdom and the EU. Such a withdrawal from the EU is unprecedented, and it is unclear how the U.K. access to the European single market for goods, capital, services and labor within the EU, and the wider commercial, legal and regulatory environment, will impact our United Kingdom. operations.

We may also face new regulatory costs and challenges that could have an adverse effect on our operations and development programs. For example, the United Kingdom will lose the benefits of global trade agreements negotiated by the EU on behalf of its members, which may result in increased trade barriers that could make our doing business in the EU and the EEA more difficult. There may continue to be economic uncertainty surrounding the consequences of Brexit, which could adversely affect our financial condition, results of operations, cash flows and market price of our common stock.

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

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

We are subject to laws and regulations on tax levies and other charges or contributions in different countries, including transfer pricing and tax regulations for the compensation of personnel and third parties. Dealings between current and former group companies as well as additional companies that may form part of our group in the future are subject to transfer pricing regulations, which may be subject to change and could affect us. Compliance with these laws and regulations will be more challenging as we expand our international operations, including in connection with potential approvals of our product candidates in Europe, the United States and elsewhere.

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. For example, whether the tax authorities in Belgium will agree with argenx BV's qualifications and proposed application of patent box tax advantages will have a significant taxation impact on argenx BV. 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 unrecognized tax assets or credits that we have built over the years. For instance, as of December 31, 2020, we had €567.8 million of consolidated tax loss carry forwards. In general, some of these tax losses 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 BV may lose its tax loss carry forwards and other tax incentives 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 BV. The tax burden would increase if profits, if any, could not be offset against tax loss carry forwards.

Risks Related to the ADSs

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

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

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

- positive or negative results of testing and clinical trials by us, strategic partners or competitors;
- the outcome of regulatory review of our product candidates;
- 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 markets 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 compliance initiatives and corporate governance practices.

As a public company, and particularly now that we no longer qualify as an "emerging growth company" as defined in the U.S. Jumpstart Our Business Startups Act of 2012, we will continue to incur significant legal, accounting and other expenses that we did not incur as a public company listed on Euronext Brussels. We are a Dutch European public company with limited liability (Societas Europaea or SE). The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Select Market, or Nasdaq, and other applicable securities rules and regulations impose various requirements on non-U.S. reporting public companies, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our board of directors and other personnel are and will continue to be required to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, these rules and regulations 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.

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

Sales of a substantial number of ADSs or ordinary shares in the public market, or the perception that these sales might occur, could depress the market price of ADSs and ordinary shares and could impair our ability to raise capital through the sale of additional equity securities. We are also unable to predict the effect that such sales may have on the prevailing market price of ADSs and ordinary shares.

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

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

Moreover, because our ordinary shares currently trade on Euronext Brussels in euros, and the ADSs trade on the Nasdaq Global Select Market in U.S. dollars, fluctuations in the exchange rate between the U.S. dollar and the euro may result in temporary differences between the value of the ADSs and the value of our ordinary shares, which may result in heavy trading by investors seeking to exploit such differences. In order to finance the growth of our activities in the United States, we have invested in U.S. dollar denominated cash deposit accounts and in current financial assets with a significant portion of the proceeds from our initial U.S. public offering completed in May 2017 and our follow-on U.S. public offerings completed in December 2017, September 2018 and June 2020. Depending on the exchange rate fluctuations of the U.S. dollar, this may result in unrealized exchange rate losses which may impact negatively the reporting of our cash, cash equivalents and current financial assets at reporting dates when translating to euros these U.S. denominated cash deposits accounts and current financial assets. In addition, as a result of fluctuations in the exchange rate between the U.S. dollar and the euro, the U.S. dollar equivalent of the proceeds that a holder of the ADSs would receive upon the sale on Euronext Brussels of any ordinary shares withdrawn from the depositary and the U.S. dollar equivalent of any cash dividends paid in euros on our shares represented by the ADSs could also decline.

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

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

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

ADSs are transferable on the books of the depositary. However, the depositary may close its books at any time or from time to time when it deems expedient in connection with the performance of its duties. The depositary

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

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

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

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

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

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

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

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

Because we are a U.S.-listed public company, our board of directors will be required to devote substantial time to compliance initiatives and corporate governance practices.

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

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

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

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

We have a number of significant shareholders. For an overview of our current significant shareholders, please see "Item 7A.—Major Shareholders." As of the date of this annual report, these significant shareholders and their affiliates, in the aggregate, own approximately 68.22% of our ordinary shares and ADSs.

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

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

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

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

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

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

As a Dutch European public company with limited liability (*Societas Europaea* or *SE*), we are subject to the Dutch Corporate Governance Code, or the DCGC. The DCGC contains both principles and best practice provisions for board of directors, management boards, supervisory boards, shareholders and general meetings of shareholders, financial reporting, auditors, disclosure, compliance and enforcement standards. The DCGC applies to all Dutch companies listed on a regulated market, including Euronext Brussels. The principles and best practice provisions apply to our board of directors (in relation to role and composition, conflicts of interest and independency requirements, board committees and remuneration), shareholders and the General Meeting (for example, regarding anti-takeover protection and our obligations to provide information to our shareholders) and financial reporting (such as external auditor and internal audit requirements). We do not comply with all the best

practice provisions of the DCGC. As a Dutch company, we are required to disclose in our annual report, filed in the Netherlands, whether we comply with the provisions of the DCGC. If we do not comply with the provisions of the DCGC (for example, because of a conflicting Nasdaq requirement or otherwise), we must list the reasons for any deviation from the DCGC in our annual report. See “Item 16.G.—Corporate Governance.”

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

We are incorporated under the laws of the Netherlands. 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 be enforceable in Belgium. This will depend on the applicable Dutch or Belgian national rules.

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 the enforceability in Belgium of a U.S. final and conclusive judgment, a declaration of enforceability by a Belgian judge will have to be obtained via a specific court procedure. A U.S. judgment will not be declared enforceable in Belgium if it infringes upon one or more of the grounds for refusal listed in the 2004 Belgian Code of Private International Law, or the PIL Code. Based on the same grounds for refusal, the recognition and enforcement of a U.S. judgment may be challenged before the Belgian judge. Notably, enforcement and recognition need to be refused if (a) due process has not been observed, (b) the Belgian courts have exclusive jurisdiction to determine the matter or (c) the effect of recognizing this judgment or declaring it enforceable would be manifestly incompatible with Belgium's (international) public policy principles. Punitive damages awards for example may be denied recognition and enforcement under the latter refusal ground. In the review of the request for enforcement or the challenge of the recognition of a U.S. judgment, the Belgian judge will not, however, review the merits of the case, nor does any reciprocity requirement apply. Enforcement and recognition of judgments of U.S. courts in Belgium are solely governed by the provisions of the PIL Code.

Under the PIL Code, in addition to the possibility of being recognized and enforced, before a Belgian court, a U.S. judgment may also serve as evidence of the factual determination of the U.S. judge provided that (i) it meets the conditions required for the authenticity of judgments according to relevant U.S. laws and (ii) the consequences thereof would not be manifestly contrary to Belgium’s (international) public policy principles.

U.S. judgments ordering to pay a certain amount that are declared enforceable in Belgium are subject to the applicable registration tax in the same way as Belgian judgments. As such, a registration tax at the rate of 3% of the amount awarded is payable by the debtor(s), if the sum of money exceeds €12,500. If multiple debtors were held jointly liable to pay, the debtors are also jointly liable to pay the registration tax.

A stamp duty is payable as of the second certified copy, with a maximum of €1,450.

In light of the 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 with regard to such matters and intend to furnish quarterly unaudited financial information to the SEC on Form 6-K.

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

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

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

We are a foreign private issuer, and therefore we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers. We may no

longer be a foreign private issuer as of June 30, 2021 (the end of our second fiscal quarter), 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, 2022 and would also trigger a 10-K filing for the year ended December 31, 2021. 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, 2021, we believe at least 50% of our outstanding ordinary shares were held by U.S. residents (assuming that all our ordinary shares represented by ADSs were held by residents of the United States). If we lose this status, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC and Nasdaq rules. The regulatory and compliance costs to us under U.S. securities laws if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be significantly higher than the cost we would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities highly time consuming and costly. We also expect that if we were required to comply with the rules and regulations applicable to U.S. domestic issuers, it would make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our board of directors.

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 and is required to issue an annual report on internal control over financial reporting, and our independent registered public accounting firm is now required to undertake an assessment of our internal control over financial reporting, which could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation. The rules governing the standards that must be met for our management to assess our internal control over financial reporting pursuant to Section 404 of the Sarbanes- Oxley Act are complex and require significant documentation, testing and possible remediation. These stringent standards require that our audit and compliance committee be advised and regularly updated on management’s review of internal control over financial reporting in connection with issuing our consolidated financial statements as of and for the year ended December 31, 2020.

Moreover, if we are not able to comply with the requirements of Section 404 applicable to us in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of the ADSs or ordinary shares could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources. Furthermore, investor perceptions of our company may suffer if deficiencies are found, and this could cause a decline in the market price of the ADSs or ordinary shares. Irrespective of compliance with Section 404, any failure of our internal control over financial

reporting could have a material adverse effect on our stated operating results and harm our reputation. If we are unable to implement these requirements effectively or efficiently, it could harm our operations, financial reporting, or financial results and could result in an adverse opinion on our internal control over financial reporting from our independent registered public accounting firm.

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

The trading market for the ADSs and ordinary shares depends 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 and ordinary shares would likely be negatively affected. If one or more of the analysts who cover us downgrade the ADSs or ordinary shares or publish inaccurate or unfavorable research about our business, the price of the ADSs or ordinary shares 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 or ordinary shares could decrease, which might cause the price of the ADSs or ordinary shares and trading volume to decline.

We believe that we were not classified as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes for the 2020 taxable year, and do not anticipate being classified as a PFIC for U.S. federal income tax purposes for the 2021 taxable year, but this conclusion is a factual determination that is made annually and thus is subject to change. If we were to be classified 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.”

We do not believe that we were classified as a PFIC for the 2020 taxable year and, 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 classified as a PFIC with respect to the 2021 taxable year. However, our status as a PFIC is a fact-intensive determination made on an annual basis, and we cannot provide any assurances regarding our PFIC status for the current, prior or future taxable years.

ITEM 4. INFORMATION ON THE COMPANY

A. HISTORY AND DEVELOPMENT OF THE COMPANY

Our legal and commercial name is argenx SE. We were incorporated under the laws of the Netherlands on April 25, 2008 as a private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*). From incorporation until August 28, 2009, our research and development activities were initially performed in the Netherlands, then Belgium, by argenx N.V and its legal predecessors. Since August 28, 2009, all our research and development activities have been performed by our wholly owned subsidiary, argenx BV, under a license provided by argenx N.V. Throughout this time, argenx BV assigned all resulting intellectual property to argenx N.V. 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*). On May 5, 2017, we transferred the legal ownership of all intellectual property rights of argenx SE to argenx BV, effective retroactively as of January 1, 2017. As a result, as of January 1, 2017, (i) argenx BV holds all legal and economic ownership of our intellectual property rights, and (ii) the research and development agreement between argenx SE and argenx BV has been terminated.

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 SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at http://www.sec.gov. The registered agent for service of process in the United States is CT Corporation System, with an address at 111 8th Avenue, New York, NY 10011.

Our actual capital expenditures for the years ended December 31, 2020, 2019 and 2018 amounted to €4.5 million, €41.7 million and €0.7 million respectively. These capital expenditures primarily consisted of acquired In-Process R&D, office and laboratory equipment and information technology equipment. We expect our capital expenditures to increase in absolute terms in the near term as we continue to advance our research and development programs and grow our operations. We anticipate our capital expenditure in 2021 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.”

B. BUSINESS OVERVIEW

We are a clinical-stage biotechnology company developing a deep pipeline of differentiated therapies for the treatment of severe autoimmune diseases and cancer. We have a particular focus on neuromuscular and hematology indications within our franchises. Our suite of antibody technologies and our Immunology Innova-tion Program, or IIP, exploring novel disease biology enables us to focus 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. Through our "argenx 2021" vision, we are on track to becoming a global, fully integrated company with the potential launch of our first product, efgartigimod, in the United States in 2021, if approved.

Our suite of technologies

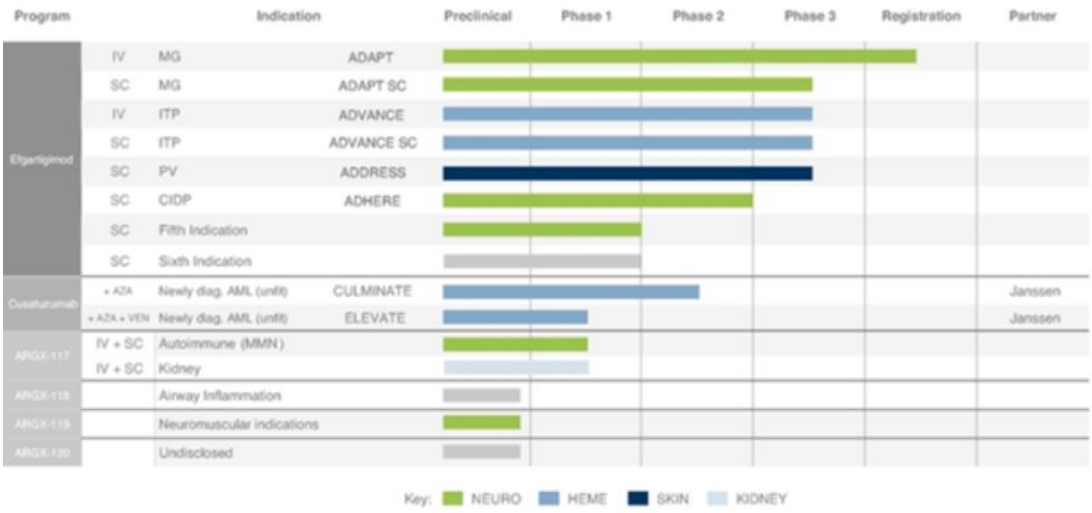
Our product candidates are focused on indications for which there is a solid biological rationale and for which we believe there is an advantage to utilizing our suite of proprietary and licensed technologies. Together with our antibody discovery and development expertise, this suite of technologies has enabled us to build our broad pipeline of product candidates, across all stages of development and we believe will ensure continuous development of innovative and relevant programs. Our key technologies are outlined below:

- Our proprietary SIMPLE Antibody™ Platform—Our SIMPLE Antibody™ Platform, based on the powerful llama immune system, together with the IIP allows us to exploit novel and complex targets, and our antibody engineering technologies are designed to enable us to expand the therapeutic index of our product candidates. The 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 towards an antigen, which is a substance that induces an immune response, and is specific for every 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 screening platforms use 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 potentially minimizing the long timelines associated with generating antibody candidates using traditional methods.

- Our proprietary engineering technologies— NHance®, ABDEG™, POTELLIGENT®, and DHS mutations—focus on engineering the Fc region of antibodies in order to augment their intrinsic therapeutic properties. In addition, we obtained a non-exclusive research license and option for the SMART-Ig® and ACT-Ig® technologies. 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 potentially modifying their half-life, tissue penetration, rate of disease target clearance and potency.

- Halozyme's ENHANZE® subcutaneous drug delivery technology for which we have exclusive access for the FcRn and C2 targets and four additional targets. The global collaboration and license agreement with Halozyme was announced in February 2019 and extended in October 2020. The ENHANZE® technology has the potential to shorten drug administration time, reduce healthcare practitioner time, and offer additional flexibility and convenience for patients.

The following table summarizes key information on our portfolio of lead product candidates as of the date of this registration document:



Our programs

Efgartigimod

In June 2018, we reported data from a Phase 1 clinical trial indicating that at the same dose level the SC formulation was comparable across key measures, including half-life, pharmacodynamics, or PD, and tolerability, to the IV formulation used in clinical studies to date. In July 2019, we also evaluated a SC formulation of efgartigimod developed incorporating the ENHANZE® drug delivery technology (licensed from Halozyme) in a Phase 1 clinical trial in healthy volunteers, which demonstrated retained PD profile of IV-formulated efgartigimod. Pursuant to our global collaboration and license agreement with Halozyme, we have exclusive access to Halozyme's ENHANZE® subcutaneous drug delivery technology for the FcRn and C2 targets and four additional targets we have not yet selected for an exclusive commercial license. We believe the ENHANZE® technology could potentially shorten drug administration time, reduce healthcare practitioner time and offer additional flexibility and convenience for patients. We continue to explore efgartigimod's pipeline-in-a-product opportunity and we therefore intend to announce a fifth and sixth indication for efgartigimod in 2021 and have planned to begin enrollment in clinical trials in each of the fifth and sixth indications of efgartigimod this year.

Also, in December 2018 we successfully completed the Phase 2 clinical trial for efgartigimod in immune thrombocytopenia, or ITP, a rare hematological autoimmune disorder, and reported proof-of-concept for our lead product candidate in a second indication with strong clinical improvement observed over placebo. These Phase 2 trial results have been published in the peer-reviewed journal Hematology in December 2019. In October 2020, we announced an updated plan for a potential registration program to include two Phase 3 trials to run concurrently. The first potential registrational Phase 3 trial of IV efgartigimod in ITP, the ADVANCE trial, was initiated in the fourth quarter of 2019 to evaluate a dose of 10 mg/kg IV efgartigimod. We expect to enroll 156 patients in this Phase 3 trial. The second potential registrational Phase 3 trial of SC efgartigimod in ITP, the ADVANCE-SC trial was initiated in the fourth quarter of 2020 to evaluate a dose of 1000 mg SC efgartigimod. We expect to enroll 156 patients in this trial as well.

At the end of 2019, we announced the initiation of a proof-of-concept Phase 2 clinical trial evaluating SC efgartigimod (co-formulated with Halozyme's ENHANZE® drug-delivery technology), the ADHERE trial, in chronic demyelinating polyneuropathy, or CIDP, a rare neurological autoimmune disease.

In May 2020, we presented updated interim detailed proof-of-concept data from a Phase 2 clinical trial of efgartigimod for the treatment of a third indication, pemphigus vulgaris, or PV, and pemphigus foliaceous, rare autoimmune blistering (skin) diseases, at the Society for Investigative Dermatology, or SID, Virtual Annual Meeting. The presentation included updated data from 34 evaluable patients treated with 10 mg/kg or 25 mg/kg of IV efgartigimod through March 25, 2020. Consistent with previously announced data, rapid disease control and clinical remission was observed with a favorable tolerability profile. We started a potential registrational Phase 3 trial of SC efgartigimod, the ADDRESS trial, for the treatment of PV in the fourth quarter of 2020, in which we will enroll 150 patients or fewer dosed with 1000 mg SC efgartigimod. The ADDRESS trial will evaluate efficacy and safety, including the potential to drive fast onset of disease control and complete remission and the ability to taper corticosteroids.

In May 2020, we also announced positive topline results from our first Phase 3 trial, the ADAPT trial, for intravenous, or IV, efgartigimod, or ARGX-113, our most advanced product candidate targeting FcRn for the treatment of the rare neurological autoimmune disease generalized myasthenia gravis, or gMG. The topline results from the ADAPT trial showed that efgartigimod was well-tolerated and able to drive responses that support plans to offer individualized dosing to gMG patients. In October 2020, we announced additional data from the ADAPT trial, which reinforced the topline data in May 2020 and in December 2020, we submitted the Biologics License Application, or BLA, for efgartigimod in gMG. We are also on track to submit a Japanese Marketing Authorization Application to Japan’s Pharmaceuticals and Medical Devices Agency in the first half of 2021 and to submit a Marketing Authorization Application to the European Medicines Agency in the second half of 2021. A Market Authorization submission in China is expected to occur shortly following potential approval in the United States.

In January 2021, we initiated a bridging study for subcutaneous, or SC, efgartigimod in gMG based on an association between total IgG reduction and clinical benefit, and feedback from the U.S. Food and Drug Administration, or FDA. The study is a registrational, non-inferiority trial comparing the pharmacodynamic effect of 1000 mg SC efgartigimod with 10 mg/kg IV efgartigimod and is expected to enroll approximately 50 patients.

In February 2021, we announced a "GO" decision to transition into the second, placebo controlled stage of this trial based on a planned efficacy and safety assessment following the enrollment of 30 patients into the initial part of the ADHERE trial. See ‘‘—Recent developments—Interim analysis from ADHERE trial’’ below. In the Phase 3 ADAPT study in gMG, as well as in the Phase 2 studies in gMG, ITP, PV and CIDP to date, efgartigimod was observed to have a favorable tolerability profile consistent with that observed in our Phase 1 clinical trials.

In March 2021, the BLA for treatment of efgartigimod in gMG was accepted for review by the FDA, with an action date set for December 17, 2021 under the Prescription Drug User Free Act, the PDUFA.

In March 2021, we launched our pre-approval access program (PAA) in the U.S. and Europe to open availability of efgartigimod to people living with gMG who have a high degree of unmet clinical need and are not able to participate in a clinical trial.

Cusatuzumab

Beyond efgartigimod, we co-develop our second lead product candidate, cusatuzumab, or ARGX-110, (targeting CD70) with our collaborator, Cilag GmbH International, an affiliate of the Janssen Pharmaceutical Companies of Johnson & Johnson, or Cilag, for the rare and aggressive hematological cancer acute myeloid leukemia, or AML, as well as high-risk myelodysplastic syndrome, or MDS. In December 2016, we initiated the dose-escalation part of the Phase 1/2 clinical trial of cusatuzumab in combination with azacytidine. In December 2018, we initially reported a 92% response rate in the treated group of newly diagnosed AML patients, which we updated in December 2019 to a 100% response rate. The transition into the Phase 2 part of this clinical trial was announced in August 2018. In the first half of 2020, the Part 1 dose escalation of this Phase 1 study was published in Nature Medicine.

In July 2020, we announced that the development strategy for clinical trials of cusatuzumab initiated under the global cusatuzumab collaboration and licensing agreement with Cilag has been aligned with the evolving

treatment landscape and anticipated global adoption of venetoclax in acute myeloid leukemia, or AML, clinical practice.

In January 2021, we announced interim data from the Phase 2 CULMINATE trial, evaluating cusatuzumab in combination with azacitidine in newly-diagnosed, elderly AML patients who are ineligible for intensive chemotherapy. The 20 mg/kg dose has been selected for ongoing and future trials. Cusatuzumab was observed to be well-tolerated and the safety data were consistent with prior studies. Final results from the CULMINATE trial will be presented in a peer-reviewed forum. The decision to initiate additional studies in the development of cusatuzumab, under the collaboration agreement with Cilag, will be determined following review of data from the ongoing Phase 1b ELEVATE trial, which is evaluating cusatuzumab in combination with venetoclax and azacitidine in newly-diagnosed, elderly patients with AML who are ineligible for intensive chemotherapy. This trial is enrolling again after a pause due to COVID-19.

ARGX-117, ARGX-118 and Immunology Innovation Program

In May 2019, we announced the addition of two new therapeutic candidates discovered via our IIP, ARGX-117 and ARGX-118, to our proprietary antibody pipeline. ARGX-117 targets the complement compound C2 with potential in severe autoimmune indications. In the third quarter of 2020, we initiated a Phase 1 healthy volunteer trial of IV and SC ARGX-117 to evaluate safety and tolerability and establish a dosing regimen. Following analysis of Phase 1 data, we plan to launch a Phase 2 proof-of-concept trial in multifocal motor neuropathy within our neuromuscular franchise and to develop ARGX-117 in additional autoimmune indications. ARGX-118 is designed to address Galectin-10 and targets airway inflammation. Two new therapeutic candidates have been added to our pipeline from our IIP, ARGX-119, which is a program that will focus on neuromuscular disease, and ARGX-120, which will focus on an undisclosed target.

Partnerships

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 potential and benefits in disease areas or patient populations that are better served by the resources of larger biopharmaceutical companies. As such, we have entered into collaborations with a number of biopharmaceutical companies, including our collaborations with Zai Lab and Cilag.

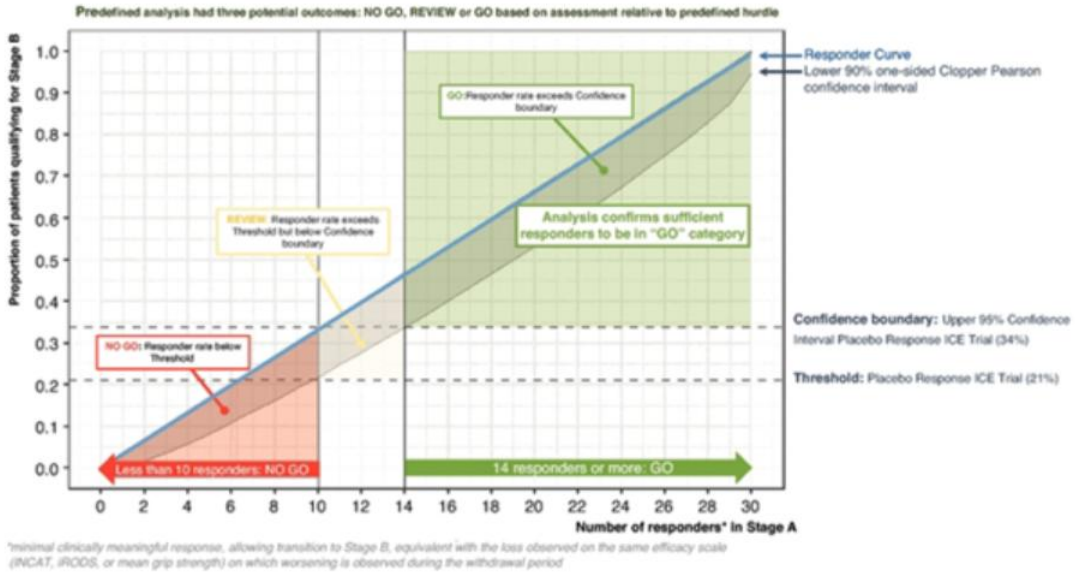
In January 2021, we entered into an exclusive license agreement with Zai Lab Limited, or Zai Lab, for the development and commercialization of efgartigimod in China, Taiwan, Hong Kong and Macau and the acceleration of efgartigimod development through Phase 2 proof-of-concept trials in new autoimmune indications. Zai Lab will also contribute Chinese patients to argenx's global Phase 3 trials of efgartigimod. Under the terms of the agreement, we are entitled to receive $175 million in collaboration payments comprised of upfront Zai Lab equity of $75 million (received in January 2021), a $75 million guaranteed development cost-sharing payment, and a $25 million milestone payment upon U.S. efgartigimod approval. We will also be eligible for tiered royalties based on annual net sales of efgartigimod in China, Taiwan, Hong Kong and Macau.

In January 2019, we received a $300 million upfront payment pursuant to collaboration with Cilag and Johnson & Johnson Innovation Inc. invested €176.7 million (approximately $200.0 million based on the exchange rate in effect as of the date the agreement was signed) in the form of an equity investment. Under our collaboration with Cilag, in December 2019, we announced the achievement of our first milestone of $25 million for achievement of an enrollment milestone in first Phase 2 trial. In addition, in August 2018, our collaborator AbbVie S.A.R.L, or AbbVie, exercised its exclusive option to license ARGX-115 (now referred to as ABBV-151), a cancer immunotherapy-focused product candidate against the novel target glycoprotein A repetitions predominant. In March 2019, AbbVie started a first-in-human clinical trial with ABBV-151, triggering a $30 million milestone payment by AbbVie to us.

Recent developments

Interim analysis from ADHERE trial

On February 1, 2021, we announced our plan to continue enrollment in the ADHERE trial evaluating SC efgartigimod in CIDP. The ADHERE trial is expected to enroll approximately 130 patients in total to support potential registration of SC efgartigimod for the treatment of CIDP. The "GO" decision was based on an initial efficacy and safety assessment following the enrollment of 30 patients into the initial part of the ADHERE trial. The interim analysis achieves the pre-defined threshold for continuation, which was based on response rates seen in precedent clinical trials of current standard of care in CIDP. The decision to continue enrollment was confirmed by an independent data monitoring committee. In addition, the safety and tolerability data observed to date is consistent with that of efgartigimod in other clinical trials.



Interim results from the Cusatuzumab CULMINATE Phase 2 trial

In January 2021, we announced interim data from the Phase 2 CULMINATE trial, evaluating cusatuzumab in combination with azacitidine in newly-diagnosed, elderly AML patients who are ineligible for intensive chemotherapy. A total of 103 patients were randomized to receive either 10 mg/kg (n=51) or 20 mg/kg (n=52) cusatuzumab plus azacitidine as part of a dose identification. The 20 mg/kg dose has been selected for ongoing and future trials. A pre-planned interim analysis was conducted of the 52 patients (46.2% adverse ELN risk classification) receiving 20 mg/kg cusatuzumab plus azacitidine treatment (intent-to-treat population, or ITT). The results from the ITT analysis showed a complete remission, or CR, rate of 27% (14/52) and composite complete remission, or CRc, including CRs with incomplete hematologic recovery, rate of 40% (21/52). The 30-day mortality rate of the ITT population was 9.6% (5/52). In a cohort where patients received at least two treatment cycles (20 mg/kg cusatuzumab plus azacitidine), 42% (14/33) achieved CR and 64% (21/33) achieved CRc. Cusatuzumab was observed to be well-tolerated and the safety data were consistent with prior studies. Final results from the CULMINATE trial will be presented in a peer-reviewed forum.

Priority Review Voucher

In November 2020, we announced the agreement to acquire an FDA Priority Review Voucher, or PRV, from Bayer Healthcare Pharmaceuticals, Inc. for $98 million. A PRV entitles the holder to FDA priority review of a single New Drug Application or BLA, which reduces the target review time and may potentially lead to an

expedited approval. We expect to redeem the PRV for a future marketing application for efgartigimod. We will not use the PRV for the BLA submission of IV efgartigimod in gMG.

Strategy and Objectives

Strategy

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

- **Rapidly advance efgartigimod in MG and four additional indications.** We are currently developing our lead product candidate, efgartigimod, for the treatment of patients with MG, ITP, PV and CIDP and plan to start proof-of-concept clinical development in a fifth and sixth indication later in 2021. We chose these indications based on the biological rationale of targeting the neonatal Fc receptor, or FcRn, thereby reducing the pathogenic immunoglobulin G, or IgG, antibody levels that drive all of these disease states.

- **Advance cusatuzumab in AML, MDS and adjacent hematological tumors.** In December 2016, we initiated an open-label, Phase 1/2 clinical trial of cusatuzumab in combination with the standard of care, azacytidine, in newly diagnosed AML and high-risk MDS patients. We reported topline results from the dose-escalation part of this clinical trial in December 2018, and we announced the transition into the Phase 2 part of this clinical trial in August 2018. In December 2018, we and our partner Cilag (Janssen) agreed to a joint global clinical development plan to evaluate cusatuzumab in AML, MDS and other potential future indications. In 2019, we initiated a dose-confirming Phase 2 trial, CULMINATE, of cusatuzumab in combination with azacytidine in newly diagnosed elderly AML patients who are unfit for intensive chemotherapy, with topline data announced early 2021. Additionally, a Phase 1b platform study was launched to study combinations with standard AML therapies with the first trial exploring combinations of venetoclax, cusatuzumab and azacytidine. The decision to initiate additional studies in the development of cusatuzumab, under the collaboration, will be determined following review of data from this ongoing Phase 1b trial.

- **Expand applications for our existing product candidates.** Our goal is to maximize the commercial potential of our existing product candidates by exploring additional indications, as well as formulations that may expand the target patient populations within existing indications. For example, our development work in efgartigimod is based on its ability to reduce circulating IgG antibodies, and this has given us the ability to leverage a single Phase 1 clinical trial in healthy volunteers into seven global trials in different indications, MG, ITP, PV and CIDP where we believe this mechanism of action may have therapeutic benefit. In addition, we believe there are other autoimmune diseases that may benefit from treatment with efgartigimod. We plan to employ a similar strategy of leveraging the strong biological rationale for other product candidates into multiple indications, thereby maximizing the value of our pipeline. We also expanded the use of our product candidates in existing indications by developing new formulations, such as a subcutaneous version of efgartigimod, which was tested in a Phase 1 healthy volunteer clinical trial, that may make our product candidates accessible to larger patient populations, including patients requiring chronic therapy, potentially outside of the hospital setting.

- **Focus our discovery and development efforts on novel and complex targets to generate new first-in-class and best-in-class product candidates for autoimmune diseases and hematology/cancer.** Our SIMPLE Antibody™ Platform together with the IIP allows us to explore novel disease biology and pathways, 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 and drug delivery technologies will allow us to augment our antibodies for maximum therapeutic effect.

- **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 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.

- **Implement our "argenx 2021" vision to become a global, fully integrated, novel immunology company and 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 ourselves, 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. As part of this strategy, we are building two commercial franchises in neuromuscular and hematology/oncology disorders, with the potential to expand into a third franchise in skin and kidney diseases. In 2021, we expect to launch efgartigimod in the U.S. in its first indication of generalized MG, or gMG, if approved. Through the building of commercial franchises, we plan to leverage capabilities and an organizational footprint for subsequent potential launches across our broad immunology pipeline.

- **Continue to build innovation into every step of our development, highlighted by our collaborative Immunology Innovation Program (formerly known as Innovative Access Program) translating immunology breakthroughs into medicines.** The Immunology Innovation Program (IIP) is our core business strategy connecting the specialized insight into disease and target biology of our external scientific and academic collaborators with our unparalleled experience as antibody engineers. Co-creation has led to a deep pipeline of highly differentiated product candidates. Through the IIP, we hope to together transcend breakthrough research and publications to our ultimate and unifying mission of creating new potential treatment options for patients. In 2019 we announced two new assets, ARGX-117 and ARGX-118 and in 2021 we will announce ARGX-119. These potential therapeutics were developed in close collaboration with world leading academic research groups.

Competitive position

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, and a multitude of companies involved in the creation, development and commercialization of novel therapeutics. These companies are highly sophisticated and often strategically collaborate with each other.

We compete with a wide range of pharmaceutical companies, biotechnology companies, academic institutions and other research organizations for novel therapeutic antibody targets, new technologies for optimizing antibodies, talent, financial resources, intellectual property rights and collaboration opportunities. Many of our competitors and potential competitors have substantially greater scientific, research and product development capabilities as well as greater financial, manufacturing, marketing and sales and human resources than we do. In addition, there is intense competition for establishing clinical trial sites and registering patients for clinical trials. Many specialized biotechnology firms have formed collaborations with large, established companies

to support the research, development and commercialization of products that may be competitive with ours. Accordingly, our competitors may be more successful than we may be in developing, commercializing and achieving widespread market acceptance.

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

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

There are several monoclonal antibody drug discovery companies that may compete with us in the search for novel therapeutic antibody targets, including Adimab LLC; Merus N.V.; Regeneron Pharmaceuticals, Inc.; Xencor Inc. and MorphoSys AG. We are aware that a product candidate in development by Scholar Rock, Inc. may compete with ARGX-115 (ABBV-151) and a product candidate in development by Ionis Pharmaceuticals, Inc. may compete with STT-5058 (formerly ARGX-116), if they are approved.

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, and hematological/oncological diseases for which the current treatment paradigm is inadequate. Our competitive strengths include:

- **Efgartigimod: Phase 3 product candidate with clinical proof-of-concept in MG, ITP and PV; pipeline-in-a-product opportunity in seven global clinical trials and two additional indications are selected.** We launched a Phase 3 clinical trial in MG for our lead product candidate, efgartigimod, in September 2018 and announced topline data of the Phase 3 in May 2020. In addition, the bridging study with SC ENHANZE® efgartigimod was launched by the end of 2020. We also announced full data from the Phase 2 clinical trial in ITP in December 2018 and launched a Phase 3 clinical trial, ADVANCE and ADVANCE SC in this indication at the end of 2019 and 2020 respectively. Also, at

the end of 2019 we initiated a Phase 2 clinical trial, ADHERE, of SC ENHANZE® efgartigimod in CIDP, and we reported interim data of the Phase 2 clinical trial of efgartigimod in PV in May 2020. MG, ITP, PV and CIDP are rare, severe autoimmune diseases with high unmet medical need. Each indication is characterized by high levels of pathogenic or IgG antibodies, and we specifically designed efgartigimod to reduce IgG antibody levels. In a Phase 1 clinical trial of efgartigimod with healthy volunteers, we observed a reduction of circulating IgG antibody levels of 50% to 85%. We believe that a reduction of pathogenic IgG antibody levels, which are a subset of circulating IgG antibodies in people with autoimmune disease, of at least 30% would be clinically meaningful. In addition, all patients in the treatment arm of our Phase 3 clinical trial in MG showed a rapid and deep reduction of their total IgG levels and disease improvement was found to correlate with reduction in pathogenic IgG levels. The treated ITP patients in the Phase 2 clinical trial showed a correla-tion between IgG reduction, platelet counts increase and reduction of bleeding events. In addition, interim data from the treated PV patients showed a rapid disease control in 28 out of 31 patients and complete clinical remission was observed in 7 out of 10 patients receiving the optimized dosing regimen. Based on these data, we believe efgartigimod is a pipeline-in-a-product opportunity in these, and potentially other, indications.

- **Productive discovery capabilities through our IIP 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, hematological disorders and cancer. Leveraging our technology suite and clinical expertise, we have advanced six product candidates into late-stage clinical development —efgartigimod, cusatuzumab, ARGX-111, ARGX-109, LP0145 (formerly ARGX-112) and ARGX-115 (ABBV-151); three into the preclinical stage — STT-5058 (formerly ARGX-116), ARGX-117 and ARGX-118; and we currently have multiple programs in the discovery stage. 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, combined with our IIP allows us to explore novel disease biology,and 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 proprietary Fc engineering technologies to modulate immune response.** We employ technologies—NHance®, ABDEG™ and POTELLIGENT®—that focus on engineering the Fc region of antibodies in order to augment their intrinsic therapeutic properties. These technologies are designed to expand the therapeutic index of our product candidates by modifying their half-life, tissue penetration, rate of disease target clearance and potency.

- **Validating strategic collaborations to maximize pipeline value or access complementary technology.** Our productive discovery capabilities and deep pipeline have provided us with multiple product candidates for which we seek to capture the greatest value. We have partnered, and expect to continue to partner, product candidates that we believe have promising utility in disease areas or patient populations that are better served by the resources of larger biopharmaceutical companies. As a result, we have entered into collaborations with a number of biopharmaceutical companies, including our collaboration with Janssen for cusatuzumab, our product candidate targeting CD70 for rare and aggressive hematological cancers and with AbbVie for ARGX-115 (ABBV-151), a cancer immunotherapy-focused product candidate against the novel target GARP. In addition, we seek partnerships with companies that have complementary technologies. For instance, under the global collaboration and license agreement we have with Halozyme for their ENHANCE® subcutaneous

drug delivery technology for which we have access for up to six targets, including exclusive rights to develop therapeutic products targeting human neonatal Fc receptor FcRn. Under the terms of the agreement, we paid an upfront payment of $30 million to Halozyme with potential future payments up to $160 million per selected target subject to achievement of specified development, regulatory and sales based milestones.

Our Product Candidates

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 enables us to create product candidates with potential first-in-class and best-in-class therapeutic activity against a wide range of targets.

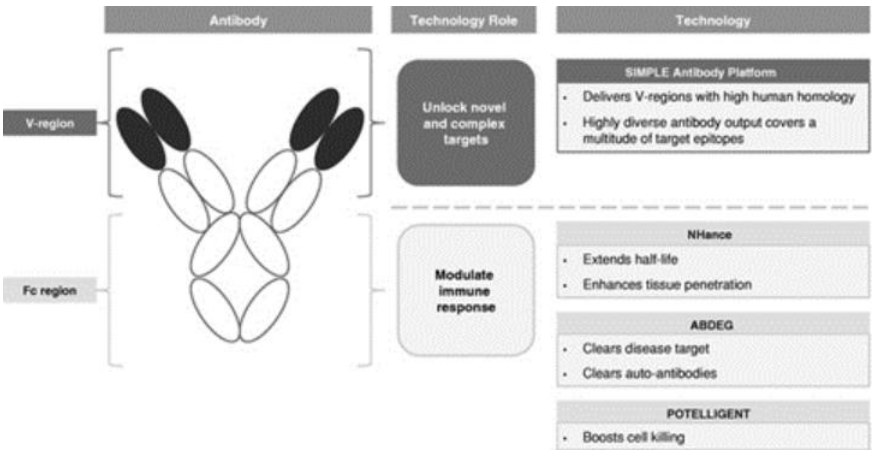


Figure 1: Overview of our suite of technologies

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 proprietary Fc Engineering Technologies

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

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

An illustration of the FcRn-mediated antibody recycling mechanism is shown in Figure 2. ❶ Serum proteins, including IgG antibodies, are routinely removed from the circulation by cell uptake. ❷ Antibodies can bind to FcRn, which serves as a dedicated recycling receptor in the endosomes, which have an acidic environment, and then ❸A return to the circulation by binding with their Fc region to FcRn. ❸B Unbound antibodies end up in the lysosomes and are degraded by enzymes. Because this Fc/FcRn interaction is highly pH-dependent, antibodies tightly bind to FcRn at acidic pH (pH 6.0) in the endosomes but release again at neutral pH (pH 7. 4) in the circulation.

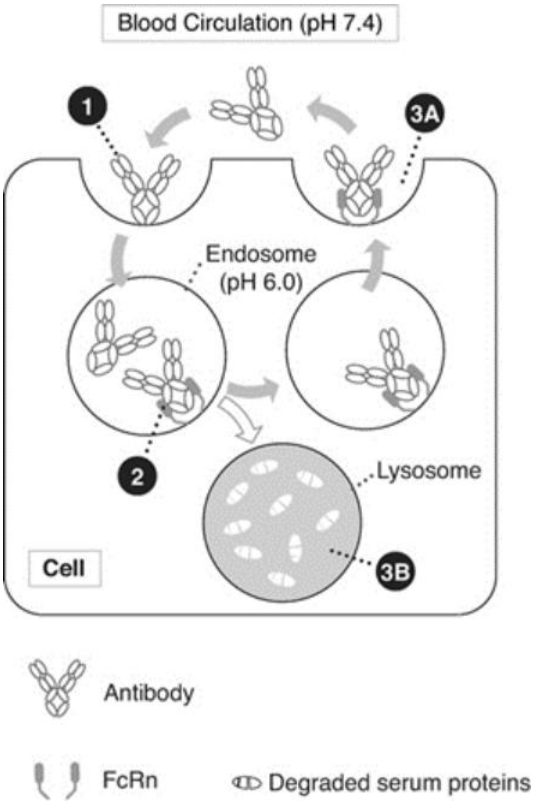


Figure 2: The FcRn-mediated recycling mechanism

NHance®

NHance® refers to two mutations that we introduce into the Fc region of an IgG antibody. NHance® is designed to extend antibody serum half-life and increase tissue penetration. In certain cases, it is advantageous to engineer antibodies that remain in the circulation longer, allowing them to potentially exert a greater therapeutic effect or be dosed less frequently. As shown in *Figure 3*, ❶ NHance® antibodies bind to FcRn with higher affinity, specifically under acidic pH conditions. ❷ Due to these tighter bonds, NHance® FcRn-mediated antibody recycling is strongly favored over lysosomal degradation, although some degradation does occur. ❸ NHance® allows a greater proportion of antibodies to return to the circulation potentially resulting in increased bioavailability and reduced dosing frequency. ARGX-111, ARGX-109, ARGX-117 and a number of our discovery-stage programs utilize NHance®.

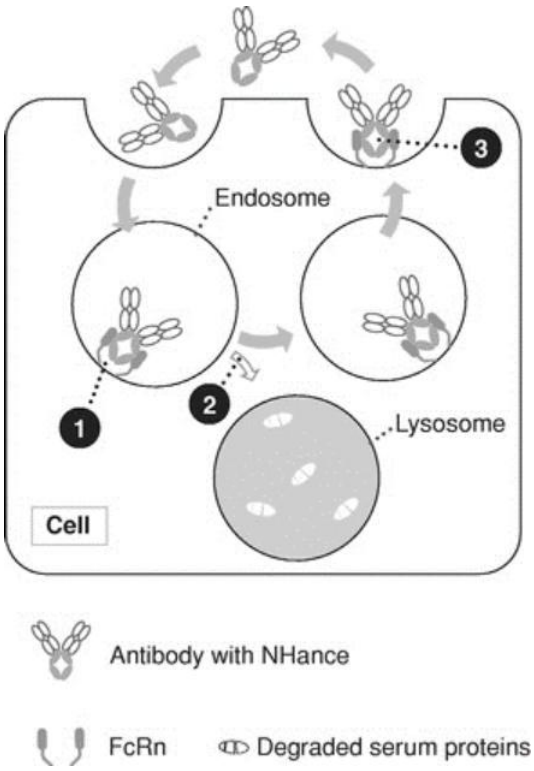


Figure 3: NHance® mutations favor the FcRn-mediated recycling of IgG antibodies

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 autoantibodies. We use our ABDEG™ technology to reduce the level of these pathogenic autoantibodies in the circulation by increasing the rate at which they are cleared by the lysosomes. ABDEG™ is a component in a number of our product candidates, including efgartigimod.

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

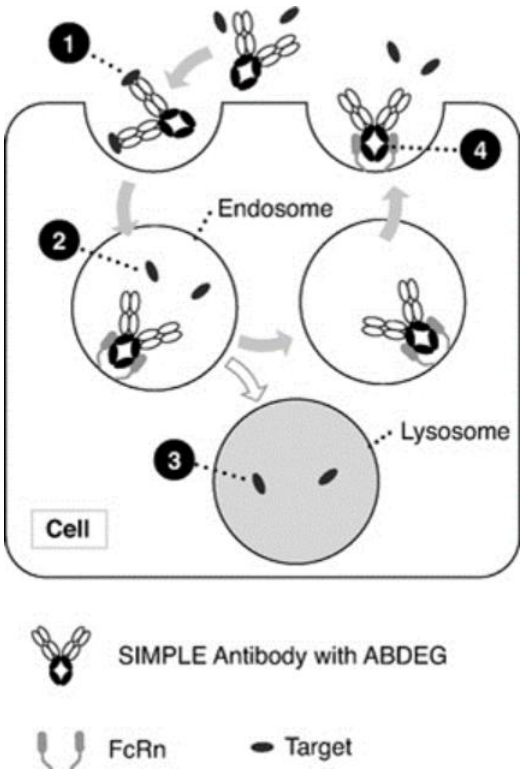


Figure 4: SIMPLE Antibody™ and ABDEG™ technologies work in concert to sweep disease targets

POTELLIGENT®: Modulation of Fc Interaction with NK Cells

POTELLIGENT® modulates the interaction of the Fc region with the Fc gamma receptor IIIa located on specialized immune cells, known as NK cells. These NK cells can destroy the target cell, resulting in enhanced ADCC. POTELLIGENT® changes the Fc structure by excluding a particular sugar unit such that it enables a tighter fit with the Fc gamma receptor IIIa. The strength of this interaction is a key factor in determining the killing potential of NK cells. An independent publication reported that the exclusion of this sugar unit of the Fc region increases the ADCC-mediated cell-killing potential of antibodies by 10- to 1000-fold. Cusatuzumab and ARGX-111 utilize POTELLIGENT® (source: Expert Opin Biol Ther 2006; 6:1161-1173; http://www.tandfonline.com/doi/full/10.1517/14712598.6.11.1161%20).

Our Wholly-Owned Programs

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

Efgartigimod (formerly referred to as ARGX-113)

We are developing our lead product candidate, efgartigimod, for the treatment of patients with MG (Phase 3), ITP (Phase 3), PV (Phase 2; Phase 3) and CIDP (Phase 2/3), all of which are rare and severe autoimmune diseases associated with high levels of circulating pathogenic IgG antibodies for which there are few innovative biologic treatments and a severe unmet medical need exists. We expect to start clinical development in a fifth and sixth indication in 2021.

Efgartigimod utilizes our ABDEG™ engineering technology and is designed to block the recycling of IgG antibodies, which results in their removal from circulation. We believe that our approach presents potential benefits relative to the current standard of care for MG, ITP and PV: corticosteroids and immunosuppressants in the early stages, followed by intravenous IgG, or IVIg, and plasma exchange, or plasmapheresis, as the disease progresses. The current standard of care for CIDP is IVIg. We believe efgartigimod's 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. Data reported to-date have shown that efgartigimod is well-tolerated, with reductions in pathogenic autoantibodies correlating with improvements in clinical scores.

Efgartigimod in MG – orphan drug status in the U.S., Europe and Japan

We announced full data from a double-blind, placebo-controlled Phase 2 clinical trial of efgartigimod in 24 patients with generalized MG in April 2018. In May 2019, we announced the publication of these Phase 2 results in the peer-reviewed journal, Neurology. The Phase 3 ADAPT trial was launched in September 2018 evaluating IV efgartigimod in gMG and topline data was announced on May 26, 2020. Also, in 2020 we have engaged the U.S. Food and Drug Administration (FDA) on a potential bridging strategy for 1,000mg subcutaneous SC ENHANZE® efgartigimod in gMG. We have presented additional data consistent with the topline results in October 2020. We expect to file a Japanese Marketing Authorization Application (J-MAA) with the Pharmaceuticals and Medical Devices Agency (PMDA) in the first half of 2021 with an expected efgartigimod launch in gMG in Japan. The commercial infrastructure readiness activities, including activities with global supply chain, are on track for the launch timeline in the U.S. and Japan. We expect to submit a market authorization application in China shortly after following potential approval in the U.S. Furthermore, we expect to file a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA) in the second half of 2021.

Efgartigimod in ITP – orphan drug status in the U.S. and Europe

In 2018, we performed a second Phase 2 clinical trial of IV efgartigimod in 38 patients with ITP for which the full study data were published in the peer-reviewed journal, Hematology in December 2019. The Phase 3 program of IV efgartigimod, ADVANCE, was initiated in the fourth quarter of 2019 and will evaluate the potential of IV efgartigimod for both induction and maintenance of platelet response. The ADVANCE SC Phase 3 trial in ITP has started in fourth quarter 2020 will evaluate the fixed dose of SC ENHANZE® efgartigimod.

Efgartigimod in PV

A Phase 2 proof-of-concept trial of IV efgartigimod is ongoing in PV and positive proof-of-concept data were presented at a medical conference during 2020. A registrational Phase 3 trial has been initiated during 2020.

Efgartigimod in CIDP

At the end of 2019, we initiated the Phase 2 ADHERE trial of SC ENHANZE® efgartigimod in patients with CIDP. We have completed the enrollment of the first 30 patients. The potential decision to expand the trial up to 130-140 patients is now expected in first quarter 2021.

Formulation Options for Efgartigimod

We are developing three formulations of efgartigimod to address the needs of patients, physicians and payors across indications and geographies, including IV efgartigimod and two SC formulations (the standalone ENHANCE® SC formulation and the SC formulation that is dosed as maintenance after IV induction).

Overview of Myasthenia Gravis

MG is an autoimmune disorder associated with muscle weakness that is triggered by IgG autoantibodies. 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 autoantibodies 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 autoantibodies can cause destruction of the neuromuscular junction by recruiting complement, a potent cell-destroying mechanism of the human immune system.

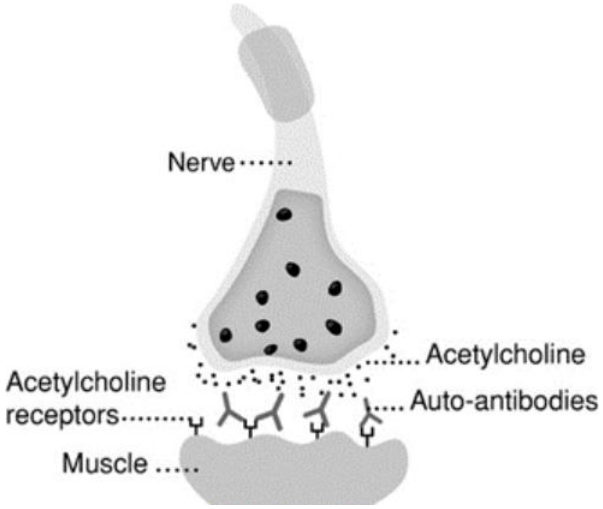


Figure 5: MG is caused by autoantibodies attacking the transmission of nerve impulses to muscles

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 (source: Philips et al, Ann NY Acad Sci. 2003; www.myasthenia.org/LinkClick.aspx?fileticket=EjpV6nDv8pU=&tabid=84). 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 (source: J Clin Neuromuscul Dis. 2011 Dec; 13(2):85–94. doi: 10.1097/CND.0b013e31822c34dd). 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.

In October 2017, the FDA and European Medicines Agency approved the use of Soliris® for the treatment of generalized MG patients who have autoantibodies directed against the acetylcholine receptor. Soliris is an anti-C5 antibody blocking the activity of complement recruited by the pathogenic IgGs directed against the acetylcholine receptor at the neuromuscular junction. However, Soliris does not address the blocking of the acetylcholine receptor by pathogenic IgGs, nor the receptor cross-linking and internalization by these IgGs. In addition, a sub-set of MG patients is known to have anti-MuSK antibodies, which are known not to activate the complement cascade. The price of Soliris in MG amounts to approximately $700,000 per patient per year, placing, we believe, a substantial cost burden on the health care system.

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

For MG patients who have advanced to the point where they are not well-controlled with corticosteroids and immunosuppressants, we believe efgartigimod may offer advantages over IVIg and plasmapheresis, including the potential to deliver a faster onset of action, a larger and longer lasting therapeutic effect and an improved safety and tolerability profile. In addition, a subcutaneous formulation of efgartigimod could further expand its use in 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 (sources: Current Medical Research and Opinion, 25:12, 2961-2969; Am J Hematol. 2012 Sep; 87(9): 848–852; Pediatr Blood Cancer. 2012 Feb; 58(2): 216–220).

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 autoantibodies for various pathways including the FcRn-dependent antibody recycling pathway, thereby lowering the impact of the autoantibodies. 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),Eltrombopag (Promacta) and Fostamatinib (Rigel) are approved as last-line therapy for ITP and have generated global revenues of $584 million and $635 million in 2016, respectively (source: Amgen Inc. Annual Report on Form 10-K for Fiscal Year Ended December 31, 2016 (page 126)).

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 autoantibodies targeting desmoglein-1 and -3, which are present on the surface of keratinocytes and important for cell-to-cell adhesion in the epithelium. Autoantibodies targeting desmogleins result in loss of cell adhesion, the primary cause of blister formation in PV. Similar to MG and ITP, disease severity of PV correlates to the amount of pathogenic IgGs targeting desmogleins.

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

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

Limitations of Current PV Treatments

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

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

Overview of Chronic Inflammatory Demyelinating Polyneuropathy

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

Limitations of Current CIDP Treatments

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

Our Solution: efgartigimod

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

Efgartigimod targets FcRn with high affinity, thereby reducing levels of all four classes of IgG antibodies, which are referred to as IgG1, IgG2, IgG3 and IgG4. In the case of MG, the large majority of patients have autoantibodies of the IgG1 and IgG3 classes, while in the case of ITP these autoantibodies consist mainly of the IgG1 class. In the case of PV, the pathogenic autoantibodies consist mainly of the IgG1 and IgG4 class. As shown in Figure 6, efgartigimod's mechanism of action is to block the recycling of IgG antibodies and remove them from circulation. Antibodies are routinely removed from circulation by being internalized into cells, where they can either become destined for degradation in the lysosomes or recycled back into circulation. IgG antibodies not bound to FcRn are degraded, while those bound to FcRn are recycled back into circulation. ❶ As a result of our ABDEG™ technology and the modifications we made to the Fc region, efgartigimod binds to FcRn with high affinity making this receptor unavailable to circulating IgG antibodies. ❷ The IgG antibodies can then no longer effectively be rescued and end up in the lysosomes where they are degraded. Compared to alternative immunosuppressive approaches, such as B-lymphocyte, or B-cell, depleting agents, efgartigimod acts in a highly selective manner by reducing IgG antibody levels, while leaving levels of antibodies of the immunoglobulin A, or

IgA, immunoglobulin M, or IgM, and immunoglobulin D, or IgD, types as well as all components of the innate immune system intact.

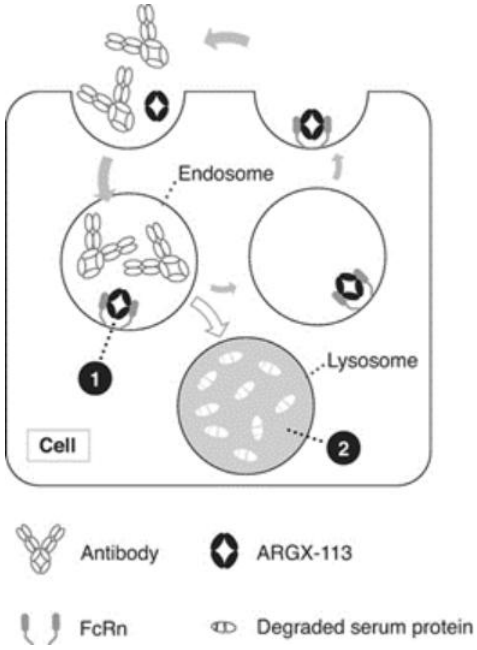


Figure 6: Efgartigimod's mechanism of action blocks the recycling of IgG antibodies and removes them from circulation

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

In addition to MG, ITP, PV and CIDP, we believe there are other autoimmune diseases that may benefit from the mechanism of action of efgartigimod therapy. We intend to pursue initial approval for MG and then plan to expand potentially to ITP, PV and CIDP because these diseases have significant unmet medical needs. We then intend to expand our clinical development efforts for efgartigimod into additional indications also mediat-ed 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 epidermyolysis bullosa; as well as with systemic lupus erythematosus and multiple sclerosis, which affect larger numbers of patients.

Global and Broad Clinical Development Plan

We are currently evaluating efgartigimod in Phase 3 clinical trials in MG and ITP. A global, multi-center Phase 3 ADAPT clinical trial, including ADAPT+ one-year open-label extension study, is currently ongoing. The ADAPT trial completed patient enrolment at the end of 2019 and topline data was announced on May 26, 2020. For ITP, a global Phase 3 program includes two potential registrational trials to be run concurrently. The first trial,

ADVANCE is launched and will evaluate 10mg/kg IV efgartigimod on top of standard of care medication. The second trial is launched in the fourth quarter of 2020 and will evaluate the 1000 mg SC ENHANZE® efgartigimod.

A Phase 2 proof-of-concept clinical trial of efgartigimod for the treatment of pemphigus vulgaris is still ongoing and positive interim proof-of concept data were reported in May 2020 during a medical meeting in 2020. We have initiated a Phase 3 ADRESS trial of efgartigimod for the treatment of pemphigus during the fourth quarter of 2020.

Finally, at the end of 2019, we initiated the Phase 2 ADHERE trial of SC ENHANZE® efgartigimod in CIDP patients, and we expect to start clinical development in a fifth and sixth indication in 2021.

Phase 2 Clinical Trial in MG

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

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

Phase 2 Topline Results

We announced full data from this Phase 2 clinical trial in April 2018 and the data were published in the peer-reviewed journal, Neurology, in 2019. The primary endpoint analysis demonstrated efgartigimod to be well-tolerated in all patients, with most treatment emergent adverse events or TEAEs observed characterized as mild (CTCAE Grading 1 and 2). No TEAEs severity with CTCAE Grade 3 or higher were reported. No clinically significant laboratory, vital signs and/or electrocardiogram findings were observed. No laboratory abnormality including albumin similar to the findings cynomolgus monkeys and in clinical trials. No TEAE leading to discontinuation, no serious TEAE and no deaths were reported during the trial. The observed tolerability profile was consistent with the Phase 1 healthy volunteer trial as well as our Phase 2 clinical trial in ITP.

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

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

TEAE/patinet count	Placebo (n = 12)	Efgartigimod (n = 12)	Total (n = 24)
TEAEs (total)	10 (83.3)	10 (83.3)	20 (83.3)
Headache	3 (25.0)	4 (33.3)	7 (29.2)
Nausea	1 (8.3)	1 (8.3)	2 (8.3)
Diarrhea	1 (8.3)	1 (8.3)	2 (8.3)
Abdominal pain upper	1 (8.3)	1 (8.3)	2 (8.3)
Arthralgia	2 (16.7)	0 (0.0)	2 (8.3)
Total lymphocyte count decrease	0 (0.0)	2 (16.7)	2 (8.3)
B-lymphocyte decrease	0 (0.0)	2 (16.7)	2 (8.3)
Monocyte count decrease	0 (0.0)	2 (16.7)	2 (8.3)
Neutrophil count increase	0 (0.0)	2 (16.7)	2 (8.3)
Myalgia	0 (0.0)	2 (16.7)	2 (8.3)
Pruritus	2 (16.7)	1 (8.3)	3 (12.5)
Rhinorrhea	1 (8.3)	1 (8.3)	2 (8.3)
Tooth abscess	2 (16.7)	0 (0.0)	2 (8.3)
Toothache	2 (16.7)	0 (0.0)	2 (8.3)

Abbreviation: TEAE = treatment-emergent adverse event.

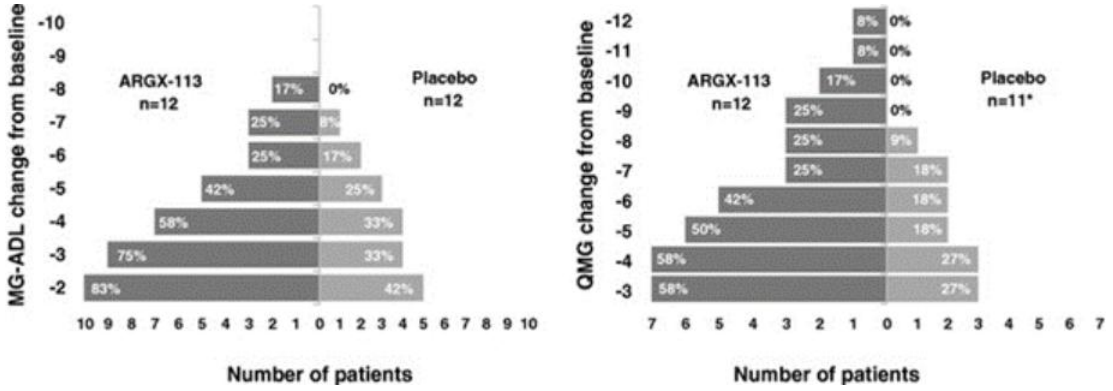
Data are n (%).

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

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

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

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



* Missing data point in one patient

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

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

Phase 2 Clinical Trial in ITP

We completed a randomized, double-blind, placebo-controlled Phase 2 clinical trial to evaluate the safety, efficacy and pharmacokinetics of efgartigimod in 38 adult primary ITP patients, who have platelet counts lower than 30 x 109/L while being on a stable dose of standard-of-care treatments consisting of corticosteroids, permitted immunosuppressants or thrombopoietin receptor agonists, or after having undergone a splenectomy or while being monitored under a 'watch & wait' approach. We conducted the clinical trial at 19 clinical centers across eight countries in the European Union. Patients were randomly assigned to three arms of 12 or 13 patients for the placebo or efgartigimod arms, respectively. All patients in this clinical trial on a drug standard-of-care treatment were to continue to receive their stable dose of standard-of-care treatment as per the protocol. One treatment arm received 5 mg/kg efgartigimod, the second arm received 10 mg/kg efgartigimod and the third arm received placebo. Dosing took place in a three-week period, which included four weekly doses of efgartigimod or placebo. Patient follow-up continued for 21 weeks after treatment. Patients from all three cohorts were eligible to enroll in a one-year open-label extension study at the 10mg/kg dose of efgartigimod, subject to meeting enrollment criteria, including platelet counts lower than 30 x 109/L.

Phase 2 Topline Results

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

We announced full data from this Phase 2 clinical trial in December 2018 and in December 2019, we announced a peer-reviewed publication of these data in *The Journal of Hematology*. The primary endpoint analysis demonstrated efgartigimod to be well-tolerated in all patients, with most treatment emergent adverse events (TEAE) observed characterized as mild (CTCAE Grading 1 and 2). Two serious TEAEs were reported for 2 (15.4%) out of 13 patients both in the efgartigimod 10 mg/kg treatment group (1 case of bronchitis and 1 case of thrombocytopenia); both serious TEAE were considered not related to the trial treatment and both serious TEAEs were downgraded after the study database locked. No deaths were reported during the study. The observed

tolerability profile was consistent with the Phase 1 healthy volunteer trial as well as our Phase 2 clinical trial in MG.

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

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

Main study	**Placebo (N = 12) n (%)**	**Efgartigimod 5 mg/kg (N = 13) n (%)**	**Efgartigimod 10 mg/kg (N = 13) n (%)**
Patients with at least 1 TEAE	7 (58.3)	9 (69.2)	11 (84.6)
Patients with at least 1 treatment-related TEAE	2 (16.7)	—	1 (7.7)
Patients with at least 1 serious TEAE	—	—	1(7.7)
Most common TEAEs (reported in ≥ 2 patients overall)			
Petechiae	1 (8.3)	2 (15.4)	2 (15.4)
Purpura	—	2(15.4)	1 (7.7)
Ecchymosis	—	1 (7.7)	1 (7.7)
Rash	—	1 (7.7)	1 (7.7)
Hematoma	—	3 (23.1)	2 (15.4)
Hypertension	1 (8.3)	—	2 (15.4)
Vomiting	—	—	2 (15.4)
Contusion	1 (8.3)	1 (7.7)	1 (7.7)
Cystitis	—	1 (7.7)	1 (7.7)
Productive cough	1 (8.3)	1 (7.7)	—
Headache	2 (16.7)	1 (7.7)	—
Open-label treatment period	**Efgartigimod 10 mg/kg (N = 12) n (%)**		
Patients with at least 1 TEAE	7 (58.3%)		
Patients with at least 1 treatment-related TEAE	—		
Patients with at least 1 serious TEAE	2 (16.7)		
Most common TEAEs (reported in ≥ 2 patients overall)			
Alanine aminotransferase increased	2 (16.7)		

Abbreviations: N, number of patients in the analysis set; n, number of patients with event within each treatment group under safety analysis set; TEAE, treatment emergent adverse event.

Clinically meaningful improvements in platelet counts were seen across ITP classifications and standard of care. 46% of patients demonstrated improved platelet count to ≥ 50x109/L during two or more visits in each of the 5 mg/kg and 10 mg/kg dosing cohorts compared to 25% in the placebo cohort. 67% of patients in the OLE trial demonstrated improved platelet count to ≥ 50x109/L during two or more visits following the first dosing cycle. Responders from the 10 mg/kg arm in the primary trial all responded again upon retreatment in the OLE trial. Onset of platelet count reaching 50x109/L for the first time ranged from week 1 to week 10, consistent with disease heterogeneity. For efgartigimod-treated patients with clinically meaningful platelet responses (≥ 50x109/L during two or more visits), the mean duration of platelet response was 40 days versus 16 days for placebo treated patients, with responses lasting the trial duration.

38% of efgartigimod-treated patients showed durable platelet count improvements to clinically meaningful and statistically significant levels of ≥ 50x109/L for at least 10 cumulative days, compared to 0% of placebo patients (p=0.03). These data are summarized in figures 8 and 9.

Figure 8: Patients achieving platelet counts of ≥ 50x109/L at least two times.

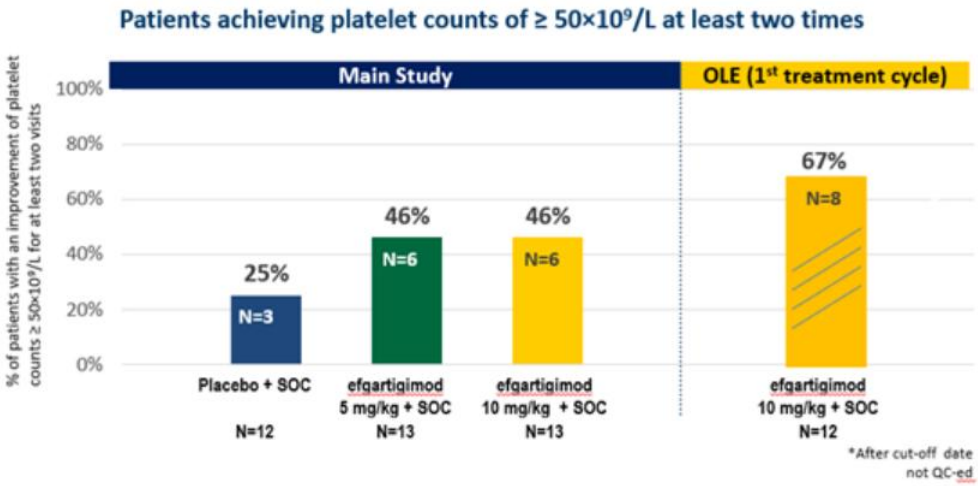
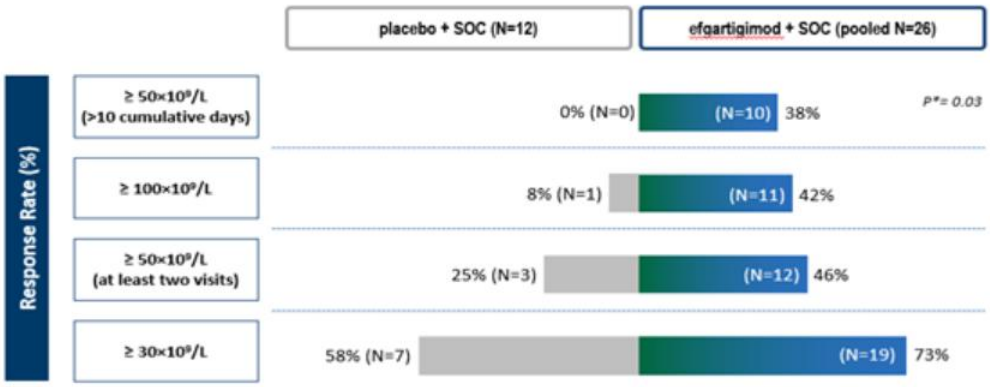


Figure 9: Post-hoc analysis of increasing thresholds of efficacy



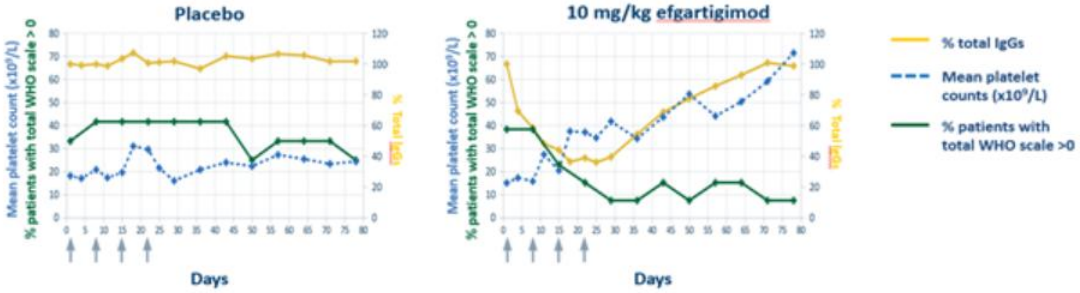
Note: Increasing threshold analysis based exact logistic regression model with the baseline result as a factor

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

Analysis of the pharmacokinetic and pharmacodynamic endpoints was generally consistent with the findings from the Phase 1 clinical trial as well as the MG Phase 2 clinical trial. Lasting IgG reductions were consistent with levels achieved in previous studies. All efgartigimod-treated patients showed a rapid and deep

reduction of total IgG levels, consistent with the pharmacodynamic effects observed in previous clinical trials. Reduction of IgG levels was consistent across IgG subtypes. Reduction in platelet-associated autoantibodies were observed in the majority of patients with clinically meaningful platelet increase. Low titer of anti-drug antibodies was detected in 16.7% of placebo patients and 30.8% of treated patients in the 10 mg/kg arm with no apparent effect on pharmacokinetics or pharmacodynamics.

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



Phase 2 Clinical Trial in PV

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

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

Phase 2 Interim Results and Next Steps

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

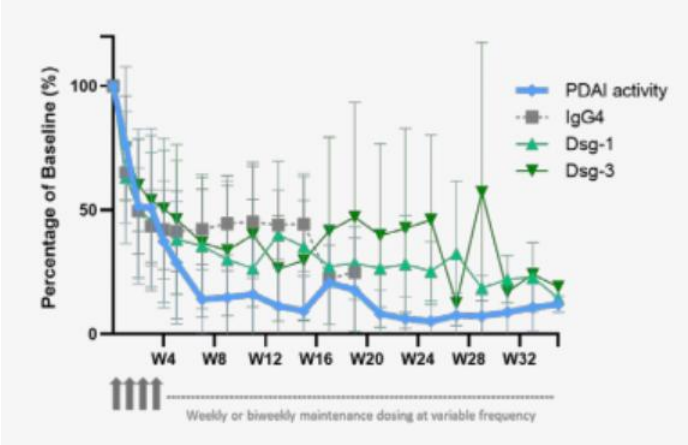
The IDMC evaluated the results of the first patient cohort and determined the tolerability profile to be favorable. The IDMC recommended maintaining the dose at 10 mg/kg but adjusted the dosing frequency and duration of the maintenance phase for the next cohort. The second patient cohort will dose every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

The Phase 2 proof-of-concept were presented in 2020. The presentation included updated data from 34 evaluable patients (31 evaluable for efficacy) treated with 10mg/kg or 25mg/kg of IV efgartigimod through May 16, 2020. In this trial, we observed that:

- 90% (28/31) of evaluable patients achieved rapid disease control; median time to disease control for monotherapy and combination therapy is 15 and 22 days, respectively;
- Complete clinical remission observed in 70% (7/10) of patients receiving optimized dosing regimen determined to be efgartigimod dosed at least every two weeks in combination with oral prednisone (0.25-0.5mg/kg);
- 73% (11/15) of patients receiving 25mg/kg efgartigimod achieved end of consolidation, including patients who preferred to taper steroid dose; and
- A favourable tolerability profile, consistent with data from previous efgartigimod studies.

The data demonstrated a clear correlation between pathogenic IgG reduction and the Pemphigus Disease Area Index score improvement (Fig. 11). 90% (28/31) of patients achieved rapid disease control; median time to disease control for both monotherapy and combination therapy was 15 and 22 days, respectively. Complete clinical remission was observed in 70% (7/10) of the patients receiving an optimized dosing regimen determined to be efgartigimod dosed at least every two weeks in combination with oral prednisone (0.25-O.5 mg/kg), and CR was achieved within 2-13 weeks. This data suggested the potential for corticosteroid sparing treatment. In addition, an independent data review committee concluded tolerability to be favorable.

Figure 11: IgG reduction correlates to PDAI score improvement in responders



A potential registrational trial has been started in the fourth quarter of 2020.

Phase 1 Clinical Trial for Subcutaneous Formulation of efgartigimod (fixed maintenance dose used after IV induction)

In addition to the intravenous product formulation of efgartigimod, we are also developing a subcutaneous product formulation designed to enable administration of efgartigimod to larger patient populations, including patients requiring chronic therapy, potentially outside the hospital setting.

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

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

Phase 1 Clinical Trial ENHANZE® SC efgartigimod (standalone SC formulation)

In addition to the subcutaneous product formulation of efgartigimod, we developed a standalone SC formulation of efgartigimod as part of our collaboration with Halozyme based on a co-formulation of efgartigimod with Halozyme's proprietary ENHANZE® drug delivery technology (hyaluronidase, rHuPH20), designed to enable a smooth and convenient SC administration with larger volumes of efgartigimod with short injection times.

We initiated a Phase 1 clinical trial in healthy volunteers for the ENHANZE® subcutaneous formulation for the treatment of chronic autoimmune diseases. The open-label, Phase 1 trial enrolled 33 healthy volunteers and included four treatment arms: three with fixed doses of SC ENHANZE® efgartigimod, and one evaluating a body weight-based dose of SC ENHANZE® efgartigimod. Clear dose dependent reductions in mean total IgG and the different IgG subtypes concentration were observed. Using PK-PD modelling, we selected a dose of 1000 mg SC ENHANZE® efgartigimod to be equivalent to the 10 mg/kg IV efgartigimod formulation with respect to the effect on IgG levels.

The SC ENHANZE® efgartigimod formulation was quickly injected with mean injection times lower than 1 minute for the smallest dose.

Single dose of SC ENHANZE® efgartigimod of 750 mg, 1250 mg, 1750 mg, or 10 mg/kg was well tolerated by all healthy subjects. No obvious TEAE were reported beyond mild and transient injection site reactions, in line with reported ENHANZE® coformulation findings. No meaningful immunogenicity was reported.

First-in-Human Clinical Development Plan and 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 efgartigimod. In the first part of the clinical trial, 30 subjects were randomized to receive a single dose of efgartigimod 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 efgartigimod 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. The full results from this clinical trial have been published in a peer reviewed during 2017.

Single Ascending Dose

We observed that a single two-hour infusion of 10 mg/kg efgartigimod 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 12. 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.

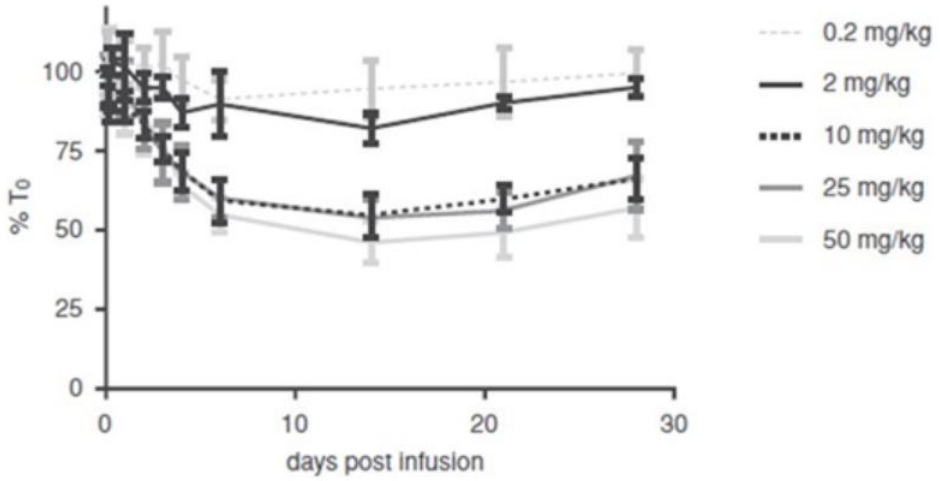


Figure 12. Selective reduction of IgG by administration of efgartigimod to healthy volunteers in the single ascending dose part of our Phase 1 clinical trial

Administration of efgartigimod 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 efgartigimod 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 efgartigimod 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 efgartigimod 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 13. 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 efgartigimod 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 efgartigimod and the effect of the ABDEG™ technology on increasing the intracellular

recycling of efgartigimod. Similar to the single ascending dose part, no significant reductions in IgM, IgA or serum albumin were observed.

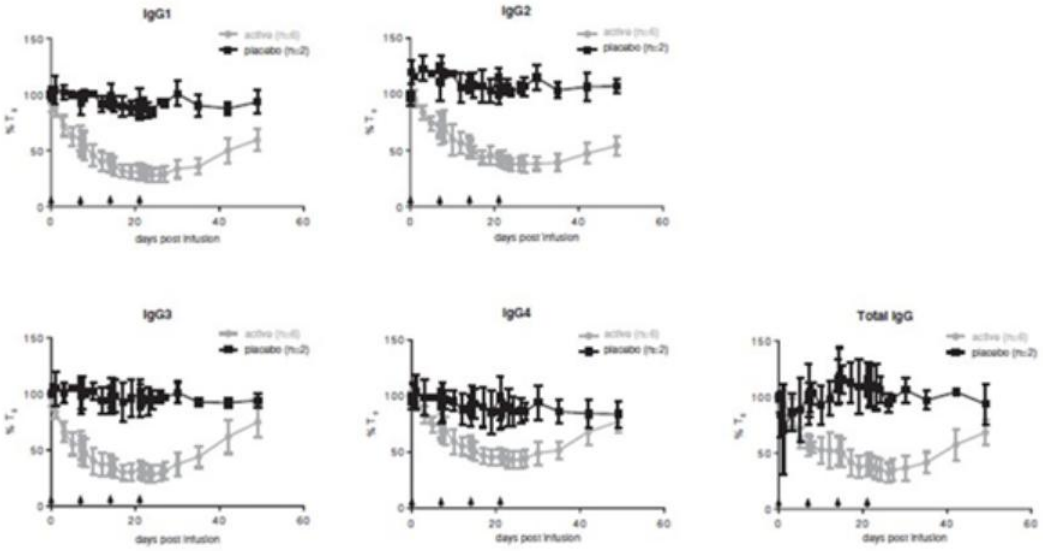


Figure 13. Reduction in the levels of four IgG antibody classes and total IgG levels in the multiple ascending dose part of our Phase 1 clinical trial of efgartigimod in healthy volunteers at a dose of 10 mg/kg every seven days

Administration of multiple efgartigimod 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 efgartigimod. Some patients had changes to C reactive protein levels that were considered clinically significant. The most frequently reported drug related adverse events included headache, feeling cold, chills and fatigue, all of which were mild or moderate and reported only in the highest dose group of 25 mg/kg.

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

Cusatuzumab (formerly referred to as ARGX-110)

We are developing cusatuzumab in hematological cancer indications, currently AML, as well as high-risk MDS. We are developing cusatuzumab with our collaborator Janssen. See “Collaboration Agreements" below.

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

Cusatuzumab is currently being evaluated in an open label registration directed Phase 2 clinical trial, CULMINATE, in combination with azacytidine, in newly diagnosed AML patients who are unfit for intensive chemotherapy or in patients with high-risk MDS. A Phase 1b platform trial is also underway in various AML subpopulations and settings with an initial trial evaluating combinations of cusatuzumab, venetoclax and azacitadine.

We reported results for the first 12 patients from the dose-escalation part of the Phase 1/2 clinical trial in combination with azacytidine in AML or high-risk MDS in December 2019, which demonstrated a favorable tolerability profile of the combination therapy and suggested evidence of biological activity across the evaluated doses.

In addition, we reported results of the Phase 2 part of the Phase 1/2 clinical trial in relapsed or refractory CD70-positive CTCL patients and an open-label Phase 1 clinical trial in patients with nasopharyngeal carcinoma.

In June, 2020, we presented maturing data from the Phase 2 CULMINATE trial of cusatuzumab in combination with azacytidine in newly diagnosed, elderly patients with AML who are ineligible for intensive chemotherapy which have shown that complete response rates are not likely to exceed those from the VIALE-A trial of venetoclax in combination with azacytidine. In this trial, we observed that:

- Based on the enrolment to date, the dose selected should be 20mg/kg;
- CULMINATE trial will continue to evaluate responses and durability for existing patients, but no new patients will be enrolled;
- Topline data were reported in the first quarter of 2021; and
- The registration strategy is to be determined following evaluation of maturing data across the cusatuzumab program and AML treatment landscape.

On January 8, 2021, we presented interim data from the Phase 2 CULMINATE trial of cusatuzumab. A pre-planned interim analysis was conducted of the 52 patients (46.2% adverse ELN risk classification) receiving 20mg/kg cusatuzumab plus azacitidine treatment (intent-to-treat population (ITT)). The results from the ITT analysis showed a complete remission (CR) rate of 27% (14/52) and composite complete remission (CRc), including CRs with incomplete hematologic recovery, rate of 40% (21/52). The 30-day mortality rate of the ITT population was 9.6% (5/52). In a cohort where patients received at least two treatment cycles (20mg/kg cusatuzumab plus azacitidine), 42% (14/33) achieved CR and 64% (21/33) achieved CRc. Cusatuzumab was observed to be well-tolerated and the safety profile was consistent with prior studies. Final results from the CULMINATE trial will be presented in a peer-reviewed forum.

Overview of Acute Myeloid Leukemia and Myelodysplastic Syndrome

AML is a hematological 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 (Siegel et al., Cancer J Clin 2015) AML is generally a disease of elderly people, with more than 60% of diagnosed patients being older than 60 years, and AML is uncommon before the age of 45. The average five-year survival rate for patients with AML is 27%, but there are significant differences in prognosis depending on several factors, including the age of the patient at diagnosis. For patients under the age of 45, the five-year survival rate is approximately 57%, while for those over the age of 65 it is only 6%. There are likely multiple reasons for this discrepancy, including the ability of younger patients to tolerate more aggressive therapy.

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

to the malignant AML cells, or blasts, therapies targeting both blasts and leukemic stem cells may be more efficacious than chemotherapy only and could increase survival rates.

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

Our Solution: cusatuzumab

We developed cusatuzumab using our SIMPLE Antibody™ Platform and the POTELLIGENT® Fc engineering technology. Cusatuzumab binds to the cell surface protein CD70 with high affinity, blocking the interaction between CD70 and its receptor CD27 and targeting CD70 expressing cells for destruction by multiple immune pathways. CD70 is a cell surface protein that is highly expressed in cancer, including in T-cell and B-cell lymphomas, leukemias and certain solid tumors. In normal tissues, CD70 expression is either low or absent. Binding of CD70 to its receptor, CD27, initiates a cascade of intracellular events leading to cell proliferation and survival. As a byproduct of CD70 binding to CD27, the extracellular portion of CD27 is cleaved, creating a soluble form of CD27 known as sCD27, which can easily be measured. sCD27 may serve as a biomarker for CD70 activity, potentially allowing us to identify target patients based on the likelihood of response to treatment, monitor disease progression and measure the impact of anti-CD70 therapy. In AML, CD70 is also expressed on leukemic stem cells. Leukemic stem cells are demonstrated to give rise to a large population of more mature leukemic blasts which lack self-renewal capacity in AML. Leukemic stem cells reside in the bone marrow and are considered difficult to target specifically. Preliminary data from the first set of patients in our clinical trial suggest cusatuzumab could be active both at the circulating and bone marrow blast level and at the leukemic stem cell level. Cusatuzumab exhibits potent ADCC and antibody dependent cellular phagocytosis potential through the use of POTELLIGENT® technology as well as complement-dependent cytotoxicity leading to the killing of cells expressing CD70.

Clinical Development Plan

In December 2016, we initiated an open-label Phase 1/2 clinical trial of cusatuzumab at three sites in Switzerland for the treatment of newly diagnosed AML or high-risk MDS patients. We reported interim results from the dose-escalation part of this clinical trial in December 2019.

The Phase 2 CULMINATE clinical trial is enrolling up to 150 patients with previously untreated AML who are not eligible for intensive chemotherapy. In this two-part trial, patients will first be randomized to receive one of two dose levels of cusatuzumab (10mg/kg and 20mg/kg) in combination with azacytidine (75mg/m2) followed by an expansion cohort to evaluate efficacy of the selected dose of cusatuzumab. A Phase 1b trial is also ongoing in AML with the initial ELEVATE trial evaluating combinations of cusatuzumab, venetoclax and azacitadine. In addition, a Phase 1 trial in Japan was initiated of cusatuzumab in combination with azacytidine evaluating newly diagnosed elderly AML patients who are ineligible for intensive chemotherapy. A randomized Phase 2 BEACON trial in higher-risk myelodysplastic syndromes (MDS) is paused due to COVID-19.

In addition, cusatuzumab was evaluated in an open-label Phase 1/2 clinical trial in relapsed or refractory CD70-positive CTCL patients and an open-label Phase 1 clinical trial in patients with nasopharyngeal carcinoma. Prior to this, cusatuzumab was evaluated in an extensive Phase 1 clinical trial in patients with advanced malignancies expressing CD70, following a stepwise adaptive clinical trial design enrolling a total of 86 patients (of whom 85 patients have been treated).

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

We are evaluating cusatuzumab in an open-label, dose-escalating Phase 1/2 clinical trial to evaluate its safety, tolerability and efficacy in combination with 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 cusatuzumab in combination with 75 mg/m2 azacitidine (standard of care for AML). Patients receive two weeks of cusatuzumab monotherapy prior to starting the combination dosing. During the Phase 1 dose-escalation part of the clinical trial, four doses of cusatuzumab, 1 mg/kg, 3 mg/kg,10 mg/kg and 20 mg/kg administered bi-weekly are being evaluated. We enrolled 12 patients in the Phase 1 part.

26 AML patients were enrolled in the Phase 2 part of its Phase 1/2 clinical trial using a 10 mg/kg dose of cusatuzumab. This is a multi-center clinical trial conducted in Europe.

We reported updated interim results for the 12 evaluable patients from the Phase 1 dose-escalation part of this clinical trial in December 2019 at the ASH annual meeting, representing the data as of February 2019. Six out of twelve Phase 1 patients were still on treatment at the time of the interim data. These interim results showed for the first 12 patients that no dose-limiting toxicity was observed for cusatuzumab and that cusatuzumab was overall reported to be well-tolerated with signs of clinical activity. To date, the tolerability profile of cusatuzumab in this Phase 1/2 clinical study in combination with azacitidine appears to be similar to what we observed in the other cusatuzumab clinical trials. We believe that the observed Grade 3 and 4 hematological toxicity for cusatuzumab in combination with azacitidine corresponds to the reported safety profile of azacitidine monotherapy and can be seen in Table 2 below. No grade 5 TEAEs were observed.

Table 2. Grade 3 or higher treatment emergent adverse events of cusatuzumab in combination with azacitidine open-label, Phase 1 dose-escalation part (first 12 evaluable patients, ongoing, as of February 2019).

Escalation phase – cusatuzumab dose: TEAEs grade 3 and 4*	**1 mg/kg (N=3)**	**3 mg/kg (N=3)**	**10 mg/kg (N=3)**	**20 mg/kg (N=3)**	**Total (N=12)**
	Number of patients				
Blood and lymphatic disorders	2	3	2	3	10
Anemia	1	3	1	—	5
Febrile neutropenia	2	—	1	2	5
Leukopenia	—	—	1	—	1
Neutropenia	—	—	1	2	3
Thrombocytopenia	—	—	1	—	1
Cardiac disorders	1	—	—	1	2
GI disorders	—	1	—	1	2
General disorders and administration site conditions	—	1	1	—	2
Infections and infestations	1	2	—	3	6
Laboratry abnormalities	3	3	—	1	7
Reproductive system and breast disorders	—	—		1	1
Vascular disorders	—	1	—	—	1
IRR AEs#	1	1	—	—	2

- AEs leading to discontinuation of study treatment n = 1 (3mg/kg dose)
- #IRR (infusion-related reaction) preferred terms: chills, pyrexia, dyspnea, malaise, tachycardia, hypo/hypertension, dizziness, hypersensitivity

More specifically at the time of the interim data, 12 out of 12 AML (100%) patients showed a response, including complete remission in eight out of 12 patients, complete remission with incomplete blood count recovery in two out of 12 patients and partial remission in two out of 12 patients. One of the patients who achieved a complete remission successfully bridged to allogeneic stem cell transplant after five cycles. One patient

discontinued from the study following an adverse event. Three patients responded during cusatuzumab monotherapy in the first two weeks.

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

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

The primary endpoint of the Phase 2 part of the clinical trial is efficacy, and secondary endpoints include safety and characterization of pharmacokinetics and immunogenicity.

Of the 26 evaluable patients (out of 27 recruited patients) under analysis, we observed an overall response rate of 23% (one complete response, five partial responses and eight patients with stable disease). Patients received a 1 mg/kg or 5 mg/kg dose of cusatuzumab. Cusatuzumab was well tolerated at both doses with a total of 106 treatment-emergent adverse events (TEAE) reported in 26 patients. Most common was pyrexia and asthenia (5 patients each). Forty events in 16 patients were considered drug-related by the investigator of which infusion-related reactions (IRRs) were the most common (22 events in 8 patients). Eighteen SAEs were reported in 11 patients, one was considered drug related.

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

Cusatuzumab was evaluated in an extensive Phase 1 part of a Phase 1/2 clinical trial in patients with advanced malignancies expressing CD70, following a stepwise adaptive clinical trial design enrolling a total of 86 patients (of whom 85 patients have been treated). No dose-limiting toxicities were observed. The most frequent grade 3 and 4 drug-related adverse events were fatigue in 48.2% of patients and mild (Grade 1–2) infusion-related reactions in 34.1% of patients. Other monoclonal antibodies engineered using 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 3.2.2 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
Number of patients	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.

ARGX-117

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

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

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

In the third quarter of 2020, we initiated a Phase 1 healthy volunteer trial of IV and SC ARGX-117 to evaluate safety and tolerability and establish a dosing regimen. Following analysis of Phase 1 data, we plan to launch a Phase 2 proof-of-concept trial in multifocal motor neuropathy within our neuromuscular franchise and to develop ARGX-117 in additional autoimmune indications.

ARGX-118

We have exercised our option to exclusively acquire rights to ARGX-118, a highly differentiated antibody against Galectin-10, the protein of Charcot-Leyden crystals, which are implicated as a major contributor to severe asthma and to the persistence of mucus plugs. ARGX-118 has the following differentiated features:

(i) acts on a novel target intended to address mucus plugging, a large unmet need in airway inflammation;

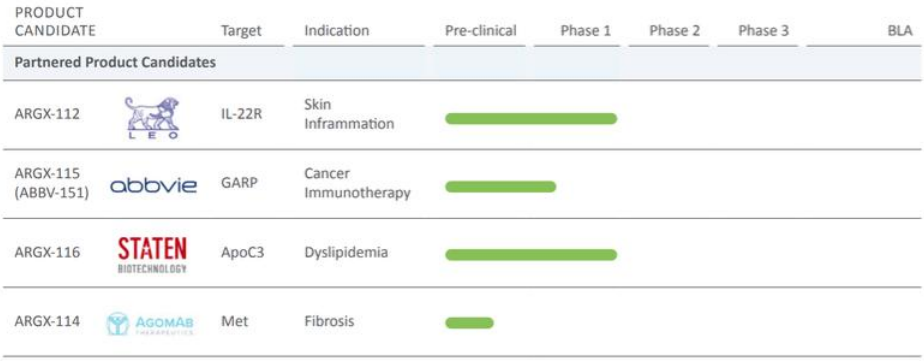
(ii) unique mechanism of action with observed crystal-dissolving properties; and

(iii) broad potential in severe airway inflammation diseases where mucus plugging plays a key role, including lung attack or asthma exacerbation, allergic bronchopulmonary aspergillosis, and chronic rhinosinusitis with nasal polyps.

ARGX-118 was developed under a collaboration with VIB, a life sciences research institute based in Flanders, Belgium. Lead optimization work on ARGX-118 for airway inflammation will continue in 2021.

Our Partnered Programs

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



The following is the pipeline for our partnered product candidates and discovery programs. For more information on our collaborations, see “Collaboration Agreements" below.

LP0145 (formerly ARGX-112) (partnered with LEO Pharma)

We are developing LP0145for the treatment of dermatologic indications involving inflammation, together with our collaboration partner LEO Pharma.

LP0145 employs our SIMPLE Antibody™ technology and blocks the interleukin-22 receptor, or IL-22R, in order to neutralize the signaling of cytokines implicated in autoimmune diseases of the skin.

The program is in a Phase 1 clinical trial and LEO Pharma is responsible to fund the clinical development of the program.

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

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

ARGX-115 (ABBV-151) employs our SIMPLE Antibody™ technology and works by stimulating a patient's immune system after a tumor has suppressed the immune system by co-opting immunosuppressive cells such as Tregs.

In August 2018, AbbVie exercised its exclusive license option to develop and commercialize ARGX-115 (ABBV-151). ARGX-115/ ABBV-151 is currently being explored in a phase 1 clinical trial by Abbvie (https://www.clinicaltrials.gov/ct2/show/NCT03821935?term=NCT03821935&draw=2&rank=1).

STT-5058 (formerly ARGX-116) (partnered with Staten Biotechnology)

We are developing STT-5058 for the treatment of dyslipidemia, together with our collaboration partner Staten Biotechnology.

STT-5058 employs our SIMPLE Antibody™ technology and blocks APOC3, a metabolic target involved in triglyceride metabolism.

STT-5058 is the first of up to three research programs under the collaboration. Under the terms of the collaboration, the parties are jointly responsible for conducting research under a mutually agreed research program, with Staten reimbursing us for all costs of carrying out our research responsibilities under each research program.

In December 2018, Staten Biotechnology announced that it will collaborate with Novo Nordisk A/S to co-develop STT-5058.

Staten initiated dosing in first-in-human clinical trial of STT-5058.

ARGX-114 (partnered with AgomAb)

ARGX-114 is an HFG-mimetic SIMPLE Antibody™ directed against the MET receptor.

ARGX-109 (partnered with Genor Biopharma)

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.

In October 2012, we entered into an exclusive license agreement with Bird Rock Bio, Inc. (formely known as RuiYi Inc. and Anaphore, Inc.), to develop and commercialize ARGX-109. In 2018, Bird Rock Bio and argenx mutually agreed to terminate this exclusive license agreement. Genor Biopharma, a sublicensee of Bird Rock Bio, will continue to develop ARGX-109 for the Chinese market.

Immunology Innovation Program

We have developed a program designed to secure access to early, cutting edge targets, which we call our Immunology Innovation Program. Through our Immunology Innovation 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 Immunology Innovation Program is ARGX-115 (ABBV-151), which was devel-oped in collaboration with the de Duve Institute / Université Catholique de Louvain. We provided antibodies to the academic groups to help validate the target. This in turn, allowed the groups to advance their work successfully, including the facilitation of supportive publications. Subsequently, this program formed the basis of our collaboration with AbbVie. ARGX-115 (ABBV-151) exemplifies how our Immunology Innovation Program enables us to generate product candidates against novel targets that may be of high interest for collaboration with biopharmaceutical partners. Another example is STT-5058, 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 Immunology Innovation Program with Broteio Pharma B.V. to develop an antibody against a novel target in the complement cascade, ARGX-117. Under the terms of the agreement, we and Broteio jointly developed the complement-targeted antibody to seek to establish preclinical proof-of-concept using our proprietary suite of technologies. Upon successful completion of these studies, we exercised an exclusive option to license the program in March 2018 and assumed responsibility for further development and commercialization.

Manufacturing and Supply

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

Efgartigimod, cusatuzumab, ARGX-111 and LP0145 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.

Intellectual Property

Introduction

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 trademarks and 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 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. Specifically, we are materially dependent on patent and other proprietary protection related to our core platform technologies, described in "Platform Technologies", and our product candidates, as described in " Product Candidates: Wholly-Owned Programs " and " Product Candidates: Partnered Programs ", below.

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

As of January 1, 2021, our patent portfolio (which includes both proprietary and in-licensed patent families) comprises at least 211 granted and 209 pending patents, including 30 issued U.S. patents, 9 granted European patents and 172 issued foreign patents.

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 POTELLIGENT® 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, Canada, Europe, United Kingdom, Israel, India and Japan, and pending applications in China and Japan (divisional). In addition, we have a second patent family containing patents granted in the United States (two), Australia, Europe, United Kingdom, Israel, India and Japan, and one patent application pending in Canada, 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 patents have a basic patent expiry date in 2031.

With regard to the ABDEG™ platform, we co-own with, and exclusively license from, the University of Texas, a patent family containing a granted U.S. patent with composition of matter claims directed to an isolated FcRn-antagonist comprising an 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. patentis expected to expire in 2036. In addition, in this patent family, we also have granted patents in Australia, China, Eurasia, Europe, Japan, Mexico, New Zealand and Singapore, and we have 13 patent applications pending in U.S. (divisional) and various other countries and regions in North America, South America, Europe, Asia and South Africa. The granted patents have a basic expiry date in 2034. In addition, we own a second patent family containing pending patent applications in the United States and 15 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 earliest in 2027 to 2028. The patent family also includes a granted European patent.

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

Product Candidates: Wholly-Owned Programs

With regard to the efgartigimod product candidate, efgartigimod incorporates the ABDEG™ technology platform, the coverage of which is discussed above under "Platform Technologies".

With regard to the cusatuzumab product candidate, we have three issued U.S. patents, one with composition of matter claims directed to the cusatuzumab antibody, one with claims directed to the epitope cusatuzumab binds to, and one with claims directed to a polynucleotide that encodes antibodies that bind to the epitope cusatuzumab binds to and two pending U.S. patent applications with method of use claims directed to the

treatment of cancer and immunological disorders with the cusatuzumab antibody. The issued U.S. patents expire in 2032 and 2033, and the U.S. patent applications, 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 Australia, China, Europe, Israel, India, Japan and Russia and five patent applications pending in Brazil, Canada, Indonesia and U.S. (two divisionals pending). Furthermore, cusatuzumab incorporates or employs the SIMPLE Antibody™ and POTELLIGENT® technology platforms, which are covered by one or more of the patents and patent applications discussed above under "Platform Technologies".

With regard to the ARGX-117 product candidate, we own or have rights in 4 patent families (including 1 in-licensed patent family from Broteio Pharma) with several granted patents and pending patent applications in multiple jurisdictions in North America, South America, Europe and Asia, directed to composition of matter claims and method of treatment claims. The in-licensed patent family from Broteio Pharma has granted pa-tents in Australia, China, Europe, Hong Kong, Mexico and U.S. (2 issued patents in U.S.), which have a basic expiry date in 2034. The other 3 patent families have basic expiry dates in 2039, 2040 and 2041.

With regard to the ARGX-118 product candidate, we co-own 1 patent family with VIB VZW and Universiteit Gent, with pending patent applications in multiple jurisdictions in North America, South America, Europe and Asia. The patent family has a basic expiry date in 2039.

Product Candidates: Partnered Programs

With regard to the ARGX-115 (ABBV-151) product candidate, we co-own with, and exclusively license from, the Ludwig Institute for Cancer Research and Université Catholique de Louvain, a granted U.S. patent with composition of matter claims directed to an antibody that binds GARP the presence of TGF-β and method of use claims directed to the use of such an antibody in the treatment of cancer. The U.S. patenthas a basic expiry date in 2034, without taking a potential patent term extension into account. In addition, the patent family contains at least 18 patent applications pending in U.S. (CIP) and 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 2 more patent families with composition of matter claims directed to an antibody that binds an epitope of a complex formed by human GARP and TGF-β and method of use claims directed to the use of such an antibody in the treatment of cancer. The 2 patent families have basic expiry dates in 2036 and 2038. Furthermore, ARGX-115 (ABBV-151) incorporates or employs the SIMPLE Antibody™ technology platform, which is covered by one or more of the patents and patent applications discussed above under "Platform Technologies".

With regard to the ARGX-109 product candidate, we have one patent family with composition of matter claims directed to ARGX-109. This patent family has granted patents in Australia, Canada, China, Colombia, Hong Kong, Israel, Japan, Mexico, New Zealand, Russia, U.S. and South Africa, and four pending patent applications in Brazil, Chili, India and U.S. (continuation application). The patent family has a basic expiry date in 2033. 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 one patent family with composition of matter claims directed to an antibody that binds human IL-22R. The patent family has a basic expiry date in 2037. 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.

Trade secret protection[1]

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.

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

Our Strategic Partnership with Janssen (for cusatuzumab)

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

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

Under the terms of the agreement, Janssen has paid us $300 million in an upfront, non-refundable and non-creditable payment. In conjunction with the collaboration agreement, we entered into an investment agreement with JJDC, Inc., or JJDC, an affiliate of Johnson & Johnson. At the closing of the transaction in January 2019, JJDC purchased 1,766,899 newly issued shares, representing 4.68% of our then outstanding shares at a price of €100.02 per share ($113.19 based on the exchange rate in effect as of the date the payment was received), for a total of €176.7 million (approximately $200.0 million based on the exchange rate in effect as of the date the payment was received).

[1] in the URD the trade secret protection section if followed by “Tendencies” – should this be included in the 20-F as well?

We are eligible to receive potentially up to $1.3 billion in development, regulatory and commercial milestone payments, in addition to tiered royalties on sales for the territory outside of the U.S. at percentages ranging from the low double digits to the high teens, subject to customary reductions. In December 2019 we announced the achievement of the first milestone of $ 25 million for achievement of an enrollment milestone in first Phase 2 trial under the collaboration. Janssen will be responsible for commercialization worldwide. We retain the option to participate in co-commercialization efforts in the U.S., where the companies have agreed to share royalties on a 50/50 basis, and outside the U.S., Janssen will pay double-digit sales royalties to us. The agreement includes customary standstill and lock-up provisions.

Under the terms of the collaboration agreement, we agreed to a joint global clinical development plan to develop cusatuzumab in AML, MDS and other potential indications in the future. Unless otherwise determined by the parties, Janssen shall be responsible for conducting the development activities specified in the global clinical development plan, to the extent that they are not allocated to the Company. The parties have equal decision-making authority and shall make consensus decisions regarding the global clinical development plan, with certain exceptions related to the territory outside of the U.S. Development costs shall be borne by both parties based on a cost sharing arrangement.

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

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

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

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

We have granted AbbVie an exclusive option, for a specified period following completion of IND-enabling studies, to obtain a worldwide, exclusive license to the ARGX-115 (ABBV-151) program to develop and commercialize products. Following the exercise of the option, AbbVie is subject to diligence obligations in respect of continuation of development and commercialization of the licensed product(s), and AbbVie will be solely responsible for all research, development and regulatory costs relating to the products. We received an upfront, non-refundable, non-creditable payment of $40.0 million (€35.1 million based on the exchange rate in effect as of the date the payment was received) from AbbVie for the exclusive option to license ARGX-115 (ABBV-151). During the course of the collaboration, we achieved two pre-defined preclinical milestones, each of which trig-gered a $10.0 million payment (€8.9 million based on the exchange rate in effect as of the date the first pre-clinical milestone payment was received and €8.7 million based on the exchange rate in effect as of the date the second pre-clinical milestone payment was received). In addition, in March 2019 we have achieved the first pre-defined clinical milestone, triggering a $30.0 million payment.

In August 2018, AbbVie exercised its option to develop and commercialize ARGX-115 (ABBV-151) and has now assumed development obligations, including being solely responsible for all research, development and regulatory costs relating to ARGX-115 (ABBV-151)-based products. Subject to the continuing progress of ARGX-115 (ABBV-151) by AbbVie, we are eligible to receive development, regulatory and commercial milestone

payments in aggregate amounts of up to $110.0 million, $190.0 million and $325.0 million, respectively, as well as tiered royalties on product sales at percentages ranging from the mid-single digits to the lower teens, subject to customary reductions.

We have the right, on a product-by-product basis to co-promote ARGX-115 (ABBV-151)-based products in the European Economic Area and Switzerland and combine the product with our own future oncology programs. The co-promotion effort would be governed by a co-promotion agreement negotiated in good faith by the parties.

Unless earlier terminated upon mutual agreement, for material breach or as otherwise specified in the agreement, the term of the option and license agreement ends, with respect to the ARGX-115 (ABBV-151) program, upon the earliest of (i) a technical failure of the IND-enabling studies which is outside of our control, (ii) AbbVie's election to not exercise its option, or (iii) following AbbVie's exercise of the option, fulfilment 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 Genor Biopharma (for ARGX 109)

In October 2012, we entered into an exclusive license agreement with Bird Rock Bio, Inc. (formely known as RuiYi Inc. and Anaphore, Inc.), to develop and commercialize ARGX-109. In 2018, we and Bird Rock Bio mutually agreed to terminate this exclusive license agreement. Recently, we agreed a direct licensing agreement with Genor Biopharma and Genor Biopharma continues to develop ARGX-109 for the Chinese market.

Our Strategic Partnership with LEO Pharma (for LP0145)

In May 2015, we entered into a collaboration agreement with LEO Pharma A/S, or LEO Pharma, to develop and commercialize LP0145. Under the terms of the collaboration, LEO Pharma funded more than half of all product development costs up to CTA approval of a first product in a Phase 1 clinical trial, with our share of such costs capped. Now that CTA approval of a first product in a Phase 1 clinical trial has been received (in April 2018), LEO Pharma is solely responsible for funding the clinical development of the program.

We received a non-refundable, non-creditable upfront payment from LEO Pharma of €3.0 million in cash. In February 2016, June 2017 and April 2018, we achieved preclinical milestones under this collaboration for which we received milestone payments. 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 LP0145 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. In such case LEO Pharma is subject to diligence obligations in respect of continuation of development and commercialization of such product. If LEO Pharma elects to exercise this option, it must pay us an option fee. We are also eligible to receive additional development, regulatory and commercial milestone payments in aggregate amounts of up to €11.5 million, €6.0 million and €102.5 million, respectively, as well as tiered royalties on product sales at percentages ranging from the low single digits to the low teens, subject to customary reductions.

If LEO Pharma does not exercise its option prior to expiration of the applicable option period, if it does not meet agreed 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 LP0145 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 STT-5058)

In January 2015, we entered into a collaboration agreement with Staten Biotechnology B.V., or Staten, to develop and commercialize products in the area of dyslipidemia therapy. Under the collaboration agreement, the parties sought to discover and characterize antibodies against a human target with therapeutic relevance in the field of dyslipidemia and/or cardiovascular disease. The parties may also commence two further research programs for targets with therapeutic relevance in these areas. Each research program will last no more than 24 months from commencement unless the parties agree otherwise. The first research program under this agreement proceeded as planned and was extended to December 2017, with STT-5058 identified as the initial product candidate. Staten exercised its exclusive option to license STT-5058 in March 2017. Under the terms of the collaboration, the parties were and are jointly responsible for conducting research under a mutually agreed research plan, with Staten reimbursing us for all costs of carrying out our research responsibilities under each research program. Staten is also responsible for additional clinical development.

On a research program-by-research program basis, up through a specified period within such research program, we have granted Staten an option to obtain an exclusive, worldwide, permanent license to research, develop and commercialize products identified in that program. If Staten elects to exercise this option for a product (as it has for STT-5058), 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. Following exercise of its exclusive option, Staten is under the diligence obligation to continue to develop and commercialize at least one product during the term of the agreement.

In December 2018, Staten announced that it had entered into a collaboration and exclusive option agreement with Novo Nordisk, to develop novel therapeutics for the treatment of hypertriglyceridemia. Specifically, Novo will provide research and development funding and support to Staten, to develop its lead asset STT-5058 for the treatment of dyslipidemia. Novo has the right under the agreement to acquire Staten and gain worldwide rights to STT-5058. Staten and its shareholders will potentially receive signing and exercise fees, research and development funding, and milestone payments of up to €430.0 million.

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

Unless earlier terminated upon mutual agreement, for material breach or as otherwise specified in the agreement, the collaboration term ends on the later of (i) January 2020, (ii) expiration of the last license granted by us under the agreement, (iii) expiration of last option period for Staten and (iv) 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 STT-5058 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 the diligence obligation to continue to develop and commercialize at least one licensed product. To exercise this option with respect to antibodies discovered against any of the three initial targets named in the agreement, Shire paid us a one-time option fee.

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

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

In addition to option fees, Shire would also be obligated to pay us on a per-product basis upon achievement of specified development, regulatory and commercial milestones and a percentage of net sales as a royalty. Milestones are paid on a first product per indication per study target basis, and we are eligible to receive payments in aggregate amounts of up to $3.8 million, $4.5 million and $22.5 million, upon achievement of development, regulatory and commercial milestones, respectively, for a product generated against one of the three initial targets named in the 2012 agreement. For products generated against additional targets nominated under the 2014 agreement, development and regulatory milestone payments remain the same, and we are eligible to receive payments in aggregate amounts of up to $60.0 million for achievement of commercial milestones. The royalties payable to us are tiered, single digit and are subject to customary reductions. Through December 31, 2020, pursuant to the agreement Shire has paid us an aggregate total of (i) €3.4 million in upfront payments, (ii) €0.3 million in milestone payments and (iii) $12.6 million in research and development funding. In addition, Shire purchased 12.0 million of our ordinary shares in July 2014 by participating in our initial public offering on Euronext Brussels.

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

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

License Agreements — General

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

Our Exclusive License with Halozyme (ENHANZE®)

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

Our first therapeutic target for which we have received an exclusive license from Halozyme is FcRn, which allows us to apply ENHANZE® to efgartigimod and any other product candidates selective and specific for FcRn. Moreover, the breadth of our exclusive license to FcRn precludes either Halozyme itself or any of its current or future partners from utilizing ENHANZE® in the context of an FcRn-targeted product. Our second therapeutic target for which we received an exclusive license from Halozyme is human complement factor C2 associated with the product candidate ARGX-117, which is being developed to treat severe autoimmune diseases. Under the license terms, we also have the right to nominate future targets - again for an exclusive ENHANZE® license if the target in question has not already been licensed by Halozyme or is not already being pursued by Halozyme. From the effective date of the license agreement, we have a four-year period in which to conduct research and preclinical studies on other target-specific molecules in combination with ENHANZE® and may nominate a maximum of one additional target we have not yet nominated for an exclusive commercial license during the four-year term.

In return for the FcRn exclusive license, we have made a $30.0 million upfront payment to Halozyme. In return for the nomination of and exclusive license on C2 we made a $10.0 million milestone payment to Halozyme in May 2019. In return for achieving the first patient dosed for ARGX-113 Ph3 for ITP we made a $15.0 million milestone payment in February 2021. Upon nomination of any future target for an exclusive commercialization license and confirmation by Halozyme that such a license is available, we will pay $10 million to Halozyme per target. We will be obligated to pay clinical development, regulatory and commercial milestones totaling $160.0 million for the first product that uses ENHANZE® and is specific for a given target. Throughout the term of the agreement, we must provide Halozyme on an annual basis a guidance forecast setting out all projected milestone payments for products for the following four calendar quarters. We are also obligated to pay Halozyme a percentage of net sales as a royalty of any licensed product that uses ENHANZE®. This royalty varies with net sales volume, ranging from the low to mid-single digits, and it is reduced by a maximum of 50% if following 10 years from the first commercial sale of the product in a country, the last valid claim within the licensed ENHANZE® patent(s) expires. Throughout the term of the agreement, we must provide Halozyme on an annual basis an estimate of royalty payments anticipated for the following four calendar quarters. We have diligence obligations with respect to the continuation of development and commercialization of product candidates, but we are not obligated to utilize ENHANZE® for every product candidate directed to a given exclusive target(s).

In October 2020, we have expanded our collaboration with Halozyme for ENHANZE® drug delivery technology to include three additional exclusive targets upon nomination bringing the total to six potential targets.

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

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

Our non-executive director James M. Daly is also a non-executive member of the board of directors of Halozyme. Despite the foregoing, our entering into the license agreement with Halozyme was not a related party transaction in accordance with IAS 24 – Related Party Disclosures, since Mr. Daly, in his role as non-executive director, does not control or have significant influence over our company or Halozyme. Mr. Daly did not participate in any discussions and decision making relating to the Halozyme license agreement. Consequently, no further disclosures regarding Halozyme have been added in "Related Party Transactions".

Our Exclusive License with AgomAb (ARGX-114)

In March 2019, we entered into an exclusive license with AgomAb Therapeutics NV, or AgomAb, for the use of certain patents rights relating to our proprietary suite of technologies for the development and commercialization of a series of agonistic anti-MET SIMPLE Antibodies, including ARGX-114, an HFG-mimetic SIMPLE Antibody™ directed against the MET receptor. AgomAb is required to use commercially reasonable efforts to develop and commercialize at least one licensed product. In connection with our entry into this agreement, we received a profit sharing certificate which entitles us to 20% of all distributions to AgomAb's shareholders (which shall be reduced to 10% following the filing of an IND and is subject to further adjustment upon the occurrence of certain financings). Upon the occurrence of a qualified IPO of AgomAb, the profit sharing certificate will automatically be converted into an equivalent number of ordinary shares of AgomAb. This agreement is subject to mutual termination for material breach or insolvency and automatically expires upon the expiration of the last to expire of our licensed patent rights.

Our Exclusive License with Broteio (ARGX-117)

In March 2017, we entered into a collaboration under our Immunology Innovation Program with Broteio Pharma B.V., or Broteio, to develop an antibody against a novel target in the complement cascade, ARGX-117. Under the terms of the agreement, we and Broteio jointly developed the complement-targeted antibody to seek to establish preclinical proof-of-concept using our proprietary suite of technologies. Upon successful completion of these studies, we exercised an exclusive option to license the program in March 2018 and assumed responsibility for further development and commercialization. Under this agreement, we are obligated to make milestone payments upon the occurrence of certain development milestones (up to an aggregate of €4.0 million), commercialization milestones (up to an aggregate of €10.0 million) and pay tiered royalties on net sales in the low single digits. We may terminate this agreement for convenience upon 90 days prior written notice. This agreement is also subject to mutual termination for material breach or insolvency and automatically expires upon the expiration of our financial obligations thereunder.

In return for achieving the first patient dosed for ARGX-117 Phase 1 we made a €1.0 million development milestone payment to Broteio in September 2020.

Our Exclusive License with VIB (ARGX-118)

In November 2016, we entered into a collaboration under our Immunology Innovation Program with VIB vzw, or VIB, an inflammation research center in Ghent, Brussels, to develop antibodies against Galectin-10, the protein of Charcot-Leyden Crystals, which play a major role in severe asthma and the persistence of mucus plugs, including ARGX-118. Under the terms of the agreement, we and VIB jointly developed antibodies against Galectin-10 using our proprietary suite of technologies. Upon successful completion of this initial research, we exercised an exclusive option to license the program and assumed responsibility for further development and commercialization. Under this agreement, including a November 2018 amendment, we are obligated to make milestone payments upon the occurrence of certain development milestones (up to an aggregate of €4.0 million), commercialization milestones (up to an aggregate of €11.0 million) and pay tiered royalties on net sales in the low single digits. We may terminate this agreement for convenience upon 90 days prior written notice. This agreement is also subject to mutual termination for material breach, insolvency or certain patent challenges and automatically expires upon the expiration of VIB's licensed patent rights.

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

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

Upon commercialization of any of our products that use the in-licensed patent rights, we will be obligated to pay UoT a percentage of net sales as a royalty until the expiration of any patents covering the product. This royalty varies with net sales volume and is subject to an adjustment for royalties we receive from a sublicensee of our rights under this agreement, but in any event does not exceed 1%. In addition, we must make annual license maintenance payments to UoT until termination of the agreement. We have assumed certain development and commercial milestone payment obligations and must report on our progress in achieving product sales on a quarterly basis. The maximum milestone payments we would be required to make is approximately $0.5 million in total. Through December 31, 2020, we have paid UoT an aggregate of $0.8 million, which includes reimbursement for UoT's patent prosecution and maintenance costs and development milestones on products using the in-licensed patent rights. We also have diligence requirements with respect to development and commercialization of products which use the in-licensed patent rights.

Under and subject to the terms of the license, we may grant sublicenses to third parties. 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 and subject to the terms of the license, we are granted a non-exclusive right to use POTELLIGENT® to research, develop and commercialize antibodies and products containing such antibodies using POTELLIGENT®. BioWa retains a right of first negotiation for the exclusive right to develop and commercialize, in certain countries only, any product we develop using POTELLIGENT®. We successfully

applied POTELLIGENT® to cusatuzumab, an anti-CD70 mAb, and ARGX-111, an anti-c-Met mAb, under this license.

Upon commercialization of our products developed using POTELLIGENT®, we will be obligated to pay BioWa a percentage of net sales of a licensed product as a royalty. This royalty varies with net sales volume, ranging in the low single digits, and it is reduced by half if during the following 10 years from the first commercial sale of the product in a country the last valid claim within the licensed patent(s) that covers the product expires or ends. In addition, we must make annual research license maintenance payments which cease with commencement of our royalty payments to BioWa. We have diligence requirements with respect to the continuation of 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 and subject to the terms of the license, we have the right to grant sublicenses to third parties.

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

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

To scale up production of our product candidates cusatuzumab and ARGX-111 for clinical trial and commercial supply, we required a license to a GMP cell line in which POTELLIGENT® antibodies could be expressed. This cell line, POTELLIGENT® CHOK1SV, was jointly developed by BioWa and Lonza. In December 2013 and August 2014, respectively, we entered into non-exclusive commercial license agreements for cusatuzumab and ARGX-111 with BioWa and Lonza Sales AG, or Lonza, for the 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 cusatuzumab and c-Met in the case of ARGX-111. Both targets are designated as reserved targets under our 2010 license agreement with BioWa, which continues to govern our research, development and commercialization of products utilizing BioWa's 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. This right of first negotiation is not applicable in cases where we intend to grant a global license to a third party to develop and commercialize a product - as was the case with our exclusive, global collaboration and license agreement for cusatuzumab with Cilag GmbH International, an affiliate of Janssen, which was entered into on December 3, 2018. BioWa retains a right of first negotiation for the exclusive right to develop and commercialize our anti-c-Met antibody ARGX-111, in certain countries only.

Upon commercialization of our products developed using 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 commercial license maintenance payments to BioWa on a per product basis which cease with commencement of payment of the BioWa royalty for the respective product, and annual payments to Lonza in the event that any product is manufactured by a party other than Lonza, us or one of our affiliates or strategic partners named in the agreement.

We have assumed certain development, regulatory and commercial milestone payment obligations to both BioWa and Lonza and must report on our progress toward achieving these milestones on an annual basis. We are required to pay such milestones to BioWa under only one license—either the POTELLIGENT® agreement or the POTELLIGENT® CHOK1SV agreement, but not both. Payments related to the development and commercialization of cusatuzumab 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, 2020, we have paid BioWa an aggregate amount of $2.5 million, which includes a one-off milestone payment, 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, 2020, we have paid Lonza an aggregate amount of £0.5 million, which includes milestone payments under our POTELLIGENT® CHOK1SV agreement.

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

We may terminate the non-exclusive commercial license agreements at any time by sending BioWa and Lonza prior written notice. Absent early termination, the agreements will automatically expire upon the expiry of our royalty obligations under the respective agreement. In the event an agreement is terminated for any reason, the license granted to us would terminate but BioWa and Lonza would grant our sublicensees a direct license following such termination. In the event an agreement is terminated other than for our failure to make milestone or royalty payments, we would retain the right to sell the respective products then on hand for a certain period of time post-termination. Our royalty payment obligations expire, on a product-by-product and country-by-country basis, on the date that is the later of (i) 10 years after the first commercial sale of such product sold in that country under the agreement or (ii) such time as there are no valid claims covering such product.

Our Collaboration with UCL and Sopartec (GARP)

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

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

Under and subject to the terms of the license, we may grant sublicenses to third parties and affiliates of such third parties. From any income we receive in connection with these sublicenses, such as from our collaboration with AbbVie (see "Our Strategic Partnership with AbbVie" above), we must pay Sopartec a percentage of that income in the lower teen digit range. Royalty payment obligations expire on a product-by-product and country-by-country basis when there are no valid claims covering the ARGX-115 (ABBV-151) product. We also have diligence obligations with respect to the continued development and commercialization of ARGX-115 (ABBV-151) products. Through December 31, 2020, we paid an aggregate amount of €6.8 million to Sopartec, as a result of the upfront and milestone payments we received from AbbVie.

Our Exclusive License with Zai Lab Limited (ARGX-113)

In January 2021, we entered into an exclusive license agreement with Zai Lab Limited, or Zai Lab, for the development and commercialization of efgartigimod in Greater China, including mainland China, Hong Kong, Taiwan and Macau. Under the terms of the agreement, Zai Lab obtains the exclusive right to develop and commercialize efgartigimod in Greater China. Zai Lab will also contribute Chinese patients to argenx's global Phase 3 trials of efgartigimod. Additionally, this agreement is expected to accelerate efgartigimod global development by enabling our partner Zai Lab to initiate multiple Phase 2 proof-of-concept trials in new autoimmune indications.

Under the terms of the agreement, argenx will receive up to $175.0 million in collaboration payments, comprised of a $75.0 million upfront payment in the form of 568,182 newly issued Zai Lab shares at a price of $132.00 per share, $75.0 million as a guaranteed non-creditable, non-refundable development cost-sharing payment, and an additional $25.0 million milestone payment upon approval of efgartigimod in the U.S.. argenx is also eligible to receive tiered royalties (mid-teen to low-twenties on a percentage basis) based on annual net sales of efgartigimod in Greater China.

Regulatory Framework

Introduction

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 other countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

Licensure and Regulation of Biologics in the United States

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

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

- nonclinical laboratory tests, animal studies and formulation studies all performed in accordance with the FDA's GLP regulations;
- submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may begin;
- approval by an institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials to establish the safety, potency and purity of the product candidate for each proposed indication, in accordance with Good Clinical Practices, or GCP;
- preparation and submission to the FDA of a Biologic License Application, or BLA, for a biological 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 biological 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 biological 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 candidate or conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns before the clinical trial can begin.

As a result, submission of the IND may result in the FDA not allowing the trial to commence or on the terms originally specified by the sponsor in the IND. If the FDA raises concerns or questions either during this initial 30-day period, or at any time during the IND process, it may choose to impose a partial or complete clinical hold. This order issued by the FDA would delay either a proposed clinical study or cause suspension of an ongoing study, or in the case of a partial clinical hold place limitations on the conduct of the study such as duration of treatment, until all outstanding concerns have been adequately addressed and the FDA has notified the company that investigation may proceed and then only under terms authorized by the FDA. This could cause significant delays or difficulties in completing planned clinical trials in a timely manner. The FDA may impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance.

Human Clinical Trials in Support of a BLA

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

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

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

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

- Phase 1 clinical trials are initially conducted in a limited population to test the product candidate for safety, including adverse effects, dose tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics in healthy humans or, on occasion, in patients, such as cancer patients.

- Phase 2 clinical trials are generally conducted in a limited patient population to identify possible adverse effects and safety risks, evaluate the efficacy of the product candidate for specific targeted indications and determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger Phase 3 clinical trials.

- Phase 3 clinical trials proceed if the Phase 2 clinical trials demonstrate that a dose range of the product candidate is potentially effective and has an acceptable safety profile. Phase 3 clinical trials are undertaken within an expanded patient population to gather additional information about safety and effectiveness necessary to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling.

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

product labeling. Failure to exhibit due diligence with regard to conducting required Phase 4 clinical trials could result in withdrawal of approval for products.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators fifteen days after the trial sponsor determines the information qualifies for reporting for serious and unexpected suspected adverse events, findings from other studies or animal or *in vitro* testing that suggest a significant risk for human subjects and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must also notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than seven calendar days after the sponsor's initial receipt of the information.

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

Compliance with cGMP Requirements

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

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

Review and Approval of a BLA

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

The FDA has 60 days after submission of the application to conduct an initial review to determine whether the BLA is sufficient to accept for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission has been accepted for filing, the FDA begins an in-depth review of the application. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or the PDUFA, the FDA has ten months in which to complete its initial review of a standard application and respond to the applicant, and six months for a priority review of an application. The

FDA does not always meet its PDUFA goal dates for standard and priority BLAs. The review process may often be significantly extended by FDA requests for additional information or clarification. The review process and the PDUFA goal date may be extended by three months if the FDA requests or if the applicant otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

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

The FDA may also refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. In particular, the FDA may refer applications for novel biological products or biological 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 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 biological 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. FDA also has authority to require post-market studies, in certain circumstances, on reduced effectiveness of a product and may require labeling changes related to new reduced effectiveness information. Other potential consequences for a failure to maintain regulatory compliance 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 an acceptable confidential request made under the regulatory provisions. The product must then go through the review and approval process like any other product in order to be marketed.

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

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

Pediatric Studies and Exclusivity

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

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Unless otherwise required by regulation, PREA does not apply to a biologic for an indication for which orphan designation has been granted, except that PREA will apply to an original BLA for a new active ingredient that is orphan-designated if the biologic is a molecularly targeted cancer product intended for

the treatment of an adult cancer and is directed at a molecular target that FDA determines to be substantially relevant to the growth or progression of a pediatric cancer.

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." 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.

U.S. Patent Term Restoration

Depending upon the timing, duration and specifics of FDA approval of our product candidates, some 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, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit restoration of the patent term of up to five years as compensation for patent term lost during the FDA regulatory review process. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product’s approval date and only those claims covering such approved product, a method for using it or a method for manufacturing it may be extended. The patent-term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved biologic is eligible for the extension and the application for the extension must be submitted prior to the

expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

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

In order to market any medicinal 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 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 and the United Kingdom generally follows the same lines as in the United States. It entails satisfactory completion of pharmaceutical development, nonclinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the medicinal product for each proposed indication. It also requires the submission to relevant competent authorities for clinical trials authorization and to the EMA or to competent authorities in European Union Member States for a marketing authorization application, or MAA, and granting of a marketing authorization by these authorities before the product can be marketed and sold in the European Union. Following the UK's departure from the European Union, a separate marketing authorization will be required in order to place medicinal products on the market in Great Britain (under the Northern Irish Protocol, the European Union regulatory framework will continue to apply in Northern Ireland and centralized European Union authorizations will continue to be recognized).

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 a 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 come into effect following confirmation of the full functionality of the Clinical Trials Information System, the centralized European Union portal and database for clinical trials foreseen by the new Clinical Trials Regulation, through an independent audit. This is currently expected to occur in December 2021. 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. The UK has implemented Directive 2001/20/EC into national law through the Medicines for Human Use (Clinical Trials) Regulations, so UK regulation of clinical trials is currently aligned with European Union regulations. The extent to which the regulation of clinical trials in the UK will mirror the new European Union Clinical Trials Regulation once that comes into effect is unknown at present.

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 a life-threatening or chronically debilitating condition and either (i) the prevalence of the condition is not more than five in ten thousand persons in the European Union when the application is made, or without incentives it is unlikely that the marketing of the drug in the European Union would generate sufficient return to justify the necessary investment in its development. 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 and, regulatory assistance. If a marketing authorization is granted for an orphan drug, this results in 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. Market exclusivity may also be revoked in very select cases, such as if (i) it is established that a similar medicinal product is safer, more effective or otherwise clinically superior; (ii) the marketing authorization holder consents; or (ii) the marketing authorization holder cannot supply enough orphan medicinal product.

From 1 January 2021, a separate process for orphan drug designation will apply in Great Britain. There will be no pre-marketing authorization orphan designation (as there is in the European Union) and the application for orphan designation will be reviewed by the Medicines and Healthcare products Regulatory Agency, or MHRA, the UK medicines regulator, at the time of a MAA. The criteria are the same as in the European Union, save that they apply to Great Britain only (e.g. there must be no satisfactory method of diagnosis, prevention or treatment of the condition concerned in Great Britain).

Marketing Authorization

To obtain a marketing authorization for a product under the European Union regulatory system, an applicant must submit a MAA, either to EMA using the centralized procedure or to competent authorities in European Economic Area, or EEA, (the European Union Member States plus Iceland, Liechtenstein and Norway) using the other procedures (decentralized procedure, national procedure, or mutual recognition procedure). A marketing authorization may be granted only to an applicant established in the EEA. Regulation (EC) No. 1901/2006 provides that prior to obtaining a marketing authorization in the EEA, 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 EEA Member States. Pursuant to Regulation (EC) No. 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of cancer and auto-immune diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which the centralized procedure is in the interest of public health, the centralized procedure may be optional.

Under the centralized procedure, the Committee for Medicinal Products for Human Use, or the CHMP, established at the EMA is responsible for conducting the assessment of a product to define its risk/benefit profile. The CHMP recommendation is then sent to the European Commission, which adopts a decision binding in all EEA Member States. 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. Clock stops may extend the timeframe of evaluation of an MAA considerably beyond 210 days. 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 (excluding clock stops), 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. Now that the UK has left the European Union, Great Britain will no longer be covered by centralized marketing authorizations (under the Northern Irish Protocol, centralized European Union authorizations will continue to be recognized in Northern Ireland). All medicinal products with a current centralized authorization were automatically converted to Great Britain marketing authorizations on 1 January 2021. For a period of two years from 1 January 2021, the MHRA may rely on a decision taken by the European Commission on the approval of a new marketing authorization in the centralized procedure, in order to more quickly grant a new Great Britain marketing authorization. A separate application will, however, still be required.

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 for a centrally authorized product, or by the competent authority of the authorizing Member State for a nationally authorized product. 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 EEA market (in the case of the centralized procedure) or on the market of the authorizing Member State for a nationally authorized product within three years after authorization, or if the drug is removed from the market for three consecutive years, 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. Great Britain has implemented European Union legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended). The regulatory regime in Great Britain at present therefore aligns with European Union Regulation, however it is possible that these regimes will diverge in future now that Great Britain’s regulatory system is independent from the European Union.

Regulation and Procedures Governing Approval of Medicinal Products in Japan

In order to market any medical products in Japan, a company must comply with numerous and varying regulatory requirements in Japan regarding quality, safety and efficacy in the context, among other things, of clinical trials, marketing approval, commercial sales and distribution of products. A person who manufactures or markets medical products in Japan is subject to the supervision of the Minister of Health, Labour and Welfare (Minister or MHLW), primarily under the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals and Medical Devices (Pharmaceutical and Medical Device Act). This entails the satisfactory completion of pharmaceutical development, nonclinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the medical product for each proposed indication. It also requires the filing of a notification of clinical trials with the Pharmaceuticals and Medical Devices Agency (PMDA) and the obtaining of marketing approval from the relevant authorities before the product can be marketed and sold in the Japanese market.

Business License

Under the Pharmaceutical and Medical Device Act, a person is required to obtain from the Minister a marketing license in order to conduct the business of marketing, leasing or providing medical products that are manufactured (or outsourced to a third party for manufacturing) or imported by such person.

Also, in order to conduct the business of manufacturing medical products which will be marketed in Japan, a person is required to obtain from the Minister a manufacturing license for each manufacturing site.

Marketing Approval

Under the Pharmaceutical and Medical Device Act, it is generally required to obtain marketing approval from the Minister for the marketing of each medical product. An application for marketing approval must be made through the PMDA, which implements a marketing approval review.

Clinical Trial

Under the Pharmaceutical and Medical Device Act, it is required to file notification of clinical trials with the PMDA Also, the data of clinical trials and other pertinent data, which must be attached for an application for marketing approval, must be obtained in compliance with the standards established by the Minister, such as Good Laboratory Practice (GLP) and Good Clinical Practice (GCP) stipulated by the ministerial ordinances of the Minister.

Regulatory Requirements after Marketing Approval

A marketing license-holder that has obtained marketing approval for a new medical product must have that medical product re-examined by the Minister or by the PMDA for a specified period after receiving marketing approval. The purpose of this re-examination process is to ensure the safety and efficacy of a newly approved medical product by imposing on the marketing license-holder the obligation to gather clinical data for a certain period after the marketing approval was granted so that the Minister has the opportunity to re-examine the product. Results of usage and other pertinent data must be attached for an application for a re-examination. A marketing license holder that has obtained a marketing approval is also required to investigate, among other things, the results of usage and to periodically report to the Minister pursuant to the Pharmaceutical and Medical Device Act.

Price Regulation

In Japan, public medical insurance systems cover virtually the entire Japanese population. The public medical insurance system, however, does not cover any medical product which is not listed on the National Health Insurance (NHI) price list published by the Minister. Accordingly, a marketing license-holder of medical products must first have a new medical product listed on the NHI price list in order to obtain its coverage under the public medical insurance system.

The NHI price of a medical product is determined either by price comparison of comparable medical products with necessary adjustments for innovativeness, usefulness or size of the market; or, in the absence of comparable medical products, by the cost calculation method, determined after considering of the opinion of the manufacturer. Prices on the NHI price list will be subject to revision, generally once every year, on the basis of the actual prices at which the medical products are purchased by medical institutions.

Coverage, Pricing and Reimbursement

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

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

In China, the newly created National Healthcare Security Administration, or NHSA, an agency responsible for administering China’s social security system, organized a price negotiation with drug companies for certain new drugs that had not been included in the National Reimbursable Drug List, or the NRDL, at the time of the negotiation in November 2019, which resulted in an average price reduction by over 60% for 70 of the 119 drugs that passed the negotiation. NHSA, together with other government authorities, review the inclusion or removal of drugs from China’s National Drug Catalog for Basic Medical Insurance, Work-related Injury Insurance

and Maternity Insurance, or provincial or local medical insurance catalogues for the national medical insurance program regularly, and the tier under which a drug or device will be classified, both of which affect the amounts reimbursable to program participants for their purchases of those drugs. These determinations are made based on a number of factors, including price and efficacy. We may also be invited to attend the price negotiation with NHSA upon receiving regulatory approval in China, but we will likely need to significantly reduce our prices, and to negotiate with each of the provincial healthcare security administrations on reimbursement ratios. On the other hand, if the NHSA or any of its local counterpart includes our drugs and devices in the NRDL or provincial RDL, which may increase the demand for our drug candidates and devices, our potential revenue from the sales of our drug candidates and devices may still decrease as a result of lower prices. Moreover, eligibility for reimbursement in China does not imply that any drug or device will be paid for in all cases or at a rate that covers our costs, including licensing fees, research, development, manufacture, sale and distribution.

In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, and the cost of these studies would be in addition to the costs required to obtain FDA or other comparable marketing approvals. Even after pharmacogenomic studies are conducted, product candidates may not be considered medically necessary or cost-effective. A decision by a third-party payor not to cover any product candidates we may develop could reduce physician utilization of such product candidates once approved and have a material adverse effect on our sales, results of operations and financial condition. Additionally, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. For example, the payor may require co-payments that patients find unacceptably high. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor. Third-party reimbursement and coverage may not be adequate to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. The insurance coverage and reimbursement status of newly approved products for orphan diseases is particularly uncertain, and failure to obtain or maintain adequate coverage and reimbursement for any such product candidates could limit our ability to generate revenue. Further, due to the COVID-19 pandemic, millions of individuals have lost/will be losing employer-based insurance coverage, which may adversely affect our ability to commercialize our products, As noted above, in the U.S., we plan to have various programs to help patients afford our products, including patient assistance programs and co-pay coupon programs for eligible patients.

The containment of healthcare costs also has become a priority of U.S. federal, state and international governments and the prices of pharmaceuticals have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our potential revenue from the sale of any products for which we may obtain approval. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more of our products for which we or our collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Obtaining and maintaining reimbursement status is time-consuming and costly. No uniform policy for coverage and reimbursement for drug products exists among third-party payors in the United States. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

Outside the United States, we will face challenges in ensuring obtaining adequate coverage and payment for any product candidates we may develop. Pricing of prescription pharmaceuticals is subject to governmental control in many countries. Pricing negotiations with governmental authorities can extend well beyond the receipt of regulatory marketing approval for a product and may require us to conduct a clinical trial that compares the

effectiveness of any product candidates we may develop to other available therapies to support cost-effectiveness. The conduct of such a clinical trial could be expensive, involve additional risk and result in delays in our commercialization efforts.

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

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

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

Healthcare Law and Regulation

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of pharmaceutical products that are granted marketing approval. Our current and future arrangements with providers, researchers, consultants, third-party payors and customers are subject to broadly applicable federal and state fraud

and abuse, anti-kickback, false claims, transparency and patient privacy laws and regulations and other healthcare laws and regulations that may constrain our business and/or financial arrangements. Restrictions under applicable federal and state healthcare laws and regulations include, without limitation, the following:

- the U.S. federal Anti-Kickback Statute, or AKS, 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. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. A person or entity can be found guilty of violating the AKS without actual knowledge of the statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil money penalties statute. Violations of the AKS carry potentially significant civil and criminal penalties, including imprisonment, fines, administrative civil monetary penalties, and exclusion from participation in federal healthcare programs. On December 2, 2020, the Office of Inspector General, or OIG, published further modifications to the federal Anti-Kickback Statute. Under the final rules, OIG added safe harbor protections under the Anti-Kickback Statute for certain coordinated care and value-based arrangements among clinicians, providers, and others. This rule (with exceptions) became effective January 19, 2021. Implementation of this change and new safe harbors for point-of-sale reductions in price for prescription pharmaceutical products and pharmacy benefit manager service fees are currently under review by the Biden administration and may be amended or repealed. We continue to evaluate what effect, if any, the rule will have on our business;

- the U.S. federal false claims and civil monetary penalties laws, including the civil False Claims Act and federal civil monetary penalty laws, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim or obligation to pay or transmit money to the federal government , or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The False Claims Act also permits a private individual acting as a "whistleblower" to bring qui tam actions on behalf of the federal government alleging violations of the False Claims Act and to share in any monetary recovery. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;

- 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 obtaining by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the pay (e.g., public or private) 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 relating to healthcare matters; similar to the U.S. federal Anti Kickback Statute, 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;

- 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 Omnibus Rule in 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 Final HIPAA Omnibus Rule, i.e. certain covered health plans, healthcare clearinghouses and healthcare providers, as well as their business associates, those independent contractors or agents of covered entities that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- the U.S. Federal Food, Drug and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;

- 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 (currently defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in civil monetary penalties for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- 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 commercial 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; state and local laws that require the licensure of sales representatives; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect; and state laws related to insurance fraud in the case of claims involving private insurers; and

- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers and data privacy and security laws and regulations that may be more stringent than those in the United States.

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. 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.

Other laws that may affect our ability to operate include:

- the anti-inducement law prohibits, among other things, the offering or giving of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person know or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a federal or state governmental program;

- the U.S. Federal Food, Drug, and Cosmetic Act, or FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices; and

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

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.

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.

Healthcare Reform

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

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

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic products, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;

- expansion of manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices and extending rebate liability to prescriptions for individuals enrolled in Medicare Advantage plans;

- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for products that are inhaled, infused, instilled, implanted or injected;

- expanding the types of entities eligible for the 340B drug discount program;

- establishing the Medicare Part D coverage gap discount program, which requires manufacturers to provide a 50% (increased to 70% effective January 1, 2019 pursuant to subsequent legislation) point-of-sale-discount off the negotiated price of applicable products to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient products to be covered under Medicare Part D;

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and

- establishment of the Center for Medicare and Medicaid Innovation, or CMMI within CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription product spending.

Since its enactment, some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial, congressional, and executive challenges. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the ACA.

Since January 2017, former President Trump has signed several executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. On January 20, 2017, former President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Further, on October 13, 2017, former President Trump signed an executive order terminating the cost-sharing subsidies, or CSRs, that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. On August 14, 2020, the Court of Appeals for the Federal Circuit affirmed a lower court ruling that the federal government is liable to insurers selling marketplace health plans for the loss of cost-sharing reduction reimbursements mandated under the ACA. It is unclear what impact this will have on our business. Further, on June 14, 2018, the U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. On April 27, 2020, the United States Supreme Court reversed the Federal Circuit decision and remanded the case to the U.S. Court of Federal Claims, concluding the government has an obligation to pay these risk corridor payments under the relevant formula. In December 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of the federal district court litigation regarding the method CMS uses to determine this risk adjustment. In addition, CMS published a final rule that would give states greater flexibility, starting in 2020, in setting benchmarks for insurers in the individual and small group marketplaces,

which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Since then, the ACA risk adjustment program payment parameters have been updated annually. It is unclear what effect this will have on our business.

While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, includes a provision that decreased the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year, commonly referred to as the "individual mandate," to $0, effective January 1, 2019. On December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA, and therefore because the mandate was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. The Trump administration and CMS have both stated that the ruling will have no immediate effect, and on December 30, 2018, the same judge issued an order staying the judgment pending appeal. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional and remanded the case to the lower court to reconsider its earlier invalidation of the full ACA. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari (a petition for review of a lower court decision) to review this case, and held oral arguments on November 10, 2020. It is unclear how this decision and any subsequent appeals and other efforts to repeal and replace the ACA will impact the ACA and our business. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. We will continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These new laws may result in additional reductions in Medicare and other healthcare funding. For example, on August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2012 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including without limitation the Bipartisan Budget Act of 2015, will remain in effect through 2030 unless additional Congressional action is taken. However, pursuant to the Coronavirus Aid, Relief and Economic Security Act, or CARES Act, and subsequent legislation, these Medicare sequester reductions are suspended from May 1, 2020 through March 30, 2021 due to the COVID-19 pandemic. Proposed legislation, if passed, would extend this suspension until the end of the pandemic. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. The Trump administration's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Additionally, the Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out-of-pocket costs of drug products paid by consumers. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from

other countries and bulk purchasing. The Department of Health and Human Services (HHS) has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. However, it is unclear whether the Biden administration will challenge, reverse, revoke or otherwise modify these executive and administrative actions after January 20, 2021.

Recently there has been other types of 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.

On July 24, 2020 and September 13, 2020, former President Trump announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. As a result, on November 20 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and would have applied in all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. However, in response to a lawsuit filed by several industry groups, on December 28, the U.S. District Court for the Northern District of California issued a nationwide preliminary injunction enjoining government defendants from implementing the MFN Rule pending completion of notice-and-comment procedures under the Administrative Procedure Act. On January 13, 2021, in a separate lawsuit brought by industry groups in the U.S. District of Maryland, the government defendants entered a joint motion to stay litigation on the condition that the government would not appeal the preliminary injunction granted in the U.S. District Court for the Northern District of California and that performance for any final regulation stemming from the MFN Interim Final Rule shall not commence earlier than 60 days after publication of that regulation in the Federal Register. Additionally, on November 20, 2020, HHS finalized a regulation removing the safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to an order entered by the U.S. District Court for the District of Columbia, the portion of the rule eliminating safe harbor protection for certain rebates related to the sale or purchase of a pharmaceutical product from a manufacturer to a plan sponsor under Medicare Part D has been delayed to January 1, 2023. Further, implementation of this change and new safe harbors for point-of-sale reductions in price for prescription pharmaceutical products and pharmacy benefit manager service fees are currently under review by the Biden administration and may be amended or repealed. Although a number of these and other proposed measures will require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, Congress has each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Several bills have been introduced in both chambers, but due to increased focus on COVID-19 relief efforts, it is not clear when, and if any, proposed legislation regarding drug costs will advance.

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.

Environmental issues which may influence the use of our material fixed assets

Our primary research and development activities take place in our facilities in Zwijnaarde, Belgium. For these activities we require, and have obtained, the necessary environmental and biohazard permits from the responsible governments, required by us for the manner in which we use said facilities.

C. ORGANIZATIONAL STRUCTURE

As of December 31, 2020, we had five 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 BV	Belgium	100.00 %	Biotechnical research on drugs and pharma processes
argenx IIP BV	Belgium	100.00 %	Biotechnical research on drugs and pharma processes
argenx US, Inc.	USA	100.00 %	Pharmaceuticals and pharmacy supplies merchant wholesalers
argenx Switzerland, SA	Switzerland	100.00 %	Pharmaceuticals and pharmacy supplies merchant wholesalers
argenx Japan KK	Japan	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 4,086 square meters, located in Zwijnaarde, Belgium. The lease for this facility expires in 2025. We also lease office space in Breda, the Netherlands, Boston, Massachusetts, and Tokyo, Japan.

In January 2021, we have entered into a binding lease agreement in relation to the envisioned relocation of our Zwijnaarde facility to a newly built office in Zwijnaarde, with an annual base rent of €1.7 million, which would be operational in the second quarter of 2023, and with an initial term of 10.5 years. Included in the binding lease commitment is a rent free period of 6 months following the completion of the building.

In January 2021, we have entered into a lease agreement in relation to office space located in Geneva, Switzerland for an initial term of 1 year including 2 office spaces.

We have a total of four facilities worldwide owned or leased as of December 31, 2020, as set forth in the following table:

Facility location	Use	Approx. size (m^2)	Lease expiry
Zwijnaarde, Belgium (leased)	Operations and Laboratory Space	4,086	March 31st, 2025
Breda, the Netherlands (leased)	Headquarters	12	July 31st, 2021
Boston, Massachusetts (leased)	Office Space	813	August 31st, 2025
Tokyo, Japan (leased)	Office Space	546	January 17th, 2024

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

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 are advancing a deep pipeline of both clinical- and preclinical-stage product candidates for the treatment of severe autoimmune diseases, hematological disorders and cancer. Leveraging our technology suite and clinical expertise, we have advanced six product candidates into late-stage clinical development —efgartigimod, cusatuzumab, ARGX-111, ARGX-109, LP0145 (formerly ARGX-112) and ARGX-115 (ABBV-151); three into the preclinical stage — STT-5058 (formerly ARGX-116), ARGX-117 and ARGX-118; and we currently have multiple programs in the discovery stage. Through December 31, 2020, we have raised aggregate gross proceeds of €2,127.7 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 (€102.1 million) from our initial U.S. public offering on the Nasdaq Global Select Market in May 2017,
(v) $265.5 million (€225.6 million) from our second U.S public offering on the Nasdaq Global Select Market in December 2017,
(vi) $300.6 million (€255.7 million) from our third U.S public offering on the Nasdaq Global Select Market in September 2018,
(vii) €176.7 million from the private placement of equity securities as part of the closing of the global collaboration and license agreement with Janssen in January 2019,
(viii) €502.2 million from a global offering in November 2019 and
(ix) $590.5 million (€531.2 million) from our U.S. public offering on the Nasdaq Global Select Market and €200.4 million from a concurrent private placement in May 2020.

In addition, as of December 31, 2020, we have received upfront payments, milestone payments and research and development service fees from our collaborators totaling €442.8 million and have received €29.0 million in grants and incentives from governmental bodies. As of December 31, 2020, we had cash, cash equivalents and current financial assets of €1,627.0 million. This balance does not include payments or proceeds from recently announced business development transactions, including the purchase of a priority review voucher from Bayer HealthCare Pharmaceuticals, Inc. and the exclusive license agreement with Zai Lab for efgartigimod in Greater China.

Our balance sheet shows our total assets accumulate to €1,857.7 million for the year ended December 31, 2020, compared to €1,433.3 million for the year ended December 31, 2019 and €587.5 million for the year ended December 31, 2018. The main reason for the material change in balance sheet total are the various equity financing rounds, completed over the period covered by the financial statements.

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, 2019 and 2020, we incurred total comprehensive losses of €163.0 million and €528.9 million, respectively. As of December 31, 2020, we had accumulated losses of €861.5 million.

We expect our expenses to increase substantially in connection with our ongoing transition to an integrated immunology company, including the build-out of global commercial infrastructure and drug product inventory ahead of the expected launch of efgartigimod in MG, the advancement of our clinical-stage pipeline, including seven clinical trials of efgartigimod, and continued investment in our immunology innovation program. In addition, we expect to continue to incur significant costs associated with operating as a public company in the United States. We anticipate that our expenses will increase substantially if and as we:

Research and Development activities:

- execute the Phase 3 clinical trials of efgartigimod in ITP and in PV
- execute the Phase 2/3 clinical trials of efgartigimod in CIDP and launch Phase 2/3 clinical trials in other indications
- continue the research and development of our other clinical- and preclinical-stage product candidates and discovery stage programs
- jointly develop cusatuzumab with Janssen as per the collaboration agreement signed in December 2018; and
- seek regulatory approvals for any product candidates that successfully complete clinical trials

Pre-commercial and commercial activities

- further build-out our sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize any product candidates for which we may obtain regulatory approval;
- jointly commercialize cusatuzumab with Janssen as per the collaboration agreement signed in December 2018; and
- expand our global reach enabling us to commercialize any product candidates for which we may obtain regulatory approval

Other activities

- seek to enhance our technology platform and discover and develop additional product candidates;
- 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, including failed studies, ambiguous trial results, safety issues or other regulatory challenges.

We expect that the costs of development and commercialization might also significantly increase due to current and future collaborations with research and development partners as well as commercial partners. As some of these collaboration agreements provide for a joint decision process to approve the development plan as well as the budget, we will not control the actual amounts spent within such approved budget and we cannot control or guarantee that these funds are spent in the most efficient way.

Information pertaining to the year ended December 31, 2018 was included in our annual report on Form 20-F for the year ended December 31, 2019 under Item 5, “Operating and Financial Review and Prospects,” which was filed with the SEC on March 31, 2020.

Basis of Presentation

Revenue from Collaborations and license agreements

Revenues to date have consisted principally of milestones, license fees, non-refundable upfront fees and research and development service fees in correction with collaboration and license agreements.

The Company recognizes revenue when the customer obtains control of promised goods or services, in an amount that reflects the consideration that the Company expects to receive in exchange for those goods and services. In order to determine revenue recognition for agreements that the Company determines to be in the scope of IFRS 15, following five steps are performed:

1. Identify the contracts

In its current collaboration and license agreements, the Company is mainly licensing its intellectual property and/or providing research and development services, which might include a cost sharing mechanism and/or in the future, selling its products to collaborative partner entities. Revenue is generated through these arrangements via upfront payments, milestone payments based on clinical and regulatory criteria, research and development service fees and future sales based milestones and sales based royalties. In some cases the arrangements also include an equity subscription component, for which is analyzed if the criteria to combine contracts, as set out by IFRS 15, are met.

2. Identify performance obligations

Depending on the type of the agreement, there can be one or more distinct performance obligations under IFRS 15. This is based on an assessment of whether the promises in an agreement are capable of being distinct and are distinct from the other promises to transfer goods and/or services in the context of the contract.

The Company has assessed that there is one single performance obligation in our material ongoing collaboration and license agreements, being the transfer of a license combined with performance of research and development services.

This is because the Company considers the performance obligations cannot be distinct in the context of the contract as the license has no stand-alone value without the Company being further involved in the research and development collaboration and that there is interdependence between the license and the research and development services to be provided.

3. Determine the transaction price

Our material ongoing collaboration and license agreements include non-refundable upfront payments or license fees; milestone payments, the receipt of which is dependent upon the achievement of certain clinical, regulatory or commercial milestones; royalties on sales and research and development service fees.

3.1 Non-refundable upfront payments or license fees

If the license to the Company’s intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable upfront fees allocated to this license at the point in time the license is transferred to the customer and the customer has the right to use the license.

For all our material ongoing collaboration and license agreements, the Company considers the performance obligations related to the transfer of the license as not distinct from the other promises to transfer goods and/or services; the Company utilizes judgement to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time

or at a point in time. If over time, revenue is then recognized based on a pattern that best reflects the transfer of control of the service to the customer.

3.2 Milestone payments other than sales based milestones

A milestone payment, being a variable consideration, is only included in the transaction price to the extent it is highly probable that a significant reversal in the amount of cumulative revenue recognition will not occur when the uncertainty associated with the variable consideration is subsequently resolved. The Company estimates the amount to be included in the transaction price upon achievement of the milestone event. The transaction price is then allocated to each performance obligation on a stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each reporting period, the Company re-evaluates the probability of achievement of such milestones and any related constraint, and, if necessary, adjusts the estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue and earnings in the period of adjustment.

3.3 Research and development service fees

Our material ongoing collaboration and license agreements may include reimbursement or cost sharing for research and development services. R&D services are performed and satisfied over time given that the customer simultaneously receives and consumes the benefits provided by us. Such costs reimbursements received are recognized in revenues when costs are incurred and agreed by the parties.

3.4 Sales based milestone payments and royalties

Our material ongoing collaboration and license agreements include sales based royalties, including commercial milestone payments based on the level of sales, and the license has been deemed to be de predominant item to which the royalties and commercial milestone payments relate. Related revenue is recognized as the subsequent underlying sales occur.

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 basis. As our ongoing license and collaboration arrangements only contain one single performance obligation, the transaction price is entirely allocated to this single performance obligation.

5. Recognize revenue

Revenue is recognized when the customer obtains control of the goods and/or services as provided in the collaboration and license agreements. The control can be transferred over time or at a point in time – which results in the recognition of revenue over time or at a point in time.

As our ongoing license and collaboration arrangements only contain one single performance obligation which is, as the customer simultaneously receive the benefits provided by the Company’s performance, satisfied over time, the Company recognizes revenue over time.

The recognition of revenue over time is based on a pattern that best reflects the satisfaction of the related performance obligation, applying the input method. The input method estimates the satisfaction of the performance obligation as the percentage of total collaboration costs that are completed each period compared to the total estimated collaboration costs.

Research and development service fees are recognized as revenue when costs are incurred and agreed by the parties as the Company is acting as a principal in the scope of its stake of the research and development activities of its ongoing collaboration and license agreements.

Other Operating Income

As a company that carries extensive research and development activities, we benefit from various grants, research and development incentives and payroll tax rebates from certain governmental agencies. These grants and research and development incentives generally aim to partly reimburse approved expenditures incurred in our research and development efforts. The primary grants, research and development incentives and payroll tax rebates are as follows:

Government Grants

- We have received several grants from agencies of the Flemish government to support various research programs focused on technological innovation in Flanders. These grants require us to maintain a presence in the Flemish region for a number of years and invest according to pre agreed budgets.

Research and Development Incentives

- Companies in Belgium can benefit from tax savings on amounts spent on research and development by applying a one time or periodic tax deduction on research and development expenditures for the acquisition or development of patents. This tax credit is a reduction of the corporate income taxes for Belgian statutory purposes and is transferrable to the next four accounting periods. These tax credits are paid to us in cash after five years to the extent they have not been offset against corporate taxes due.

Payroll Tax Rebates

- We also benefit from certain rebates on payroll withholding taxes for scientific personnel. The government grants and research and development incentives generally aim to partly reimburse approved expenditures incurred in our research and development efforts and are credited to the income statement, under other operating income, when the relevant expenditure has been incurred and there is reasonable assurance that the grant or research and development incentive is receivable.

Research and Development Expenses

Research and development expenses consist principally of:

- personnel expense related to compensation of research and development staff and related expenses, including salaries, benefits and share-based compensation expenses;
- external research and development expenses related to (i) chemistry, manufacturing and control costs for our product candidates, both for preclinical and clinical testing, all of which is conducted by specialized contract manufacturers, (ii) fees and other costs paid to contract research organizations in connection with preclinical testing and the performance of clinical trials for our product candidates and (iii) costs associated with regulatory submissions and approvals, quality assurance and pharmacovigilance;
- materials and consumables expenses;
- depreciation and amortization of tangible and intangible fixed assets used to develop our product candidates; and

- other expenses consisting of (i) costs associated with obtaining and maintaining patents and other intellectual property and (ii) other costs such as travel expenses related to research and development activities.

We incur various external expenses under our collaboration and license agreements for material and services consumed in the discovery and development of our partnered product candidates. Under our agreements with Shire, LEO Pharma and Staten, our collaboration partner reimbursed us for part or all of these external expenses and compensates us for time spent on the project by our employees. Under our agreement with AbbVie, our own research and development expenses are not reimbursed. Research and development expenses are recognized in the period in which they are incurred. Under our agreement with Janssen, we assume certain development obligations, and are jointly responsible with Janssen for all research, development and regulatory costs relating to the product. Under our agreement with Zai, we are responsible for certain costs relating to future clinical trials involving efgartigimod conducted partially by Zai.

Our research and development expenses may vary substantially from period to period based on the timing of our research and development activities, including the timing of the initiation of clinical trials, production of product batches and enrolment of patients in clinical trials. Research and development expenses are expected to increase as we advance the clinical development of efgartigimod and cusatuzumab and further advance the research and development of our other preclinical and discovery stage programs. The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing and estimated costs of the efforts that will be necessary to complete the development of, or the period, if any, in which material net cash inflows may commence from, any of our product candidates. This is due to numerous risks and uncertainties associated with developing drugs, as fully described in “Item 3.D.—Risk Factors,” and including the uncertainty of:

- the scope, rate of progress and expense of our research and development activities;
- the successful enrollment in, and completion of clinical trials;
- the ability to market, commercialize and achieve market acceptance for efgartigimod, cusatuzumab or any other product candidate that we may develop in the future, if approved;
- 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 successful completion of preclinical studies necessary to support IND applications in the United States or similar applications in other countries;
- the expense of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; and
- our current and future collaborators continuing their collaborations with us.

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, marketing, commercial and support functions, (ii) consulting fees relating to professional fees for business development, marketing, 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 general and administrative expenses to increase as we continue to support our growth and operate as a public company in the United States. Such costs include increases in our finance and legal personnel, additional external legal and audit fees, and expenses and costs associated with compliance with the regulations governing public companies. We expect our selling expenses to increase significantly with preparatory marketing and market access activities with respect to the potential future commercialization of one or more of our product candidates, if approved.

Changes in fair value on non-current financial assets

In 2019, the Company entered into a license agreement with AgomAb Therapeutics NV for the use of HGF-mimetic SIMPLE Antibodies™, developed under the Company's Innovative Access Program. In exchange for granting this license, the Company received a profit share in AgomAb Therapeutics NV. The profit share has been designated as a non-current financial asset held at fair value through profit or loss. As a result, any change in fair value of the profit sharing instrument results in a fair value gain on financial assets at fair value through profit or loss.

Financial Income (Expense)

Financial income mainly reflects interest earned on our cash and cash equivalents and current financial assets and net gains on our cash and cash equivalents and current financial assets held at fair value through profit or loss. Financial expense corresponds mainly to net losses on cash and cash equivalents and current financial assets held at fair value through profit or loss and other financial expenses.

Exchange Gains (Losses)

Our exchange gains (losses) relate to (i) our transactions denominated in foreign currencies, mainly in U.S. dollars, Swiss francs, British pounds and Japanese yens, 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 was our functional and presentation currency until January 1, 2021 and therefore the presentation currency throughout this reporting period. For more information on currency exchange fluctuations on our business, please see "Item 11—Quantitative and Qualitative Disclosures about Market Risk—Foreign Exchange Risk." We have no derivative financial instruments to hedge interest rate and foreign currency risk.

Income Tax

We have a history of losses. We expect to continue incurring losses as we continue to invest in our clinical and pre-clinical development programs and our discovery platform, and as we prepare for the potential future commercial launch of one or more of our product candidates, if approved. Consequently, we do not have any deferred tax asset on our consolidated statements of financial position.

We are incurring income tax expense on the profit generated in argenx US, Inc and argenx Japan K.K. in view of the transfer price agreements set up between argenx BV and argenx US, Inc. and between argenx BV and argenx Japan K.K.

Critical Accounting Policies and Significant Judgments and Estimates

In the application of the Company's accounting policies, which are described above, the Company is required to make judgments, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period or in the period of the revision and future periods if the revision affects both current and future periods.

The following areas are areas where key assumptions concerning the future, and other key sources of estimation uncertainty at the end of the reporting period, have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year.

Critical estimates in applying accounting policies

Research and development cost accruals

The Company recognizes costs of €52.6 million, as specified in note 15 to the financial statements, incurred for clinical trial activities and manufacturing of drug products, as research and development expenses based on an evaluation of its vendors' progress toward completion of specific tasks. Timing of payment may differ significantly from the period in which the costs are recognized as expense, resulting in clinical trial accruals recognized within "Trade and other payables" in the consolidated statements of financial position.

Quantification of the research progress and the translation of the progress to these accruals requires estimates, because the progress is not directly observable. In estimating the vendors' progress toward completion of specific tasks, the Company therefore uses non-financial data such as patient enrollment, clinical site activations and vendor information of actual costs incurred. This data is obtained through reports from or discussions with Company personnel and outside service providers as to the progress or state of completion of trials, or the completion of services. Costs are expensed over the service period the services are provided. Costs for services provided that have not yet been paid are recognized as accrued expenses. Research and development cost accruals directly impact the revenue recognized, given the satisfaction of the single performance obligation is measured using the input method.

Results of Operation

Comparison of Years Ended December 31, 2020 and 2019

	Year ended December 31,		
	2020	2019	% Change
	(In thousands)		
Revenue	€ 36,425	€ 69,783	(48)%
Other operating income	18,109	12,801	41 %
Total operating income	**54,534**	**82,584**	**(34)%**
Research and development expenses	(325,479)	(197,665)	65 %
Selling, general and administrative expenses	(149,367)	(64,569)	131 %
Total operating expenses	**(474,846)**	**(262,234)**	81 %
Change in fair value on non-current financial assets	2,544	1,096	132 %
Operating loss	**(417,769)**	**(178,554)**	**134 %**
Financial income/(expenses)	(1,414)	14,275	(110)%
Exchange gains (losses)	(106,956)	6,066	(1,863)%
Loss before taxes	**€ (526,139)**	**€ (158,213)**	**233 %**
Income tax expense	(2,784)	(4,752)	(41)%
Loss for the period and total comprehensive loss	**€ (528,923)**	**€ (162,965)**	**225 %**
Weighted average number of shares outstanding	45,410,442	38,619,121	
Basic and diluted loss per share (in €)	(11.65)	(4.22)	

Revenue

	Year ended December 31,		
	2020	2019	% Change
	(In thousands)		
Upfront payments	**€ 30,348**	**€ 22,360**	**36 %**
Janssen	29,818	20,056	49 %
AbbVie	497	761	(35) %
Agomab	—	1,499	(100) %
Other	33	44	(25) %
Milestone payments	**3,021**	**28,085**	**(89) %**
Janssen	2,333	1,569	49 %
AbbVie	671	26,494	(97) %
Other	17	22	(25) %
Research and development service fees	**3,056**	**19,338**	**(84) %**
Janssen	2,807	18,968	(85) %
Other	249	370	(33) %
Total revenue	**€ 36,425**	**€ 69,782**	**(48) %**

Our revenue decreased by €33.4 million for the year ended December 31, 2020 to €36.4 million, compared to €69.8 million for the year ended December 31, 2019, a result of a decrease in revenue recognition from milestone payments and research and development service fees, partly offset by an increase in revenue recognition from upfront payments.

The increase in revenue recognition from upfront payments is primarily driven by the increased over-time recognition of the upfront payment received under the collaboration and license agreement for cusatuzumab with Janssen.

The decrease in revenue recognition from milestone payments of €25.0 million is mainly driven by revenue recognition in 2019 of the $30.0 million (€26.6 million) milestone payment under the AbbVie collaboration, following the first-in-human clinical trial with ABBV-151, achieved in 2019, whereas in 2020 no such milestone payments were achieved.

The decrease in revenue recognition from research and development service fees of €16.2 million is primarily driven by the decrease under the Janssen collaboration. In 2020, the Company transferred the activities related to the development of cells banks, development of manufacturing process and the production of drug substance to Janssen, resulting in a decrease in costs reimbursement under the cost sharing arrangement.

Other Operating Income

	Year ended December 31,		
	2020	2019	% Change
	(In thousands)		
Grants	€ 1,226	€ 2,289	(46)%
Research and development incentives	8,875	4,818	84 %
Payroll tax rebates	8,008	5,694	41 %
Total	**€ 18,109**	**€ 12,801**	**41 %**

Other operating income increased by €5.3 million for the year ended December 31, 2020 to €18.1 million, compared to €12.8 million for the year ended December 31, 2019. The increase is primarily driven by:

- the increase in research and development incentives, as a result of the increased research and development costs incurred; and
- the increase in payroll tax rebates, as a direct result of the increase in the employment of highly qualified research and development personnel, eligible for specific payroll tax rebates.

For more information regarding governmental policies that could affect our operations, see "Item 4.B.—Business Overview—Government Regulation."

Research and Development Expenses

	Year ended December 31,		
	2020	2019	% Change
		(In thousands)	
Personnel expense	€ 75,121	€ 45,733	64 %
External research and development expenses	228,438	137,050	67 %
Materials and consumables	3,099	2,027	53 %
Depreciation and amortization	2,472	1,641	51 %
Other expenses	16,349	11,214	46 %
Total	**€ 325,479**	**€ 197,665**	**65 %**

Our research and development expenses totaled €325.5 million and €197.7 million for the years ended December 31, 2020 and 2019, respectively. The increase of €127.8 million compared to 2019 primarily results from an increase in external research and development expenses and personnel expenses, primarily related to the efgartigimod program in various indications, cusatuzumab program and other clinical and preclinical programs. Furthermore, the personnel expenses increased due to a planned increase in headcount.

The increase of €29.4 million in personnel expense for the year ended December 31, 2020 corresponded primarily to (i) an increase of €13.9 million for share-based compensation expenses related to the grant of stock options to our research and development employees, and (ii) increased costs associated with additional research and development personnel. We employed on average 213.0 full time equivalents in our research and development functions in the year ended December 31, 2020, compared to 121.6 in the year ended December 31, 2019.

Our external research and development expenses for the year ended December 31, 2020 totaled €228.4 million, compared to €137.1 million for the year ended December 31, 2019. The increase reflects higher clinical trial costs and manufacturing expenses related to the development of our product candidate portfolio. The table below provides additional detail on our external research and development expenses by program:

	Year ended December 31,		
	2020	2019	% Change
		(In thousands)	
efgartigimod	€ 160,379	€ 84,180	91 %
cusatuzumab	43,672	38,692	13 %
Other programs	24,388	14,178	72 %
Total	€ 228,438	€ 137,050	67 %

External research and development expenses for our lead product candidate efgartigimod totaled €160.4 million for the year ended December 31, 2020, compared to €84.2 million for the year ended December 31,

2019. This increase of €76.2 million corresponds primarily to increased manufacturing and clinical development activities in relation to:

- the execution of two Phase 3 clinical trials in MG ;
- the initiation of the bridging study for ENHANZE® efgartigimod in MG;
- the execution of two Phase 2 clinical trials in CIDP;
- the execution of two Phase 3 clinical trials in ITP; and
- the execution of the Phase 2 clinical trial and initiation of the Phase 3 clinical trial in PV.

External research and development expenses for cusatuzumab totaled €43.7 million for the year ended on December 31, 2020 compared to €38.7 million for the year ended December 31, 2019. This increase of €5.0 million resulted primarily from:

- the initiation of a Phase 1b, evaluating cusatuzumab in combination with venetoclax and azacytidine in newly-diagnosed, elderly patients with AML who are ineligible for intensive chemotherapy;
- the initiation and execution of a Phase 2 and Phase 1b platform trial evaluating cusatuzumab in combination with venetoclax and azacytidine; and
- the initiation and execution of a Phase 2 trial of cusatuzumab in combination with azacytidine versus azacytidine alone.

External research and development expenses on other programs increased by €10.2 million to €24.4 million for the year ended December 31, 2020, compared to €14.2 million for the year ended December 31, 2019. The increase is primarily due to increased research and development expenses in relation to the advancement of our ARGX-117 program, a complement-targeting antibody against C2.

Selling, General and Administrative Expenses

	Year ended December 31,		
	2020	2019	% Change
		(In thousands)	
Personnel expense	€ 94,251	€ 40,082	135 %
Consulting fees	42,459	16,343	160 %
Supervisory board	4,243	2,792	52 %
Other expenses	8,414	5,352	57 %
Total	**€ 149,367**	**€ 64,569**	**131 %**

Our selling, general and administrative expenses totaled €149.4 million and €64.6 million for the years ended December 31, 2020 and 2019, respectively. The increase in our selling, general and administrative expenses for the year ended December 31, 2020 was principally due to an increase of personnel expense and consulting fees, resulting from:

- increased costs of the share-based payment compensation plans related to the grant of stock options to our selling, general and administrative employees;
- increased costs associated with additional employees recruited to strengthen our selling, general and administrative activities, in preparation of the potential commercial launch of efgartigimod in the U.S; and
- increased consulting fees, primarily in preparation of the potential commercial launch of efgartigimod in the U.S.

We employed on average 119.5 full time equivalents in our selling, general and administrative functions in the year ended December 31, 2020, compared to 56.3 in the year ended December 31, 2019.

Financial Income (Expense)

For the year ended December 31, 2020, financial expense amounted to €1.4 million compared to a financial income of €14.3 million for the year ended December 31, 2019. The decrease of €15.7 million in 2020 related primarily to financial expenses incurred as a result of a decrease in net asset value on the current financial assets following the impact of the COVID-19 outbreak on the financial markets, partly offset by the interest received on our cash and cash equivalents and current financial assets.

Exchange Gains (Losses)

Exchange losses totaled €107.0 million for the year ended December 31, 2020, compared to exchange gains of €6.1 million for the year ended December 31, 2019. The decrease was mainly attributable to unrealized exchange rate losses on the cash, cash equivalents and current financial assets position in U.S. dollars.

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, 2020, we have raised gross proceeds of €2,127.7 million from private and public offerings of equity securities, received €442.8 million in revenue from our collaborators, and €29.0 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, 2020, we had cash, cash equivalents and current financial assets of €1,627.0 million, compared to €1,335.8 million on December 31, 2019.

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 leases and our commitments to Lonza which are detailed in “Note 29—Commitments” in our consolidated financial statements which are appended to our annual report for the period ended December 31, 2020 and which are incorporated herein by reference.

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 26—Financial management” in our consolidated financial statements which are appended to our annual report for the period ended December 31, 2020 and which are incorporated herein by reference.

Cash Flows

Comparison for the Years Ended December 31, 2020 and 2019

The table below summarizes our cash flows for the years ended December 31, 2020 and 2019.

	Year ended December 31,		
	2020	2019	Variance
		(In thousands)	
Cash and cash equivalents at beginning of the period	**€ 331,282**	**€ 281,040**	**€ 50,242**
Net cash flows (used in) / from operating activities	(346,349)	134,584	(480,933)
Net cash flows (used in) / from investing activities	310,250	(744,338)	1,054,588
Net cash flows (used in) / from financing activities	747,897	659,359	88,538
Effect of exchange rate differences on cash and cash equivalents	(51,471)	637	(52,108)
Cash and cash equivalents at end of the period	**€ 991,609**	**€ 331,282**	**€ 660,327**

Net Cash Used in Operating Activities

Net cash outflow from our operating activities increased by €480.9 million to a net outflow of €346.3 million for the year ended December 31, 2020, compared to a net inflow of €134.6 million for the year ended December 31, 2019. The net cash outflow from operating activities for the year ended December 31, 2020 resulted primarily from (i) the research and development expenses incurred in relation to the manufacturing and clinical development activities of efgartigimod, cusatuzumab and the advancement of other preclinical and discovery-stage product candidate, (ii) the personnel expenses and consulting expenses incurred in preparation of the potential commercial launch of efgartigimod in the U.S., and (iii) the manufacturing of pre-launch inventory ahead of the potential commercial launch of efgartigimod in the U.S. . The net cash inflow of €134.6 million for the year ended December 31, 2019 was primarily influenced by the closing of the exclusive global collaboration and license agreement for cusatuzumab with Janssen, which triggered a $300 million upfront payment, whereas in the year ended December 31, 2020 no such cash inflows occurred.

Net Cash Used in Investing Activities

Investing activities consist primarily of the divestment of current financial assets, interest received from the placements of our cash and cash equivalents and current financial assets. Cash flow from investing activities represented a net inflow of €310.2 million for the year ended December 31, 2020, compared to a net outflow of €744.3 million for the year ended December 31, 2019. The net inflow for the year ended December 31, 2020 related primarily to the net divestment of €307.6 million of current financial assets, including money market funds and U.S. term deposit accounts to money market funds classified as cash equivalents, compared to a net investment of €708.1 for the year ended December 31, 2019.

Net Cash Provided by Financing Activities

Financing activities primarily 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 €747.9 million for the year ended December 31, 2020, compared to a net cash inflow of €659.4 million for the year ended December 31, 2019. The net cash inflow for the year ended December 31, 2020 was attributed to (i) €731.1 million net cash proceeds from our global offering and concurrent private placement in May 2020, compared to €655.9 million net cash proceeds from our global offering in November 2019 and our private placement in January 2019 following the closing of the exclusive global collaboration and license agreement for cusatuzumab with Janssen in January 2019 and (ii) €19.1 million proceeds received from the exercise of stock options in 2020, compared to €4.8 million for the year ended December 2019.

Operating and Capital Expenditure Requirements

We have never achieved profitability and, as of December 31, 2020, we had accumulated losses of €861.5 million. We expect to continue to incur significant operating losses for the foreseeable future as we continue our research and development efforts and seek to obtain regulatory approval and commercialization of our product candidates.

On the basis of current assumptions, we expect that our existing cash and cash equivalents and current financial assets will enable us to fund our operating expenses and capital expenditure requirements through at least the next 12 months. Because of the numerous risks and uncertainties associated with the development and commercialization of efgartigimod, cusatuzumab and our other product candidates and discovery stage programs and because the extent to which we may enter into collaborations with third parties for the development of these product candidates is unknown, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates. Our future capital requirements for efgartigimod, cusatuzumab and our other product candidates and discovery stage programs will depend on many factors, including:

- the progress, timing and completion of preclinical testing and clinical trials for our current or any future product candidates;
- the number of potential new product candidates we identify and decide to develop;
- the 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;
- manufacturing activities undertaken ahead of the potential commercialization of our current or any future product candidates, if approved, and costs involved in the creation of an effective supply chain.
- 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 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; and
- developments related to COVID-19 and its impact on the costs and timing associated with the conduct of our clinical trials, preclinical programs, manufacturing activities and other related activities.

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, 2020 to December 31, 2020 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

Below an overview is given of our material contractual obligations at December 31, 2020

Lease obligations

	Payments due by period				
	Total	Less than 1 year	1–3 years	3–5 years	More than 5 years
	(In thousands)				
Lease liabilities	€ 8,299	€ 3,043	€ 4,085	€ 1,171	€ —
Lease commitments not commenced	€ 16,911	€ —	€ 282	€ 3,382	€ 13,247

We signed lease agreements for laboratory and office space in Zwijnaarde, Belgium, offices in Breda, Netherlands, Boston, USA, and Tokyo, Japan, as disclosed in “Item 4.D.—Property, Plant and Equipment”.

In January 2021, we have entered into a binding lease agreement related to the envisioned relocation of our Zwijnaarde facility to a newly built office in Zwijnaarde, with an annual base rent of €1.7 million, which would be operational in the second quarter of 2023, and with an initial term of 10.5 years. Included in the binding lease commitment is a rent free period of 6 months following the completion of the building. The total future cash outflows related to this lease are represented above as “Lease commitments not commenced”.

In addition, our lease liabilities include a lease plan for company cars with maturity dates up to four years.

For a discussion of contractual obligations, please see “Note 29—Commitments” in our consolidated financial statements which are appended to our annual report for the period ended December 31, 2020 and which are incorporated herein by reference.

G. SAFE HARBOR

This annual report contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act and as defined in the Private Securities Litigation Reform Act of 1995. See “Cautionary Statement with Respect to Forward Looking Statements” at the beginning of this annual report.

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. DIRECTORS AND SENIOR MANAGEMENT

Our Board of Directors

We have a one-tier board structure consisting of an executive director who is responsible for our day-to-day management and non-executive directors who are responsible for the supervision of the executive directors. Our executive directors and our non-executive directors are collectively responsible for our general affairs. We may be represented by our board of directors or by two executive directors acting jointly. Our board of directors is currently comprised of one executive director and seven 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, 2020:

Name	Age	Position	Nationality	Date of last (re)-appointment	Term expiration
Tim Van Hauwermeiren	49	Executive Director (Chief Executive Officer)	BE	May 8, 2018	2022
Peter K.M. Verhaeghe	62	Non-Executive Director (chairperson)	BE	May 8, 2018	2022
David L. Lacey	68	Non-Executive Director	US	May 8, 2018	2022
Werner Lanthaler	52	Non-Executive Director (vice chairperson)	AT	May 8, 2018	2022
J. Donald deBethizy	70	Non-Executive Director	US	May 7, 2019	2023
Pamela Klein	59	Non-Executive Director	US	May 12, 2020	2024
A.A. Rosenberg	68	Non-Executive Director	UK	April 26, 2017	2021
James M. Daly	59	Non-Executive Director	US	May 8, 2018	2022

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

A.A. Rosenberg is expected to be nominated for re-appointment at the General Meeting to be held in 2021.

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. Mr. Van Hauwermeiren currently holds the positions set out in the table "Our Executive Management" below.

Peter K. M. Verhaeghe has served as a member and chairperson of the supervisory board of arGEN-X B.V. since October 2008 and as non-executive director on 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, French, US and Swiss life sciences 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 as a member of the board of directors of CzechPak Manufacturing s. r. o. He previously also served as director of Innogenetics (Belgium), Tibotec-Virco NV, Biocartis SA, and as the chairman of the board of directors of PharmaNeuroBoost NV and as liquidator in charge of KBC Private Equity Fund Biotech NV from April 2009 to December 2012. Mr. Verhaeghe serves the board of directors of Participatiemaatschappij Vlaanderen (PMV) NV since May 2018, as chairman of the board of Haretis SA (Luxembourg) since March 2011, and as member of the Board of Directors of miDiagnostics since April 2020. Mr. Verhaeghe also serves as the chairman of the LP & advisory committee of Bioqube Factory Fund I Nv. 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 Bioxell SpA and Pantec Biosolutions AG. Dr. Lanthaler holds a degree in psychology, a Ph.D. in business administration from Vienna University of Economics and Business and a Master's degree in public administration from Harvard University.

Dr. J. Donald deBethizy has served as a member of our board of directors since May 2015. Dr. deBethizy has 30 years of experience in research and development and financial, business and operating management and board work 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, Lophora ApS 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, and from July 2015 to November 2017, he served as chairman of Rigotec GmbH. He previously served on the boards of Asceneuron SA, Serendex Pharmaceuticals A/S, Enbiotix Inc., Targacept Inc. and Biosource Inc. Dr. 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 and is a Consulting CMO for Olema Oncology in San Francisco, Calif. 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, his own consultancy firm advising on business development, licensing and mergers and acquisitions and as consultant to PJT Ltd and SB Biotech. Previously Mr. Rosenberg

held the positions of Managing Director at MPM Capital, a venture capital firm (2015 until 2020), Head of M&A and Licensing of Novartis International (2013 to 2015) and Head of Business Development and Licensing at Novartis Pharma (2005 to 2012). Mr. Rosenberg currently serves on the boards of directors of SiO2 Material Science, Oculis SA (chairman) and Cullinan Oncology (chairman), and previously served on the boards of directors at Radius Health Inc., TriNetX, Inc., iOmx Therapeutics AG and Clinical Ink. Msc. A.A. Rosenberg has a B.Sc. (Hons) from the University of Leicester and a M.Sc. Physiology from the University of London.

James M. Daly has served as a member of our board of directors since May 2018. He joined GlaxoSmithKline in 1985 where he held various positions, including Sr. Vice President – Respiratory Division with full responsibility for sales, marketing and medical affairs. He moved to Amgen in 2002 where he was Sr. Vice President for the North America Commercial Operations 2011. In 2012 he joined Incyte, a publicly traded company focused on oncology and inflammation, where he was chief commercial officer until June 2015. James Michael Daly currently serves as a director of Chimerix, Inc., Acadia Pharmaceuticals Inc., Halozyme Therapeutics, Inc., Bellicum Pharmaceuticals, Inc. and Madrigal Pharmaceuticals, all Nasdaq-listed companies. James Michael Daly holds a Bachelor in Science and a Master in Business Administration from the State of New York University.

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, 2020:

Name	Age	Position	Nationality	Date of appointment
Tim Van Hauwermeiren	49	Chief Executive Officer and Executive Director	BE	July 15, 2008
Eric Castaldi	56	Chief Financial Officer	FR	April 1, 2014
Keith Woods	53	Chief Operating Officer	US	April 5, 2018
Hans de Haard	61	Chief Scientific Officer	NL	July 1, 2008
Wim Parys	61	Chief Medical Officer	BE	July 1, 2019
Arjen Lemmen	36	Vice President Corporate Development & Strategy	NL	May 1, 2019
Dirk Beeusaert	57	General Counsel	BE	April 1, 2017
Marc Schorpion	63	Global Head of Human Resources	BE	February 1, 2019
Andria Wilk	48	Global Head of Quality	UK	January 13, 2020

The address for our executive management is Industriepark Zwijnaarde 7, Building C, 9052 Zwijnaarde (Ghent), Belgium.

Please note that as part of our evolution to become a commercial-stage company, we have planned to recruit a U.S. based Chief Financial Officer. In this regard, we plan to enter into a transition agreement with Mr. Castaldi.

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 29 years of international financial executive management experience, including 20 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 SA, a Euronext-listed French biopharmaceutical company specializing in oncology. From 1987 to 1989, Mr. Castaldi served as chief financial officer/chief operating officer of Safety-Kleen Corp. From 1989 to 1997, he served as chief financial officer/chief operational officer of MY Kinda Town PLC. Mr. Castaldi graduated with a degree in finance, accountancy and administration from the University of Nice.

Keith Woods has served as our Chief Operating Officer since April 2018. Mr. Woods has over 25 years of experience in the biopharmaceutical industry. He most recently served as Senior Vice President of North American Operations for Alexion Pharmaceuticals Inc. (Alexion), where he managed a team of several hundred people in the U.S. and Canada and was responsible for more than $1 billion in annual sales. Within Alexion, he previously served as Vice President and Managing Director of Alexion UK, overseeing all aspects of Alexion's U.K. business; Vice President of U.S. Operations; and Executive Director of Sales, leading the launch of Soliris in atypical hemolytic uremic syndrome. Prior to joining Alexion, he held various positions of increasing responsibility within Roche, Amgen and Eisai over a span of 20 years. Keith Woods holds a B.S. in Marketing from Florida State University.

Wim Parys obtained a MD degree from the Katholieke Universiteit Leuven, Belgium. He was in private practice for 9 years before joining the Janssen Research Foundation in Beerse, Belgium where he held several R&D positions and developed galantamine (Reminyl™ / Razadyne™) for Alzheimer's Disease. In 2000 he became the Head of Development at the biotech company Tibotec and relocated to the US to establish Tibotec Inc., the US based subsidiary. Under his tenure, Tibotec (then acquired by J&J) developed and launched Prezista™, Intelence™ and Edurant™, three innovative HIV drugs. As Development Head of Janssen's Infectious Diseases and Vaccines therapeutic area, he lead the discovery and development of other medicines for HIV, Hepatitis C (Incivo™, Olysio™/Sovriad™), TB (Sirturo™) and respiratory viral diseases. In 2013 he became the R&D head of the newly established Global Public Health group, responsible for a portfolio including programs in HIV, TB, other mycobacterial infections, Dengue and Malaria. Wim joined argenx early 2019 as a development consultant and transitioned to the role of Chief Medical Officer on July 1, 2019.

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.

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 board of directors of Cubigo NV and The Fourth Law 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.

Arjen Lemmen serves as the head of our strategy and corporate development activities. He joined argenx in 2016 and has successfully executed several transactions including a number of programs within our Immunology Innovation Program and our strategic collaboration with Janssen on cusatuzumab. Prior to joining argenx, he served as a corporate finance specialist at Kempen & Co focusing on M&A, Equity Capital Markets and strategic advisory transactions in the European life sciences industry. Mr. Lemmen holds a B.Sc. in Life Science & Technology from the University of Groningen (the Netherlands) and Master of Engineering Management from Duke University. Arjen was promoted to Vice-President of Corporate Development & Strategy per June 1, 2019.

Marc Schorpion joined argenx as Global Head of Human Resources in December 2018. Mr. Schorpion spent his 35-year career with Johnson & Johnson, most recently as Vice President, Human Resources. In this role, he had global responsibility for talent management and leadership support covering all R&D and Science-based Innovation organizations across Johnson & Johnson. From 2003-2013, Mr. Schorpion led worldwide Human Resources for the Johnson & Johnson Pharmaceuticals Group. He started his career with Johnson & Johnson in 1983 at Janssen Pharmaceutica in Belgium. He holds a Licentiate degree in Applied Economics and a Master of Business Administration from the University of Antwerp. In 2019 Mr. Schorpion co-founded United Support for Mothers and Children of India (USMCI), a U.S.-based not-for-profit organization. Mr. Schorpion also serves on the Board of Directors of IGNITE Growth Bands and International School Services (ISS).

Andria Wilk joined argenx as Global Head of Quality in January 2020. Mrs. Wilk has more than 20 years of experience in QA within the pharmaceutical industry. Most recently, Mrs. Wilk served as Senior Director, Head of Medical, Regulatory & Clinical QA (MRC QA) at Lundbeck, where she managed the global MRC QA group based in the EU, US and Asia. In this role, she was responsible for the global audit programmes and QA support for all clinical trial and post-marketing activities and related computerized systems. Prior to Lundbeck, she held various QA positions of increasing responsibility within AstraZeneca, Takeda Global Research and Development (TGRD) and Astellas Pharmaceuticals. Mrs. Wilk holds a joint B.Sc. in Pharmacology and Biochemistry and is a member of Research Quality Association (MRQA).

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.

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:

- fixed base compensation;

- short-term variable compensation;
- long-term variable compensation, in the form of stock options;
- severance arrangements; and
- pension and fringe benefits.

Fixed base compensation. The base compensation of our executive management is determined on the basis of a benchmarking analysis completed by an independent consulting firm. In accordance with this benchmarking analysis, our board of directors has resolved to aim for a compensation of our executive management in the 75th percentile of the compensation offered by the European peer group for executive management living in Europe and 50th percentile offered by the US peer group for executive management living in US, each time as identified by the independent consulting firm used in this analysis. The base compensation of the executive director will be determined around the median compensation levels payable within a blend of both European and US peer group.

Short-term variable compensation. The objective of this short-term annual 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 short-term variable incentive of his/her annual base compensation. The target percentage for this purpose was set at 55% of the annual base compensation of a member of the executive management team. 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, or Option Plan, as set out below. Typically, options are granted annually in accordance with our stock option grant scheme which is regularly reviewed by our board of directors and particularly our remuneration and nomination committee.

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, 2020:

Tim Van Hauwermeiren

	Compensation (€)
Base salary	525,000
Option awards(1)	6,142,917
Employer social security contribution stock options	—
Non-equity incentive plan compensation(2)	433,125
Pension contributions	22,609
Social security costs	10,587
Other(3)	10,522
TOTAL	7,144,760

(1) Amount shown represents the expenses with respect to the option awards granted in 2020 to Mr. Van Hauwermeiren measured using the Black Scholes formula. For a description of the assumptions used in valuing these awards, see Note 14 to our financial statements included elsewhere in this annual report. These amounts do not reflect the actual economic value realized by Mr. Van Hauwermeiren.

(2) We have an established practice to provide the variable pay partially in the form of over the counter (OTC) options. For those beneficiaries that opt to receive their bonus through OTC options rather than through a payment in cash. As a result, whereas the basis for calculating the cash bonus is a maximum of 55% of base salary, this may be paid in OTC options, representing a higher percentage of the annual base salary (in 2020: 62.49%), which provides a benefit to argenx as well as the employee.

(3) Consists of €10,342 attributable to the lease of a company car and €180 in employer-paid medical insurance premiums.

(4) The U.S. peer group used to determine (equity) incentive grant levels in 2020 consisted of Acadia Pharmaceuticals, Acceleron Pharma, Agios Pharmaceuticals, Aimmune Therapeutics, Alnylam Pharmaceuticals, Amicus Therapeutics, bluebird bio, Blueprint Medicines, CRISPR Therapeutics, Esperion Therapeutics, FibroGen, Global Blood Therapeutics, Moderna, MyoKardia, Portola Pharmaceuticals, Reata Pharmaceuticals, Sage Therapeutics, Sarepta Therapeutics, Spark Therapeutics, Xencor and Zogenix.

The following table sets forth information regarding aggregate compensation paid by us for the members of our executive management (excluding Tim Van Hauwermeiren) during the year ended December 31, 2020:

	Compensation (€)
Base salary	2,316,641
Option awards(1)	31,350,063
Employer social security contribution stock options(2)	9,811,342
Non-equity incentive plan compensation	888,738
Termination benefits	336,663
Pension contributions	118,090
Social security costs	648,965
Other(3)	126,935
TOTAL	45,597,437

(1) Amount shown represents the expenses with respect to the option awards granted in 2020 to Mr. Keith Woods, Prof. Hans de Haard, Mr. Wim Parys, Mr. Arjen Lemmen, Miss. Andria Wilk, Mr. Marc Schorpion and Mr. Dirk Beeusaert measured using the Black Scholes formula. For a description of the assumptions used in the valuing these awards, see Note 14 to our consolidated financial statements incorporated by reference in this annual report. These amounts do not reflect the actual economic value realized by these members of our executive management.

(2) The Company incurs employer social security costs with respect to the option awards granted to the members of our executive management. The amount of employer social security costs depends on the actual economic value realized and therefore varies based on the price of our ordinary shares. At each reporting date, the Company makes a calculation of the exposure.

(3) Consists of €75,445 attributable to the leases of company cars, €24,627 in car, housing and other allowances and €26,863 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, 2020:

Name	Stock options	Expiration date	Exercise price
Tim Van Hauwermeiren (1)	50,000	12/21/2030	€ 247.60
Hans de Haard (1)	50,000	12/21/2030	€ 247.60
Keith Woods	50,000	12/21/2030	€ 247.60
Wim Parys (1)	50,000	12/21/2030	€ 247.60
Marc Schorpion	25,000	6/25/2030	€ 196.15
Arjen Lemmen (1)	50,000	12/21/2030	€ 247.60
Dirk Beeusaert	50,000	6/25/2025	€ 196.15
Andria Wilk (1)	9,900	12/21/2030	€ 247.60

(1) On December 21, 2020, the Company has granted options for which the beneficiary has a 60 day period to choose between a contractual term of five or ten years.

Pursuant to our remuneration policy and practices, our CEO Tim van Hauwermeiren was offered 80.000 stock options in 2020, but at his request the Board of Directors agreed to reduce the number of options granted for 2020 to 50,000 and to distribute the difference to certain top performing lower level employees of the company in 2021.

The table below shows the stock options held at the start of the year ended December 31, 2020 and the stock options granted to our executive management which have vested during the year ended December 31, 2020, as well as the stock options to vest in the years ending December 31, 2021, December 31, 2022 and December 31, 2023 (in number of stock options), and the respective exercise price of such stock options:

Name	Total options held on January 1, 2020	Options granted in 2020	Options forfeited in 2020	Options exercised in 2020	Total options held on December 31, 2020	Exercise price	Options vested until 2019	Options vested in 2020	Options to vest in 2021	Options to vest in 2022	Options to vest in 2023
Tim Van Hauwermeiren	386,200	50,000	—	(146,200)	290,000	€ 21.17	53,333	26,667			
						€ 86.32	26,667	26,666	26,667		
						€ 135.75		26,667	26,666	26,667	
						€ 247.60			16,667	16,666	16667
Total	**386,200**	**50,000**	**—**	**(146,200)**	**290,000**		**80,000**	**80,000**	**70,000**	**43,333**	**16,667**
Eric Castaldi	227,800	—	—	(56,400)	171,400	€ 14.13	28,200				
						€ 21.17	28,800	14,400			
						€ 86.32	16,667	33,333			
						€ 135.75		50,000			
Total	**227,800**	**—**	**—**	**(56,400)**	**171,400**		**73,667**	**97,733**	**—**	**—**	**—**
Keith Woods	150,000	50,000	—	(45,000)	155,000	€ 21.17	5,000				
						€ 86.32	16,667	16,666	16,667		
						€ 135.75		16,667	16,666	16,667	
						€ 247.60			16,667	16,666	16,667
Total	**150,000**	**50,000**	**—**	**(45,000)**	**155,000**		**21,667**	**33,333**	**50,000**	**33,333**	**16,667**
Hans De Haard	495,975	50,000	—	—	545,975	€ 2.44	144,822				
						€ 7.17	109,000				
						€ 9.47	28,200				
						€ 11.47	28,200				
						€ 14.13	28,200				
						€ 18.41	11,961	2,392			
						€ 21.17	28,800	14,400			
						€ 86.32	16,667	16,666	16,667		
						€ 135.75		16,666	16,668	16,666	
						€ 247.60			16,667	16,666	16,667
Total	**495,975**	**50,000**	**—**	**—**	**545,975**		**395,850**	**50,124**	**50,002**	**33,332**	**16,667**
Wim Parys	175,000	50,000	—	—	225,000	€ 86.32	41,667	41,666	41,667		
						€ 135.75		16,667	16,666	16,667	
						€ 247.60			16,667	16,666	16,667
Total	**175,000**	**50,000**	**—**	**—**	**225,000**		**41,667**	**58,333**	**75,000**	**33,333**	**16,667**
Arjen Lemmen	101,276	50,000	—	(15,065)	136,211	€ 11.47	3,215				
						€ 14.13	3,215				
						€ 18.41	3,110	1,196			
						€ 21.17	2,995	3,333			
						€ 80.82	695	1,666	834		
						€ 86.32	952	7,500	7,500		
						€ 135.75		24,963	12,519	12,518	
						€ 247.60			16,667	16,666	16,667
Total	**101,276**	**50,000**	**—**	**(15,065)**	**136,211**		**14,182**	**38,658**	**37,520**	**29,184**	**16,667**
Dirk Beeusaert	154,682	50,000	—	—	204,682	€ 18.41	33,068	6,614			
						€ 21.17	10,000	5,000			
						€ 80.82	14,100	9,400	4,700		
						€ 86.32	7,267	7,266	7,267		
						€ 113.49	11,513	19,244	12,829	6,414	
						€ 196.15		12,756	12,415	12,415	12,415
Total	**154,682**	**50,000**	**—**	**—**	**204,682**		**75,948**	**60,280**	**37,211**	**18,829**	**12,415**
Marc Schorpion	25,000	25,000	—	—	50,000	€ 113.49	—	12,500	8,333	4,167	
						€ 196.15			12,500	8,333	4,167
Total	**25,000**	**25,000**	**—**	**—**	**50,000**		**—**	**12,500**	**20,833**	**12,500**	**4,167**
Andria Wilk	9,400	9,900	—	—	19,300	€ 135.75	—	4,693	2,353	2,354	
						€ 247.60			3,300	3,300	3,300
Total	**9,400**	**9,900**	**—**	**—**	**19,300**		**—**	**4,693**	**5,653**	**5,654**	**3,300**

The table below shows the remaining term of the stock options held by our executive management during the year ended December 31, 2020.

Name	Number of stock options	Remaining term on December 31, 2020 (rounded up)
Tim Van Hauwermeiren	80,000	7 years
	80,000	8 years
	80,000	9 years
	50,000	5 years / 10 years (1)
Eric Castaldi	17,360	3 years
	5,000	4 years
	28,200	6 years
	43,200	7 years
	32,640	8 years
	45,000	9 years
Keith Woods	5,000	7 years
	50,000	8 years
	50,000	9 years
	50,000	10 years
Hans De Haard	69,360	2,5 years
	39,636	3 years
	35,826	4 years
	109,000	4 years
	28,200	5 years
	28,200	5,5 years
	28,200	6 years
	14,353	6,5 years
	43,200	7 years
	50,000	8 years
	50,000	9 years
	50,000	5 years / 10 years (1)
Wim Parys	125,000	3 years
	50,000	9 years
	50,000	5 years / 10 years (1)
Arjen Lemmen	2,500	2,5 years
	50,000	4 years
	3,215	5,5 years
	3,215	6 years
	4,306	6,5 years
	6,328	7 years
	695	7,5 years
	15,952	8 years
	50,000	5 years / 10 years (1)
Marc Schorpion	25,000	8,5 years
	25,000	9,5 years
Dirk Beeusaert	28,200	2,5 years
	21,800	3 years
	50,000	3,5 years
	50,000	4,5 years
	39,682	6,5 years
	15,000	7 years
Andria Wilk	9,400	4 years
	9,900	5 years / 10 years (1)

(1) On December 21, 2020, the Company has granted options for which the beneficiary has a 60 day period to choose between a contractual term of five or ten years.

The table below shows the stock options exercised by our executive management during the year ended December 31, 2020 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	35,000	€	7.17
Tim Van Hauwermeiren	30,600	€	9.47
Tim Van Hauwermeiren	50,000	€	11.47
Tim Van Hauwermeiren	30,600	€	14.13
Eric Castaldi	28,200	€	9.47
Eric Castaldi	28,200	€	11.47
Keith Woods	45,000	€	21.17
Arjen Lemmen	585	€	11.47
Arjen Lemmen	785	€	14.13
Arjen Lemmen	1,670	€	18.41
Arjen Lemmen	3,672	€	21.17
Arjen Lemmen	1,805	€	80.82
Arjen Lemmen	6,548	€	86.32
Total	**262,665**		

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 and compliance committee, the research and development committee or the remuneration and nomination committee;
- a fixed fee for board committee membership; and
- a long-term variable incentive, in the form of stock options.

Fixed fee. The board of directors has set the annual base remuneration for non-executive directors at €35,000, additional remuneration for the chairperson of the board of directors at €30,000, additional remuneration for the chairperson of the audit and compliance committee and the research and development committee of the board of directors at €15,000 and additional remuneration for the chairperson of the remuneration and nomination committee and the commercial committee of the board of directors at €10,000. Board committee members, other than the chairman of the relevant committee, receive an annual retainer of €5,000 for the remuneration and nomination committee and a €7,500 retainer for the members of the audit and compliance 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 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 Option Plan. The conditions of our Option Plan apply to our non-executive directors, as set forth below 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). To date, no such success payments have been made or promised by us to our non-executive directors.

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, 2020:

Name	Fees earned or paid in cash (€)	Option awards (€)(1)	Total
Peter K.M. Verhaeghe	77,500	1,228,583	€ 1,306,083
David L. Lacey	50,000	1,192,599	1,242,599
Werner Lanthaler	55,000	1,192,599	1,247,599
Pamela Klein	42,500	1,192,599	1,235,099
J. Donald deBethizy	52,500	1,192,599	1,245,099
A.A. Rosenberg	42,500	1,192,599	1,235,099
James M. Daly	35,000	1,192,599	1,227,599

(1) These amounts do not reflect the actual economic value realized by the non-executive director. Amount shown represents the expenses with respect to the option awards granted in 2020 to the non-executive directors measured using the Black Scholes formula. For a description of the assumptions used in valuing these awards, see note 14 to our consolidated financial statements incorporated by reference in annual report.

The table below shows the stock options held at the start of the year ended December 31, 2020 and the stock options granted to the non-executive directors which have vested during the year ended December 31, 2020,

as well as the stock options to vest in the years ending December 31, 2021, December 31, 2022 and December 31, 2023 (in number of stock options), and the respective exercise price of such stock options:

Name	Total options held on January 1, 2020	Options granted in 2020	Options exercised in 2020	Total options held on December 31, 2020		Exercise price	Options vested until 2019	Options vested in 2020	Options to vest in 2021	Options to vest in 2022	Options to vest in 2023
Peter Verhaeghe	54,585	10,000	(5,990)	58,595	€	2.44	11,626				
					€	3.95	1,969				
					€	7.17	5,000				
					€	11.38	10,000				
					€	86.32	3,333	3,334	3,333		
					€	135.75		3,333	3,334	3,333	
					€	247.60			3,333	3,334	3,333
Total	**54,585**	**10,000**	**(5,990)**	**58,595**			**31,928**	**6,667**	**10,000**	**6,667**	**3,333**
David L. Lacey	64,443	10,000	(6,643)	67,800	€	11.38	12,800				
					€	21.17	10,000	5,000			
					€	86.32	10,000	3,334	3,333		
					€	135.75	3,333	3,333	3,334	3,333	
					€	247.60	—		3,333	3,334	3,333
Total	**64,443**	**10,000**	**(6,643)**	**67,800**			**36,133**	**11,667**	**10,000**	**6,667**	**3,333**
Werner Lanthaler	20,000	10,000	—	30,000	€	86.32	3,333	3,334	3,333		
					€	135.75		3,333	3,334	3,333	
					€	247.60			3,333	3,334	3,333
Total	**20,000**	**10,000**	**—**	**30,000**			**3,333**	**6,667**	**10,000**	**6,667**	**3,333**
J. Donald deBethizy	45,000	10,000	(7,500)	47,500	€	11.44	7,500				
					€	11.38	10,000				
					€	86.32	3,333	3,334	3,333		
					€	135.75		3,333	3,334	3,333	
					€	247.60			3,333	3,334	3,333
Total	**45,000**	**10,000**	**(7,500)**	**47,500**			**20,833**	**6,667**	**10,000**	**6,667**	**3,333**
Pamela Klein	45,000	10,000	(5,000)	50,000	€	11.44	10,000				
					€	11.38	10,000				
					€	86.32	3,333	3,334	3,333		
					€	135.75		3,333	3,334	3,333	
					€	247.60			3,333	3,334	3,333
Total	**45,000**	**10,000**	**(5,000)**	**50,000**			**23,333**	**6,667**	**10,000**	**6,667**	**3,333**
A.A. Rosenberg	35,000	10,000		45,000	€	14.13	15,000				
					€	86.32	3,333	3,334	3,333		
					€	135.75		3,333	3,334	3,333	
					€	247.60			3,333	3,334	3,333
Total	**35,000**	**10,000**	**—**	**45,000**			**18,333**	**6,667**	**10,000**	**6,667**	**3,333**
James M. Daly	35,000	10,000	(10,000)	35,000	€	80.32	—	2,500	2,500		
					€	86.32	3,333	3,334	3,333		
					€	135.75		3,333	3,334	3,333	
					€	247.60			3,333	3,334	3,333
Total	**35,000**	**10,000**	**(10,000)**	**35,000**			**3,333**	**9,167**	**12,500**	**6,667**	**3,333**

The table below shows the remaining term of the stock options held by the non-executive directors during the year ended December 31, 2020.

Name	Number of stock options	Remaining term on December 31, 2020 (rounded up)
Peter K.M. Verhaeghe	5,560	2,5 years
	3,181	3 years
	4,854	4 years
	5,000	4 years
	10,000	5,5 years
	10,000	8 years
	10,000	9 years
	10,000	10 years
David L. Lacey	12,800	4 years
	10,000	5,5 years
	15,000	7 years
	10,000	8 years
	10,000	9 years
	10,000	10 years
Werner Lanthaler	10,000	3 years
	10,000	9 years
	10,000	10 years
J. Donald deBethizy	7,500	4,5 years
	10,000	5,5 years
	10,000	8 years
	10,000	9 years
	10,000	10 years
Pamela Klein	10,000	4,5 years
	10,000	5,5 years
	10,000	8 years
	10,000	9 years
	10,000	10 years
A.A. Rosenberg	15,000	6 years
	10,000	8 years
	10,000	9 years
	10,000	10 years
James M. Daly	5,000	7,5 years
	10,000	8 years
	10,000	9 years
	10,000	10 years

The table below shows the stock options exercised by our non-executive directors during the year ended December 31, 2020 and the exercise price of those stock options. Per exercised option, one share was issued.

Name	Number of stock options	Exercise price
David Lacey	6,643	€ 2.44
Don deBethizy	7,500	€ 11.44
Jim Daley	10,000	€ 80.82
Pam Klein	5,000	€ 11.44
Peter Verhaeghe	5,990	€ 3.95
Total	**35,133**	

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 and November 25, 2019 and the board of directors on December 18, 2019 and November 5, 2020. 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.

The Company expects to amend the Option Plan in 2021, whereby, among other things, equity incentives will not only be granted in the form of stock options, but also in the form of restricted stock units (RSUs).

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 in 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 based between the 50th and the 75th percentile of our reference group.

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 instalments with the option fully vesting upon the third anniversary of the date of grant, subject, in each case, to the optionee's continued status. Options are exercisable when vested, and in any case not after the option expiration date included in each individual option grant, which is (at the election of the optionee) either 5 years or 10 years from the date of grant.

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 five or ten years from the date of grant. Optionees may prefer to elect the 5 year period as this may limit their personal tax obligations in respect of the option, compared to a 10 year option. In the case of a (i) sale, merger, consolidation, tender offer or similar acquisition of shares or other transaction or series of related transactions as a result of which a change in control occurs, (ii) sale or other disposition of all or substantially all of the Company's assets or (iii) dissolution and/or liquidation of the Company, then 100% of any unvested options shall vest.

Our board of directors, upon approval of a majority of the non-executive directors may amend or terminate the Option Plan or may amend the terms of any outstanding options, provided that no amendment or termination may affect any existing rights without the consent of the affected optionees.

The table below sets forth the details of all options granted under the Option Plan in force as of December 31, 2020, 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 (€)	Options Number of options granted	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	102,150	1,220	—	5/11/2013	5/11/2020
SOP A	11/30/2010	3.95	62,460	62,460	—	—	11/30/2013	11/30/2020
SOP A	2/1/2011	3.95	3,800	3,800	—	—	2/1/2014	2/1/2021
SOP B	5/23/2013	2.44	305,740	222,610	—	83,130	5/23/2016	5/23/2023
SOP B	12/4/2013	2.44	174,747	92,184	—	82,563	12/4/2016	12/4/2023
SOP B	6/30/2014	2.44	109,820	104,320	—	5,500	6/30/2017	6/30/2024
Reshuffling A	9/30/2014	3.95	55,746	49,508	—	6,238	9/30/2017	9/30/2024
Reshuffling B1	9/30/2014	2.44	174,362	81,748	—	92,614	9/30/2017	9/30/2024
Reshuffling B2	9/30/2014	2.44	19,719	17,747	—	1,972	9/30/2017	9/30/2024
SOP 2014.12.18	12/18/2014	7.17	585,250	243,333	47,750	294,167	12/18/2017	12/18/2024
SOP 2015.06.18	6/18/2015	11.44	56,500	17,500	17,500	21,500	6/18/2018	6/18/2025
SOP 2015.09.03	9/3/2015	10.34	3,000	2,050	—	950	9/3/2018	9/3/2025
SOP 2015.12.15	12/15/2015	9.47	243,400	121,118	8,050	114,232	12/15/2018	12/15/2025
SOP 2016.05.25	5/25/2016	11.47	288,950	154,051	7,647	127,252	5/25/2019	5/25/2026
SOP 2016.06.18	6/18/2016	11.38	60,000	15,000	—	45,000	6/18/2019	6/18/2026
SOP 2016.12.13	12/13/2016	14.13	363,226	172,615	14,185	176,426	12/13/2019	12/13/2026
SOP 2017.06.26	6/26/2017	18.41	120,536	17,597	460	102,479	6/26/2020	6/26/2027
SOP 2017.12.14	12/14/2017	21.17	653,825	160,237	32,887	460,701	12/14/2020	12/14/2027
SOP 2018.06.28	6/28/2018	80.82	97,100	—	4,523	92,577	6/28/2021	6/28/2023
SOP 2018.06.28	6/28/2018	80.82	81,800	32,585	7,183	42,032	6/28/2021	6/28/2028
SOP 2018.12.21	12/21/2018	86.32	369,760	6,380	37,719	325,661	12/21/2021	12/21/2023
SOP 2018.12.21	12/21/2018	86.32	491,815	40,553	69,945	381,317	12/21/2021	12/21/2028
SOP 2019.06.28	6/28/2019	113.49	89,529	—	516	89,013	6/28/2022	6/28/2024
SOP 2019.06.28	6/28/2019	113.49	307,533	61,564	44,627	201,342	6/28/2022	6/28/2029
SOP 2019.06.28	6/28/2019	113.49	22,161	—	—	22,161	6/28/2019	6/28/2024
SOP 2019.06.28	6/28/2019	113.49	4,364	—	—	4,364	6/28/2019	6/28/2029
SOP 2019.12.20	12/20/2019	135.75	172,313	—	8,979	163,334	12/20/2022	12/20/2024
SOP 2019.12.20	12/20/2019	135.75	2,150	—	—	2,150	12/20/2023	12/20/2024
SOP 2019.12.20	12/20/2019	135.75	700,440	1,700	63,738	635,002	12/20/2022	12/20/2029
SOP 2019.12.20	12/20/2019	135.75	1,400	—	1,400	—	12/20/2023	12/20/2029
SOP 2019.12.20	12/20/2019	135.75	29,968	—	—	29,968	12/20/2019	12/20/2024
SOP 2019.12.20	12/20/2019	135.75	15,616	—	—	15,616	12/20/2019	12/20/2029
SOP 2020.04.14	4/14/2020	119.53	9,285	—	—	9,285	4/14/2023	4/14/2025
SOP 2020.04.14	4/14/2020	119.53	9,283	—	—	9,283	4/14/2024	4/14/2025
SOP 2020.04.14	4/14/2020	119.53	432	—	—	432	4/14/2020	4/14/2025
SOP 2020.04.14	4/14/2020	119.53	60,885	—	—	60,885	4/14/2023	4/14/2030
SOP 2020.04.14	4/14/2020	119.53	60,884	—	—	60,884	4/14/2024	4/14/2030
SOP 2020.04.14	4/14/2020	119.53	1,931	—	—	1,931	4/14/2020	4/14/2030
SOP 2020.06.25	6/25/2020	196.15	82,903	—	—	82,903	6/25/2023	6/25/2025
SOP 2020.06.25	6/25/2020	196.15	16,355	—	—	16,355	6/25/2024	6/25/2025
SOP 2020.06.25	6/25/2020	196.15	32,512	—	—	32,512	6/25/2020	6/25/2025
SOP 2020.06.25	6/25/2020	196.15	297,724	—	42,500	255,224	6/25/2023	6/25/2030
SOP 2020.06.25	6/25/2020	196.15	112,161	—	8,670	103,491	6/25/2024	6/25/2030
SOP 2020.06.25	6/25/2020	196.15	8,435	—	—	8,435	6/25/2020	6/25/2030
SOP 2020.10.01	10/1/2020	200.22	14,376	—	—	14,376	10/1/2023	10/1/2025
SOP 2020.10.01	10/1/2020	200.22	81,666	—	—	81,666	10/1/2024	10/1/2025
SOP 2020.10.01	10/1/2020	200.22	7,887	—	—	7,887	10/1/2020	10/1/2025
SOP 2020.10.01	10/1/2020	200.22	9,837	—	—	9,837	10/1/2023	10/1/2030
SOP 2020.10.01	10/1/2020	200.22	79,058	—	—	79,058	10/1/2024	10/1/2030
SOP 2020.10.01	10/1/2020	200.22	3,676			3,676	10/1/2020	10/1/2030
SOP 2020.12.21 (1)	12/21/2020	247.60	777,062	—	—	777,062	12/21/2023	12/21/2030
SOP 2020.12.21 (1)	12/21/2020	247.60	131,300	—	—	131,300	12/21/2024	12/21/2030
Total			**7,568,052**	**1,782,810**	**419,499**	**5,365,743**		

(1) On December 21, 2020, the company had granted options for which the beneficiary had a 60-day period to choose between a contractual term of five or ten years.

C. BOARD PRACTICES

Director Independence

As a foreign private issuer, under the listing requirements and rules of Nasdaq, we are not required to have independent directors on our board of directors, except that our audit and compliance 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, including the members of our audit and compliance committee, are "independent directors" under Rule 10A-3 of the Exchange Act and the applicable rules of the Nasdaq Stock Market and all members of our audit and compliance committee are independent under the applicable rules of the Dutch Corporate Governance Code. 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 Dutch Corporate Governance Code 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 Registration Document, all non-executive directors meet the independence criteria contained in the Dutch Corporate Governance Code. Therefore, in the opinion of the non-executive directors, the composition of our non-executive directors complies with the independence requirements of best practice provisions 2.1.7 to 2.1.9 of the Dutch Corporate Governance Code. Our board of directors has consequently also determined that all members of our committees are independent under the applicable rules of the Dutch Corporate Governance Code.

As of the date of this Registration Document (or in any period before), none of the members of our board of directors and executive management has or has had a family relationship with any other member of our board of directors or executive management.

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 and compliance 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 director(s) 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, provided that the board of directors must consist of at least three members.

Our directors are appointed by the shareholders at the General Meeting for a period of four years. In accordance with best practice principle 2.2.1 of the Dutch Corporate Governance Code, executive directors may be re-appointed for periods of not more than four years at a time. In accordance with best practice principle 2.2.2 of the Dutch Corporate Governance Code, non-executive directors are appointed for a period of four years and may

subsequently be re-appointed for another four-year period, which appointment may be extended by at most two years. 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 or non-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 an executive 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 argenx SE) 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.

Pursuant to the Articles of Association, a member of our board of directors will retire not later than on the day on which the first General Meeting is held following lapse of four years since his appointment. A retiring member of our board of directors may be re-appointed.

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 (Section 2:134 paragraph 1 of the DCC), 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

In accordance with the Dutch Corporate Governance Code, our non-executive directors can set up specialized committees to analyze specific issues and advise the non-executive directors on those issues.

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 and compliance committee;
- a remuneration and nomination committee;
- a research and development committee; and
- a commercial committee.

The composition and function of all of our committees complies with all applicable requirements of Euronext Brussels, the Dutch Corporate Governance code, the Exchange Act, the exchanges on which the ordinary shares are listed and SEC rules and regulations.

Only non-executive directors qualify for membership of the committees. The audit and compliance 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 and Compliance Committee

Our audit and compliance committee consists of three members: Werner Lanthaler (chairperson), Peter K. M. Verhaeghe and Anthony A. Rosenberg. Our board of directors has established that Werner Lanthaler qualifies as an "audit committee financial expert" as defined under the Exchange Act and article 39 paragraph 1 of Directive 2014/56/EU of the European Parliament and of the Council of 16 April 2014 amending Directive 2006/43/EC on statutory audits of annual accounts and consolidated accounts and that the composition of the audit and compliance committee meets the requirements under the Dutch Decree on Establishing Audit Committees.

Our audit and compliance committee assists our board of directors in overseeing the accuracy and integrity of our accounting and financial reporting processes and audits and reviews 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 and compliance committee is governed by a charter that complies with Nasdaq listing rules and the Dutch Corporate Governance Code. Our audit and compliance committee is responsible for, among other things, establishing methods and procedures for supervising, and where necessary requiring improvements of, the financial reporting, compliance and organization of the Company for the purpose of making appropriate recommendations to the Board of Directors in that regard.

Our audit and compliance committee meets as often as is required for its proper functioning, but at least four times a year. Our audit and compliance committee meets at least once a year with our independent auditor.

Our audit and compliance 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 and compliance 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 and compliance committee shall exercise this right in consultation with the chairperson of the audit and compliance committee.

The audit and compliance committee has deliberated seven times in the course of 2020. At these meetings, the main points of discussion were:

- discussion of the Compliance Gap Analysis;
- review of the financial statements for the year ended December 31, 2019 and related press release;
- review of the 20-F and universal registration document with respect to the year ended December 31, 2019
- review of our Independent Registered Accounting Firm’s 2019 audit report;
- discusion and review of the 2020 Independent Registered Accounting Firm’s proposal and renewal of their mandate;
- review of interim consolidated financial statements and related press releases,
- review of our Independent Registered Accounting Firm’s report on interim financial statements;

- review of quarterly forecasts, updates on internal control activities, updates on corporate audit activities, updates on cash, cash equivalents and financial assets; and
- review of compliance committee charter.

The meeting attendance rate for our directors in the audit and compliance committee is set out in the table below:

Audit and Compliance Committee	Number of meetings attended in 2020	Attendance %
Peter Verhaeghe	7/7	100%
Werner Lanthaler	7/7	100%
Tony Rosenberg	7/7	100%

Remuneration and Nomination Committee

We have established a remuneration and nomination committee, which serves as both the remuneration committee and selection and appointment committee as prescribed by the Dutch Corporate Governance Code.

Our remuneration and nomination committee consists of three members: J. Donald deBethizy (chairperson), Peter K. M. Verhaeghe and Werner Lanthaler.

Our remuneration and nomination committee is responsible for, among other things:

- regularly reviewing the remuneration policy in light of all relevant circumstances and benchmarks, and currently drafting a proposal to the non-executive directors for the remuneration policy to be pursued and recommending to the non-executive directors the remuneration of the individual executive directors;
- advising the Board of Directors in respect of the remuneration for the non-executive directors;
- preparing the remuneration report to be included in the Company's annual report;
- drawing up selection criteria and appointment procedures for directors and making proposals for appointment and re-appointment of the directors;
- periodically assessing the size and composition of the Board of Directors and making a proposal for a composition profile of the non-executive directors;
- periodically assessing the functioning of individual directors and reporting on this to the non-executive directors; and
- supervising the policy of the executive 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.

The remuneration and nomination committee has deliberated two times in the course of 2020. The main topics of discussion were the update of the remuneration policy, board rotation and succession process and plan, option allocation scheme, remuneration report and the taxation of US stock options.

The meeting attendance rate for our directors in the remuneration and nomination committee is set out in the table below:

Remuneration and Nomination Committee	Number of meetings attended in 2020	Attendance %
Peter Verhaeghe	2/2	100%
Werner Lanthaler	2/2	100%
Don deBethizy	2/2	100%

Other Committees

Research and Development Committee

The research and development committee consists of members of the Board of Directors and other persons, which composition may vary from time to time. Currently, the research and development committee consists of three members: David L. Lacey (chairperson), J. Donald deBethizy and Pamela Klein.

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 endeavours 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. 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.

The research and development committee meets at least quarterly. The main topics of discussion during the course of 2020 were the research and development goals, strategies and measures of the Company, reviewing the Company’s early-stage programs, pre-clinical and clinical research activities and portfolio strategy.

Commercial committee

The commercial committee consists of members of the Board of Directors and other persons, which composition may vary from time to time. Currently, the commercial committee consists of two members: Jim Daly and Tony Rosenberg.

The commercial committee is responsible for, among other things:

- serving as a sounding board to the Company's branded and unbranded strategic marketing plans, size and scope of the Company's franchises, pre and post launch market access plan of action;
- advising the board of directors on the effectiveness of the governance, risk management and legal compliance of the commercial activities, with an underlying aim of ensuring that these activities are set up and pursued consistent with the achievement by the Company of its strategic goals;
- reviewing and discussing global commercial and political trends affecting the industry and the development of the Company; and
- reporting to the board of directors on the outcome of the strategic reviews.

The non-executive directors shall appoint and dismiss the members of the commercial committee. All members of the commercial committee shall have adequate industrial, academic and/or practical experience with the commercialization of (bio)pharmaceuticals.

Our commercial committee meets as often as is required for its proper functioning and reports regularly to our Board of Directors on the outcome of its strategic reviews. The main topics of discussion during the course of 2020 were discussing and reviewing the Company's marketing plans in light of the envisaged launch of efgartigimod, reviewing the size and scope of the Company's three core franchises, review and discuss the pre-launch market access plan of action for the envisaged launch of efgartigimod in MG, review and advise on the Company's updated internal risk matrix and discussing global trends affecting the industry and their potential impact on the envisaged launch of efgartigimod in MG.

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, 2020, we had 336 employees. At each date shown below, we had the following number of employees, broken out by department and geography:

	At December 31,		
	2020	2019	2018
Function:			
Research and development	193	118	75
Selling, general and administrative	143	70	30
Total	**336**	**188**	**105**
Geography:			
Zwijnaarde, Belgium	213	145	94
Boston, USA	108	40	11
Tokyo, Japan	13	3	—
Breda, the Netherlands	—	—	—
Geneva, Switzerland	2	—	—
Total	**336**	**188**	**105**

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, 2021 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, 2021. The percentage ownership information shown in the table is based upon 51,305,610 ordinary shares outstanding as of March 16, 2021.

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, 2021. 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.

	Shares beneficially owned	
Name of beneficial owner	**Number**	**Percentage**
3% or Greater Shareholders:		
T. Rowe Price Group, Inc. (1)(2)	4,998,028	11.68 %
FMR LLC (1)(3)	5,025,092	9.80 %
Baillie Gifford & Co.(1)(4)	2,966,216	6.24 %
Artisan Investments GP LLC(1)(5)	2,575,257	5.02 %
Federated Equity Management Company of Pennsylvania (1)(6)	1,895,001	4.97 %
The Goldman Sachs Group, Inc.(1)(7)	2,514,651	4.92 %
Wellington Management Group LLP (1)(8)	2,276,361	4.81 %
Blackrock, Inc. (1)(9)	2,431,314	4.74 %
Johnson & Johnson Innovation - JJDC, Inc (1)(10)	1,766,899	4.66 %
The Vanguard Group (1)(11)	1,978,464	4.16 %
Directors and Executive Management:		
Tim Van Hauwermeiren(12)	417,778	*
Peter Verhaeghe(13)	89,412	*
David Lacey(14)	107,822	*
Werner Lanthaler(15)	32,222	*
Donald deBethizy(16)	67,222	*
Pamela Klein(17)	72,222	*
A.A. Rosenberg(18)	62,222	*
James M. Daly(19)	41,389	*
Eric Castaldi(20)	342,800	*
Keith Woods(21)	171,111	*
Hans de Haard(22)	953,061	1.87 %
Wim Parys(23)	294,444	*
Arjen Lemmen(24)	146,280	*
Dirk Beeusaert(25)	350,742	*
Marc Schorpion(26)	40,278	*
Andria Wilk(27)	14,877	*
All directors and executive management as a group (16 persons)	2,714,531	5.35 %

* 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 filed with the AFM.

(2) Based solely on (1) the most recent transparency notification filed with the Netherlands Authority for the Financial Markets (the "AFM") as of March 16, 2021 and (2) a Schedule 13G/A filed with the SEC on February 16, 2021. Consists of 1,571 ordinary shares and 4,996,457 ADSs. T. Rowe Price Associates, Inc. ("Price Associates") does not serve as custodian of the assets of any of its clients; accordingly, in each instance only the client or the client's custodian or trustee bank has the right to receive dividends paid

with respect to, and proceeds from the sale of, such securities. The ultimate power to direct the receipt of dividends paid with respect to, and the proceeds from the sale of, such securities, is vested in the individual and institutional clients which Price Associates serves as investment adviser. Any and all discretionary authority which has been delegated to Price Associates may be revoked in whole or in part at any time. Not more than 5% of the class of such securities is owned by any one client subject to the investment advice of Price Associates. With respect to securities owned by any one of the T. Rowe Price Funds, only the custodian for each of such Funds has the right to receive dividends paid with respect to, and proceeds from the sale of, such securities. No other person is known to have such right, except that the shareholders of each such Fund participate proportionately in any dividends and distributions so paid. The address for Price Associates is 100 East Pratt Street, Baltimore, MD 21202.

(3) Based solely on (1) the most recent transparency notification filed with the AFM as of March 16, 2021 and (2) a Schedule 13G/A filed with the SEC on February 10, 2021. Consists of 4,757,128 ordinary shares. 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. FMR Co. LLC 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.

(4) Based solely on the most recent transparency notification filed with the AFM as of March 16, 2021. Consists of 2,966,216 ordinary shares. Other information regarding this shareholder's beneficial ownership of our shares is not known to us or, to our knowledge, ascertainable from public filings.

(5) Based solely on the most recent transparency notification filed with the AFM as of March 16, 2021. Consists of 105,864 ordinary shares and 2,469,393. Other information regarding this shareholder's beneficial ownership of our shares is not known to us or, to our knowledge, ascertainable from public filings.

(6) Based solely on (1) the most recent transparency notification filed with the AFM as of March 16, 2021. Consists of 1,522,200 ordinary shares and 372,801 ADSs. Represents shares beneficially owned by registered investment companies and separate accounts advised by subsidiaries of Federated Investors, Inc. that have been delegated the power to direct investment and power to vote the securities by the registered investment companies' board of trustees or directors and by the separate accounts' principals. All of the voting securities of Federated Investors, Inc. are held in the Voting Shares Irrevocable Trust, the trustees of which are Thomas R. Donahue, Rhodora J Donahue, and J. Christopher Donahue. The address of Federated Investors, Inc. is Federated Investors Tower, Pittsburgh, PA 15222-3779.

(7) Based solely on the most recent transparency notification filed with the AFM as of March 16, 2021. Consists of 80,359 ordinary shares and 403,018 ADSs. From the notification filed with the AFM on February 19, 2021 we understand the Goldman Sachs Group is participating through various entities, namely Goldman Sachs Asset Management, L.P., Goldman Sachs International, Goldman Sachs & Co. LLC, Goldman Sachs Asset Management International, United Capital Financial Advisors, LLC, Goldman Sachs Bank Europe SE, and Folio Investments Inc.

(8) Based solely on the most recent transparency notification filed with the AFM March 16, 2021. Consists of voting rights on 1,545,652 ordinary shares, 729,479 ADSs and 1,230 equity swaps. Other information regarding this shareholder's beneficial ownership of our shares is not known to us or, to our knowledge, ascertainable from public filings. Consisting of 80,359 ordinary shares, 403,018 ADSs, 60,000 call-options, 2,168 warrants, 985,271 contracts for difference, 963,835 swaps and 20,000 put options. Number of shares (short): 1,970,975. Capital interest percentage (short): 3.84% (indirectly).

(9) Based solely on the most recent transparency notification filed with the AFM March 16, 2021. Consists of 1,545,652 ordinary shares and 729,479 ADSs. Other information regarding this shareholder's beneficial ownership of our shares is not known to us or, to our knowledge, ascertainable from public filings.

(10) Based solely on the most recent transparency notification filed with the AFM as of March 16, 2021. Consists of 1,648,122 ordinary shares and 440,644. Other information regarding this shareholder's beneficial ownership of our shares is not known to us or, to our knowledge, ascertainable from public filings.

(11) Based solely on the most recent transparency notification filed with the AFM March 16, 2021. Consists of 1,766,899 shares. Other information regarding this shareholder's beneficial ownership of our shares is not known to us or, to our knowledge, ascertainable from public filings.

(12) Based solely on the most recent transparency notification filed with the AFM March 16, 2021. Consists of 1,978,464 shares. Other information regarding this shareholder's beneficial ownership of our shares is not known to us or, to our knowledge, ascertainable from public filings.

(13) Consists of 240,000 shares and 177,778 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 16, 2021.

(14) Consists of 48,595 shares and 40,817 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 16, 2021.

(15) Consists of 57,800 shares and 50,022 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 16, 2021.

(16) Consists of 20,000 shares and 12,222 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 16, 2021.

(17) Consists of 37,500 shares and 29,722 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 16, 2021.

(18) Consists of 40,000 shares and 32,222 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 16, 2021.

(19) Consists of 35,000 shares and 27,222 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 16, 2021.

(20) Consists of 25,000 shares and 16,389 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 16, 2021.

(21) Consists of 171,400 shares and 171,400 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 16, 2021.

(22) Consists of 105,000 shares and 171,111 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 16, 2021.

(23) Consists of 495,975 shares and 457,086 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 16, 2021.

(24) Consists of 175,000 shares and 119,444 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 16, 2021.

(25) Consists of 86,211 shares and 60,069 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 16, 2021.

(26) Consists of 204,682 shares and 146,060 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 16, 2021.

(27) Consists of 25,000 shares and 15,278 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 16, 2021.

(28) Consists of 9,400 shares and 5,477 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of March 16, 2021.

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.

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, 2021, assuming that all of our ordinary shares represented by ADSs are held by residents of the United States, we estimate that approximately 75% of our outstanding ordinary shares were held in the United States by approximately 188 institutional holders of record.

To our knowledge, and other than changes in percentage ownership as a result of the shares issued in connection with our initial and follow-on U.S. public offerings, there has been no significant change in the percentage ownership held by the major shareholders listed above, except as set forth below. On January 31, 2018, we received a transparency notification from Forbion Capital Fund II Coöperatief U.A. indicating that as a result of the sale of its entire position, its shareholding has decreased below the 3% notification threshold of argenx's voting rights. Per its transparency notification dated January 10, 2018, Bank of America reported total shareholdings of over 6% of argenx's voting rights. On March 14, 2018, we received a transparency notification from Bank of America Corporation indicating that as a result of the sale of nearly all of its position, its shareholding has decreased below the 3% notification threshold of argenx's voting rights. On September 21, 2018, we received a transparency notification from Shire plc indicating that as a result of the sale of its shares, its shareholding has decreased below the 3% notification threshold of argenx's voting rights. On January 24, 2019, we received a transparency notification from Perceptive Advisors LLC indicating that as a result of the increased number of argenx's outstanding shares, its shareholding has decreased below the 3% notification threshold of argenx's voting rights. On February 15, 2019, we received a transparency notification from LSP IV Management B.V. indicating that as a result of the sale of its shares, its shareholding has decreased below the 3% notification threshold of argenx's voting rights.

B. RELATED PARTY TRANSACTIONS

Since January 1, 2014, there has not been, nor is there currently proposed, any material transaction or series of similar material transactions to which we were or are a party in which any of the members of our board of directors or senior management, holders of more than 10% of any class of our voting securities, or any member of the immediate family of any of the foregoing persons, had or will have a direct or indirect material interest, other than the compensation and shareholding arrangements we describe in the sections of this annual report titled "Item 6.B.—Compensation" and "Item 7.A.—Major Shareholders," and the transactions we describe below.

Agreements with Our Executive Management

We have entered into a management agreement with Tim Van Hauwermeiren as our Chief Executive Officer. The Chief Executive Officer is our sole executive director. The key terms of his agreement are as follows

	Tim Van Hauwermeiren
Base salary	€ 525,000
Cash bonus	maximum 55% of base salary based on previously determined bonus targets established by the non-executive directors
Pension contributions(1)	€ 21,532
Duration	Indefinite

(1) Amounts shown represent pension contributions paid during the year-ended December 31, 2020.

We may terminate Mr. Van Hauwermeiren's services upon 18 months' notice, or payment of 18 months' pro-rated base compensation in lieu of notice. Mr. Van Hauwermeiren would be entitled to the same payment in lieu of notice in the event he terminates 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. Mr. Van Hauwermeiren may be dismissed immediately as an executive director.

Eric Castaldi, our Chief Financial Officer, has an employment contract with our subsidiary, argenx BV, 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. The Company is currently recruiting a U.S.-based chief financial officer and has entered into a transition agreement with Mr. Castaldi.

Keith Woods, our Chief Operating Officer, has an employment contract with our subsidiary, argenx US Inc., for an indefinite term. His employment contract may be terminated at any time by us, subject to a notice period and a severance payment of at least 12 months.

Wim Parys, our Chief Medical Officer, has an employment contract with our subsidiary argenx BV, 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 BV, 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.

Arjen Lemmen, our VP Corporate Development & Strategy, has an employment contract with our subsidiary, argenx BV, 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.

Dirk Beeusaert, our General Counsel, has an employment contract with our subsidiary, argenx BV, 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.

Marc Schorpion, our Global Head of Human Resources, has an employment contract with our subsidiary, argenx B.V., 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.

Andria Wilk, our Global Head of Quality, has an employment contract with our subsidiary, argenx BV, for an indefinite term. Her employment contract may be terminated at any time by us, subject to a notice period and a severance payment of at least 12 months.

Indemnification Agreements

In connection with our initial U.S. public offering, we entered into indemnification agreements with each of our non-executive directors and each member of our executive management. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to non-executive directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Transactions with Related Companies

Agreement with FairJourney Biologics LDA

FairJourney Biologics LDA, or FairJourney, is a fee-for-service company focused on antibody discovery and engineering services. FairJourney was founded in 2012 and, as compensation for their support with the formation of FairJourney, our chief executive officer and executive director Tim Van Hauwermeiren acquired shares representing 5% of the equity securities of FairJourney, and our chief scientific officer, Hans de Haard, acquired shares representing 20% of the equity securities of FairJourney. In July 2012, we entered into a license

and exclusive option agreement with FairJourney, pursuant to which we granted FairJourney a worldwide, non-exclusive license to our SIMPLE Antibody™ Platform to develop, manufacture and commercialize SIMPLE Antibodies to certain targets selected by FairJourney. Under the terms of the agreement, once FairJourney has advanced a product candidate discovered under the agreement to near proof-of-concept stage, we have the option to acquire patent rights generated by FairJourney specific to such product candidate along with a non-exclusive license to additional FairJourney intellectual property useful for further development, manufacture, or commercialization of the product candidate. Upon exercising this option, we must pay FairJourney an option fee equal to two times the expenses incurred by FairJourney for advancing such product candidate through the option exercise date, and we are required to pay a specified royalty in the mid-single digits on any sub-licensing revenue received by us for such product candidate. Alternatively, if we elect not to exercise the option, FairJourney is required to pay us a specified royalty in the mid-single digits on any sub-licensing revenue received by FairJourney for such product candidate. In connection with the agreement, we acquired shares of FairJourney representing 15% of the fully-diluted equity securities of FairJourney at the time of issuance. In December 2017, the company and executive director Tim Van Hauwermeiren sold their respective shareholding in FairJourney Biologics LDA, and thus FairJourney Biologics LDA is no longer a related company. In January 2020, the stake held by Hans de Haard in FairJourney was sold. This means that at the date of this annual report, FairJourney LDA no longer qualifies as related party.

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.

B. SIGNIFICANT CHANGES

Please see Note 32 to our consolidated financial statements included elsewhere in this Annual Report for details regarding events subsequent to the reporting period.

ITEM 9. THE OFFER AND LISTING

A. OFFER AND LISTING DETAILS

Our ADSs have been listed on the Nasdaq Global Select Market under the symbol “ARGX” since May 18, 2017. Prior to that date, there was no public trading market for our ADSs. Our ordinary shares have been trading on Euronext Brussels under the symbol “ARGX” since July 2014. Prior to that date, there was no public trading market for our ADSs or our ordinary shares. Our initial U.S. public offering in May 2017 was priced at $17.00 per ADS.

B. PLAN OF DISTRIBUTION

Not applicable.

C. MARKETS

The ADSs have been listed on NASDAQ under the symbol “ARGX” since May 18, 2017, and our ordinary shares have been listed on Euronext Brussels under the symbol “ARGX” since July 2014.

D. SELLING SHAREHOLDERS

Not applicable.

E. DILUTION

Not applicable.

F. EXPENSES OF THE ISSUE

Not applicable.

ITEM 10. ADDITIONAL INFORMATION

A. SHARE CAPITAL

Not applicable.

B. MEMORANDUM AND ARTICLES OF ASSOCIATION

The information set forth in our Registration Statement on Form F-3ASR (File No. 333-225370), automatically effective upon filing with the SEC on June 1, 2018, under the heading “Description of Share Capital” as supplemented by the section titled “Description of Share Capital” in the final prospectus supplement on Form 424(b)(5) dated May 27, 2020 filed with the SEC on May 29, 2020 is incorporated herein by reference.

C. MATERIAL CONTRACTS

For additional information on our material contracts, please see the sections of this annual report titled “Item 4—Information on the Company,” “Item 7.A.—Major Shareholders,” and “Item 7.B.—Related Party Transactions.”

D. EXCHANGE CONTROLS

Pursuant to Dutch law, there are no exchange controls applicable to the transfer to persons outside of the Netherlands of dividends or other distributions with respect to, or of the proceeds from the sale of, shares of a Dutch company.

Pursuant to Dutch law, there are no exchange controls applicable to our import or export of capital, including the availability of cash and cash equivalents to us as a Dutch company.

E. TAXATION

Certain Material U.S. Federal Income Tax Considerations to U.S. Holders

The following is a summary of certain material U.S. federal income tax considerations relating to the ownership and disposition of ADSs by a U.S. holder (as defined below). This summary addresses only the U.S. federal income tax considerations for U.S. holders that hold ADSs as capital assets for U.S. federal income tax purposes. This summary does not address all U.S. federal income tax matters that may be relevant to a particular U.S. holder. This summary does not address tax considerations applicable to a holder of ADSs that may be subject to special tax rules including, without limitation, the following:

- banks, financial institutions or insurance companies;
- brokers, dealers or traders in securities, currencies, commodities, or notional principal contracts;
- tax-exempt entities or organizations, including an “individual retirement account” or “Roth IRA” as defined in Section 408 or 408A of the Code (as defined below), respectively;
- real estate investment trusts, regulated investment companies or grantor trusts;
- persons that hold the ADSs as part of a “hedging,” “integrated” or “conversion” transaction or as a position in a “straddle” for U.S. federal income tax purposes;
- partnerships (including entities or arrangements classified as partnerships for U.S. federal income tax purposes) or other pass-through entities (including S corporations), or persons that will hold the ADSs through such an entity;
- certain former citizens or long-term residents of the United States;
- persons that received the ADSs as compensation for the performance of services;
- holders that own directly, indirectly, or through attribution 10% or more of the voting power or value of our ordinary shares and ADSs; and
- holders that have a “functional currency” for U.S. federal income tax purposes other than the U.S. dollar.

Further, this summary does not address U.S. federal estate, gift, or alternative minimum tax considerations, any election to apply Section 1400Z-2 of the Code to gains recognized with respect to ADSs, or any U.S. state, local, or non-U.S. tax considerations of the ownership and disposition of ADSs.

This description is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code; existing, proposed and temporary U.S. Treasury Regulations promulgated thereunder, administrative and judicial interpretations thereof; and the income tax treaties between the Netherlands and the United States, and Belgium and the United States, in each case as in effect and available on the date hereof. All the foregoing is subject to change, which change could apply retroactively, and to differing interpretations, all of which could affect the tax considerations described below. There can be no assurances that the U.S. Internal Revenue Service, or the IRS, will not take a contrary or different position concerning the tax consequences of the ownership and disposition of our ordinary shares or that such a position would not be sustained. Holders should consult their own tax advisors concerning the U.S. federal, state, local and non-U.S. tax consequences of owning and disposing of ADSs in their particular circumstances.

For the purposes of this summary, a "U.S. holder" is a beneficial owner of ADSs that is (or is treated as), for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation, or other entity that is treated as a corporation for U.S. federal income tax purposes, created or organized in or under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust, if a court within the United States is able to exercise primary supervision over its administration and one or more U.S. persons have the authority to control all of the substantial decisions of such trust or have a valid election in effect under applicable U.S. Treasury Regulations to be treated as a United States person.

If a partnership (or any other entity or arrangement treated as a partnership for U.S. federal income tax purposes) holds ADSs, the U.S. federal income tax consequences relating to an investment in those ADSs will depend in part upon the status of the partner and the activities of the partnership. Such a partner or partnership should consult its tax advisor regarding the U.S. federal income tax considerations of owning and disposing of ADSs in its particular circumstances.

In general, a U.S. holder who owns ADSs will be treated as the beneficial owner of the underlying shares represented by those ADSs for U.S. federal income tax purposes. Accordingly, no gain or loss will generally be recognized if a U.S. holder exchanges ADSs for the underlying shares represented by those ADSs.

As indicated below, this discussion is subject to U.S. federal income tax rules applicable to a "passive foreign investment company," or a PFIC, discussed under "—Passive Foreign Investment Company Considerations."

Persons considering an investment in the ADSs should consult their own tax advisors as to the particular tax consequences applicable to them relating to the ownership and disposition of ADSs, including the applicability of U.S. federal, state and local tax laws and non-U.S. tax laws.

Distributions. Although we do not currently plan to pay dividends, and subject to the discussion under "—Passive Foreign Investment Company Considerations" below, the gross amount of any distribution (before reduction for any amounts withheld in respect of Dutch or Belgian withholding tax) actually or constructively received by a U.S. holder with respect to ADSs will be taxable to the U.S. holder as a dividend to the extent of the U.S. holder's pro rata share of our current and accumulated earnings and profits as determined under U.S. federal

income tax principles. Distributions in excess of earnings and profits will be non-taxable to the U.S. holder to the extent of, and will be applied against and reduce, the U.S. holder's adjusted tax basis in ADSs. Distributions in excess of earnings and profits and such adjusted tax basis will generally be taxable to the U.S. holder as either long-term or short-term capital gain depending upon whether the U.S. holder has held the ADSs for more than one year as of the time such distribution is received. However, since we do not calculate our earnings and profits under U.S. federal income tax principles, it is expected that any distribution will be reported as a dividend, even if that distribution would otherwise be treated as a non-taxable return of capital or as capital gain under the rules described above. Non-corporate U.S. holders may qualify for the preferential rates of taxation with respect to dividends on ADSs applicable to long-term capital gains (i.e., gains from the sale of capital assets held for more than one year) applicable to qualified dividend income (as discussed below) if we are a "qualified foreign corporation" and certain other requirements (discussed below) are met. A non-U.S. corporation (other than a corporation that is classified as 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. Our ADSs are listed on the Nasdaq Global Select Market, which is an established securities market in the United States, and we expect our ADSs to be readily tradable on the Nasdaq Global Select Market. However, there can be no assurance that the ADSs will be considered readily tradable on an established securities market in the United States in any taxable year. 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.

In general, the amount of a distribution paid to a U.S. holder in a foreign currency will be the dollar value of the foreign currency calculated by reference to the spot exchange rate on the day the U.S. holder receives the distribution, regardless of whether the foreign currency is converted into U.S. dollars at that time. Any foreign currency gain or loss a U.S. holder realizes on a subsequent conversion of foreign currency into U.S. dollars will be U.S. source ordinary income or loss. If dividends received in a foreign currency are converted into U.S. dollars on the day they are received, a U.S. holder should not be required to recognize foreign currency gain or loss in respect of the dividend.

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.

For a cash basis taxpayer, units of foreign currency paid or received are translated into U.S. dollars at the spot rate on the settlement date of the purchase or sale. In that case, no foreign currency exchange gain or loss will result from currency fluctuations between the trade date and the settlement date of such a purchase or sale. An accrual basis taxpayer, however, may elect the same treatment required of cash basis taxpayers with respect to purchases and sales of the ADSs that are traded on an established securities market, provided the election is applied consistently from year to year. Such election may not be changed without the consent of the IRS. For an accrual basis taxpayer that does not make such an election, units of foreign currency paid or received are translated into U.S. dollars at the spot rate on the trade date of the purchase or sale. Such an accrual basis taxpayer may recognize exchange gain or loss based on currency fluctuations between the trade date and the settlement date. Any foreign currency gain or loss a U.S. holder realizes will be U.S. source ordinary income or loss.

Net Investment Income 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 Net Investment Income Tax to its income and gains in respect of its investment in ADSs.

Passive Foreign Investment Company Considerations. If we are classified as a passive foreign investment company, or PFIC, for any taxable year, a U.S. holder would be subject to special rules generally intended to reduce or eliminate any benefits from the deferral of U.S. federal income tax that a U.S. holder could derive from investing in a non-U.S. company that does not distribute all of its earnings on a current basis.

A corporation organized outside the United States generally will be classified as a PFIC for U.S. federal income tax purposes for any taxable year in which, after applying certain look-through rules, either: (i) at least 75% of its gross income is "passive income" or (ii) at least 50% of the average quarterly value of its total gross assets (for which purpose, assuming we are treated as a publicly traded company pursuant to Section 1297(e)(3) of the Code, 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 classified as 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 classified as a PFIC for any taxable year will depend on the composition of our income and the projected composition and estimated fair market values of our assets in each year, and because this is a factual determination made annually after the end of each taxable year, there can be no assurance that we will not be considered a PFIC for any taxable year. The market value of our assets may be determined in large part by reference to the market price of our ordinary shares and ADSs, which is likely to fluctuate after a public offering. Based on the foregoing, we do not anticipate that we will be classified as a PFIC for the 2020 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 classified as 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 classified as 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 classified as 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 classified as 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 classified as 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 (and with respect to any of our subsidiaries that

also may be classified as a PFICs), generally with the U.S. holder's federal income tax return for that year. If our company were classified as a PFIC for a given taxable year, then you should consult your tax advisor concerning your annual filing requirements.

The U.S. federal income tax rules relating to PFICs are complex. Prospective U.S. investors are urged to consult their own tax advisors with respect to the ownership and disposition of ADSs, the consequences to them of an investment in a PFIC, any elections available with respect to our ordinary shares and the IRS information reporting obligations with respect to the ownership and disposition of the ADSs.

Backup Withholding and Information Reporting. U.S. holders generally will be subject to information reporting requirements with respect to dividends on ADSs and on the proceeds from the sale, exchange or disposition of the ADSs that are paid within the United States or through U.S.- related financial intermediaries, unless the U.S. holder is an "exempt recipient." In addition, U.S. holders may be subject to backup withholding on such payments, unless the U.S. holder provides a correct taxpayer identification number and a duly executed IRS Form W-9 or otherwise establishes an exemption. Backup withholding is not an additional tax, and the amount of any backup withholding will be allowed as a credit against a U.S. holder's U.S. federal income tax liability and may entitle such holder to a refund, provided that the required information is timely furnished to the IRS.

Foreign Asset Reporting. Certain U.S. holders who are individuals and certain entities controlled by individuals may be required to report information relating to an interest in ADSs, subject to certain exceptions (including an exception for shares held in accounts maintained by U.S. financial institutions) by filing IRS Form 8938 (Statement of Specified Foreign Financial Assets) with their federal income tax return. U.S. holders are urged to consult their tax advisors regarding their information reporting obligations, if any, with respect to their ownership and disposition of the ADSs.

THE DISCUSSION ABOVE IS A GENERAL SUMMARY. IT DOES NOT COVER ALL TAX MATTERS THAT MAY BE OF IMPORTANCE TO A PROSPECTIVE INVESTOR. EACH PROSPECTIVE INVESTOR IS URGED TO CONSULT ITS OWN TAX ADVISOR ABOUT THE TAX CONSEQUENCES TO IT OF AN INVESTMENT IN THE ADSs IN LIGHT OF THE INVESTOR'S OWN CIRCUMSTANCES.

Material Dutch Tax Consequences

The following summary outlines certain material Dutch tax consequences in connection with the acquisition, ownership and disposal of the ADSs. All references in this summary to the Netherlands and Dutch law are to the European part of the Kingdom of the Netherlands and its law, respectively, only. The summary does not purport to present any comprehensive or complete picture of all Dutch tax aspects that could be of relevance to the acquisition, ownership and disposal of the ADSs by a (prospective) holder of the ADSs who may be subject to special tax treatment under applicable law. The summary is based on the tax laws and practice of the Netherlands as in effect on the date of this annual report, which are subject to changes that could prospectively or retrospectively affect the Dutch tax consequences.

For purposes of Dutch income and corporate income tax, shares, or certain other assets, which may include depositary receipts in respect of shares, legally owned by a third party such as a trustee, foundation or similar entity or arrangement, a "Third Party", may under certain circumstances have to be allocated to the (deemed) settlor, grantor or similar originator, the "Settlor", or, upon the death of the Settlor, such Settlor's beneficiaries, the "Beneficiaries", in proportion to their entitlement to the estate of the Settlor of such trust or similar arrangement, the "Separated Private Assets".

The summary does not address the Dutch 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 such holder's 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 such holder, whether alone or together with such holder's 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.

Furthermore, this summary does not address the Dutch tax consequences of a holder of the ADSs who:

(a) is an individual and receives income or realizes capital gains in respect of the ADSs in connection with such holder's employment activities or in such holder's capacity as (former) board member 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 DUTCH 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 our 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 for Dutch tax purposes 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 for Dutch tax purposes 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 for tax purposes with which the Netherlands has a tax treaty in effect, may, depending on the terms of such tax treaty 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) tax resident in (i) a Member State of the European Union, (ii) Iceland, Norway or Liechtenstein, or (iii) a country with which the Netherlands has concluded a tax treaty that includes an article on dividends and (b) that is in its state of residence under the terms of a tax treaty concluded with a third state, not considered to be resident for tax purposes in a country with which the Netherlands has not concluded a tax treaty that includes an article on dividends (not being a Member State of the European Union, Iceland, Norway or Liechtenstein), is generally entitled, subject to the anti-abuse rules and the anti-dividend stripping rules described below, to a full exemption from Dutch dividend withholding tax on dividends received if it holds an interest of at least 5% (in shares or, in certain cases, in voting rights) in the company or if it holds an interest of less than 5%, in either case where, had the holder of the ADSs been a Dutch resident, it would have had the benefit of the participation exemption (this may include a situation where another related party holds an interest of 5% or more in the company).

The full exemption from Dutch dividend withholding tax on dividends received by a holder of the ADSs, that is a legal entity (a) tax 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 (x) 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), or (y) the holder of ADSs has a similar function to a qualifying investment institution (*fiscale beleggingsinstelling*) or a qualifying exempt investment institution (*vrijgestelde beleggingsinstelling*).

A holder of the ADSs, that is an entity tax 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 does not have a similar function to a qualifying investment institution (*fiscale beleggingsinstelling*) or a qualifying exempt investment institution (*vrijgestelde beleggingsinstelling*), 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.

Irrespective of meeting the conditions of the relevant provisions of the U.S. Tax Treaty, dividends distributed by the company to a U.S. resident holder (i) who is a legal entity resident in the U.S. and (ii) that is in the U.S. under the terms of a tax treaty 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), are generally, subject to the anti-dividend stripping rules described above, fully exempt from Dutch dividend withholding tax if the U.S. resident holder of ADSs holds an interest of at least 5% in the company or if it holds an interest of less than 5%, in either case where, had the holder of ADSs been a Dutch resident, it would have had the benefit of the participation exemption (this may include a situation where another related party holds an interest of 5% or more in the company). The full exemption from Dutch dividend withholding tax on dividends received by a U.S. holder of ADSs that is a legal entity is however *not* granted if (x) the interest held by such U.S. 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) or (y) the U.S. holder of ADSs has a similar function to a qualifying investment institution (*fiscale beleggingsinstelling*) or a qualifying exempt investment institution (*vrijgestelde beleggingsinstelling*).

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 for Dutch tax purposes 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 49.5%.

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 for Dutch tax purposes 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 31% 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 2021 tax year, the deemed income derived from savings and investments will amount to 1.90% of the individual's yield basis up to and including €50,000, 4.50% of the individual's yield basis exceeding €50,000 up to and including €950,000 and 5.69% of the individual's yield basis in excess of €950,000. The tax-free threshold for 2021 is €50,000. The percentages to determine the deemed income will be reassessed every year.

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 institution (*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 Dutch corporate income tax, generally levied at a rate of 25% (15% over profits up to and including €245,000) 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 Dutch 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 49.5%.

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 Dutch 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% (15% over profits up to and including €245,000), 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 in case of a gift 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 that individual, at the time of the individual's death, is resident or deemed to be resident in the Netherlands.

For purposes of Dutch gift and inheritance tax, an individual with the Dutch nationality will be deemed to be resident in the Netherlands if such individual has been resident in the Netherlands at any time during the ten years preceding the date of the gift or such individual's death. For purposes of Dutch gift tax, an individual not holding the Dutch nationality will be deemed to be resident of the Netherlands if such individual 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 such Settlor's 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 for tax purposes by reason only of the acquisition, or the holding, of the ADSs or the performance by the company under the ADSs.

Material Belgian Tax Consequences

The paragraphs below present a summary of certain Belgian federal income tax consequences of the ownership and disposal of ADSs by an investor that purchases such ADSs. The summary is based on laws, treaties and regulatory interpretations in effect in Belgium on the date of this annual report, all of which are subject to change, including changes that could have retroactive effect.

Investors should appreciate that, as a result of evolutions in law or practice, the eventual tax consequences may be different from what is stated below.

This summary does not purport to address all tax consequences of the ownership and disposal of ADSs, and does not take into account the specific circumstances of particular investors, some of which may be subject to special rules, or the tax laws of any country other than Belgium. This summary does not describe the tax treatment of investors that are subject to special rules, such as banks, insurance companies, collective investment undertakings, dealers in securities or currencies, persons that hold, or will hold, ADSs as a position in a straddle, share-repurchase transaction, conversion transactions, synthetic security or other integrated financial transactions. This summary does not address the local taxes that may be due in connection with an investment in shares, other than the local surcharges which generally vary between 0% and 9% of the investor's income tax liability in Belgium.

In addition to the assumptions mentioned above, it is also assumed in this discussion that for purposes of the domestic Belgian tax legislation, the owners of ADSs will be treated as the owners of the ordinary shares represented by such ADSs. However, this assumption has not been confirmed by or verified with the Belgian Tax Authorities.

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 the purposes of this summary, a resident investor is:

- an individual subject to Belgian personal income tax, i.e. (i) an individual having its domicile in Belgium, (ii) when not having its domicile in Belgium, an individual having its seat of wealth in Belgium, or (iii) an individual assimilated to a resident for purposes of Belgian tax law;

- a company (as defined by Belgian tax law) subject to Belgian corporate income tax, i.e. a corporate entity having its principal establishment, administrative seat or effective place of management in Belgium (and that is not excluded from the scope of the Belgian corporate income tax). A company having its registered seat in Belgium shall be presumed, unless the contrary is proved, to have its principal establishment, administrative seat or effective place of management in Belgium; or

- a legal entity subject to the Belgian tax on legal entities, i.e. a legal entity other than a company subject to Belgian corporate income tax having its principal establishment, administrative seat or effective place of management in Belgium.

A non-resident investor is any individual, company or legal entity that does not fall in any of the three previous classes.

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, a repayment of capital is not fully imputed to fiscal capital if the company also has certain reserves. Indeed, in such case, a reimbursement of capital is proratedly imputed on, on the one hand, fiscal capital and, on the other hand, taxed reserves (whether or not incorporated in capital) and tax-exempt reserves incorporated in capital (according to a specific priority rule). The part imputed on the reserves is treated as a dividend distribution subject to applicable tax rules.

Belgian withholding tax of 30% is normally levied on dividends by any intermediary established in Belgium that is in any way involved in the processing of the payment of non-Belgian sourced dividends (e.g. a Belgian financial institution). This withholding tax rate is subject to such relief as may be available under applicable domestic or tax treaty provisions.

The Belgian withholding tax is calculated on the dividend amount after deduction of any non-Belgian dividend withholding tax.

In the case of a redemption of the ADSs, the redemption distribution (after deduction of the part of the fiscal capital represented by the redeemed ADSs) will be treated as a dividend subject to a Belgian withholding tax of 30%, subject to such relief as may be available under applicable domestic or tax treaty provisions. No withholding tax will be triggered if this redemption is carried out on a stock exchange and meets certain conditions.

In the event of our liquidation, any amounts distributed in excess of the fiscal capital will in principle be subject to the 30% withholding tax, subject to such relief as may be available under applicable domestic or tax treaty provisions.

Under Belgian law, non-Belgian dividend withholding tax is not creditable against Belgian income tax and is not reimbursable to the extent that it exceeds Belgian income tax. Please refer to “Item 10.E.—Taxation—Dutch Tax consequences—Dividend Withholding Tax” for a description of withholding tax that may be imposed on dividends by the Netherlands.

Belgian Resident Individuals

For Belgian resident individuals who acquire and hold ADSs as a private investment, the Belgian dividend withholding tax fully discharges their personal income tax liability. They may nevertheless need to report the dividends in their personal income tax return if no intermediary established in Belgium was in any way involved in the processing of the payment of the non-Belgian sourced dividends. Moreover, even if an intermediary established in Belgium was involved, they can opt to report the income in their personal income tax return. If (and only if) the dividends are reported, they will normally be eligible for a tax exemption with respect to ordinary dividends in an amount of up to €800 (for income year 2021) 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 ADSs) are taken into account to assess whether the said maximum amount is reached.

Where the beneficiary needs or, as applicable, opts to report them, dividends will normally be taxable at the lower of the generally applicable 30% Belgian withholding tax rate on dividends or, in case globalization is more advantageous, at the progressive personal income tax rates applicable to the taxpayer’s overall declared income. In addition, if the dividends are reported, the Belgian dividend withholding tax levied at source may be credited against the personal income tax due and is reimbursable to the extent that it exceeds the personal income tax due, provided that the dividend distribution does not result in a reduction in value of or a capital loss on our

ADSs. The latter condition is not applicable if the individual can demonstrate that it has held 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 local surcharges. Belgian withholding tax levied may be credited against the personal income tax due and is reimbursable to the extent that it exceeds the income tax due, subject to two conditions: (i) the taxpayer must own the ADSs in full legal ownership on the dividend record date and (ii) the dividend distribution may not result in a reduction in value of or a capital loss on the ADSs. The latter condition is not applicable if the investor can demonstrate that it has held the full legal ownership of the ADSs for an uninterrupted period of 12 months prior to the payment or attribution of the dividends.

Belgian Resident Companies

Dividends received by Belgian resident companies are exempt from Belgian withholding tax provided that the investor satisfies the identification requirements in Article 117, par. 11 of the Royal Decree implementing the ITC.

For Belgian resident companies, the gross 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 25%, except that a reduced corporate income tax rate of 20% applies to small companies and medium sized enterprises (as defined by Article 1:24, §1 to §6 of the Belgian Code on Companies and Associations) on the first €100,000 of taxable profits (subject to certain conditions).

Belgian resident companies can generally (although subject to certain limitations) deduct 100% of the gross dividend received from their taxable income, or the Dividend Received Deduction, provided that at the time of a dividend payment or attribution: (i) the Belgian resident company holds ADSs representing at least 10% of our share capital or a participation with an acquisition value of at least €2,500,000 (it being understood that only one out of the two tests must be satisfied); (ii) the shares representing our share capital have been or will be held in full ownership for an uninterrupted period of at least one year; and (iii) the conditions described in Article 203 of the ITC (relating to the taxation of the underlying distributed income and the absence of abuse), or the Article 203 of the ITC Taxation Condition, are met, or together, the Conditions for the application of the dividend deceived deduction regime.

Conditions (i) and (ii) above are, in principle, not applicable for dividends received by an investment company within the meaning of art. 2, §1, 5°, f) ITC. The Conditions for the application of the dividend received deduction regime depend on a factual analysis and for this reason the availability of this regime should be verified upon each dividend distribution.

Any Belgian dividend withholding tax levied at source can be credited against the ordinary Belgian corporate income tax and is reimbursable to the extent it exceeds such corporate income tax, subject to two conditions: (i) the taxpayer must own the ADSs in full legal ownership on the dividend record date and (ii) the dividend distribution does not result in a reduction in value of or a capital loss on the ADSs. The latter condition is not applicable: (i) if the taxpayer can demonstrate that it has held the ADSs in full legal ownership for an uninterrupted period of 12 months immediately prior to the payment or attribution of the dividends or (ii) if, during that period, the ADSs never belonged to a taxpayer other than a Belgian resident company or a non-resident company that has, in an uninterrupted manner, invested the ADSs in a permanent establishment, or PE, in Belgium.

Belgian resident Organizations for Financing Pensions

For organizations for financing pensions, or OFPs, *i.e.*, Belgian pension funds incorporated under the form of an OFP (*organisme de financement de pensions/organisme voor de financiering van pensioenen*) within the

meaning of Article 8 of the Belgian Law of October 27, 2006, dividend income generally does not constitute taxable income.

Dividends distributed through the intervention of a Belgian intermediary are generally subject to Belgian dividend withholding tax. If dividends are paid or attributed without the intervention of a Belgian intermediary, the applicable Belgian withholding tax will have to be reported and paid by the OFP to the Belgian tax administration.

The Belgian dividend withholding tax can in principle be credited against the OFPs' corporate income tax and is reimbursable to the extent it exceeds the corporate income tax due. However, such Belgian withholding cannot be credited by an OFP if the shares on which the dividends are paid have not been held uninterruptedly in full ownership for at least 60 days, unless the OFP demonstrates that the dividends are not connected to an arrangement (or a series of arrangements) that is not genuine ("kunstmatig"/"pas authentique") and has been put in place for the main purpose or one of the main purposes of obtaining this withholding tax credit.

Other Belgian resident Taxable Legal Entities

For taxpayers subject to the Belgian income tax on legal entities, the Belgian dividend withholding tax in principle fully discharges their income tax liability. If the dividend is paid outside Belgium without the intervention of a Belgian paying agent and without the deduction of Belgian withholding tax, the legal entity is in principle required to declare and pay the 30% withholding tax to the Belgian tax authorities.

Belgian Non-Resident Individuals and Companies

Dividend payments on the ADSs through a professional intermediary in Belgium will, in principle, be subject to the 30% withholding tax, unless the shareholder is resident in a country with which Belgium has concluded a double taxation agreement and delivers the requested affidavit. Non-resident investors can also obtain an exemption of Belgian dividend withholding tax if they are the owners or usufructors of the ADSs and they deliver an affidavit confirming that they have not allocated the ADSs to business activities in Belgium and that they are non-residents, provided that the dividend is paid through a Belgian credit institution, stock market company or recognized clearing or settlement institution.

If the ADSs are acquired by a non-resident investor in connection with a business in Belgium, the investor must report any dividends received, which are taxable at the applicable non-resident individual or corporate income tax rate, as appropriate. Any Belgian withholding tax levied at source can be credited against the non-resident individual or corporate income tax and is reimbursable to the extent it exceeds the income tax due, subject to two conditions: (i) the taxpayer must own the ADSs in full legal ownership on the dividend record date and (ii) the dividend distribution does not result in a reduction in value of or a capital loss on the ADSs. The latter condition is not applicable if (i) the non-resident individual or the non-resident company can demonstrate that the ADSs were held in full legal ownership for an uninterrupted period of 12 months immediately prior to the payment or attribution of the dividends or (ii) with regard to non-resident companies only, if, during the said period, the ADSs have not belonged to a taxpayer other than a resident company or a non-resident company which has, in an uninterrupted manner, invested the ADSs in a Belgian PE.

Non-resident companies that have invested the ADSs in a Belgian establishment can deduct up to 100% of the gross dividends included in their taxable profits if, at the date dividends are paid or attributed, the Conditions for the application of the Dividend Received Deduction regime are satisfied. Application of the Dividend Received Deduction regime depends, however, on a factual analysis to be made upon each distribution and its availability should be verified upon each distribution.

Capital Gains and Losses on ADSs

Belgian Resident Individuals

In principle, Belgian resident individuals acquiring the ADSs as a private investment should not be subject to Belgian capital gains tax on the disposal of the ADSs; capital losses are not tax deductible.

Capital gains realized in a private (*i.e.*, non-professional) context on the transfer for consideration of shares by a private individual, are taxable at 33% (plus local surcharges) if the capital gain is deemed to be realized outside the scope of the normal management of the individual's private estate. Capital losses are, however, not tax deductible in such event.

Gains realized by Belgian resident individuals upon the redemption of the ADSs or upon our liquidation are generally taxable as a dividend.

Belgian resident individuals who hold the ADSs for professional purposes are taxable at the ordinary progressive personal income tax rates (plus local surcharges) on any capital gains realized upon the disposal of the ADSs, except for ADSs held for more than five years, which are taxable at a flat rate of 16.5% (plus local surcharges). Capital losses on the ADSs incurred by Belgian resident individuals who hold the ADSs for professional purposes are in principle tax deductible.

Belgian Resident Companies

Belgian resident companies are normally not subject to Belgian capital gains taxation on gains realized upon the disposal of our ADSs provided that (i) the shares represent at least 10% of our share capital or a participation with an acquisition value of at least € 2,500,000 (it being understood that only one out of the two tests must be satisfied), (ii) the Article 203 ITC Taxation Condition is satisfied and (iii) the ADSs have been held in full legal ownership for an uninterrupted period of at least one year immediately preceding the disposal.

If one of the above conditions is not met, the capital gains realized upon the disposal of our ADSs by a Belgian resident company are taxable at the ordinary corporate income tax rate of, currently, 25%, unless the reduced corporate income tax rate of 20% on the first €100,000 of taxable profits applies (see above).

Capital losses on our ADSs incurred by resident companies are as a general rule not tax deductible.

Our ADSs held in the trading portfolios (*portefeuille commercial/handelsportefeuille*) of qualifying credit institutions, investment enterprises and management companies of collective investment undertakings which are subject to the Royal Decree of 23 September 1992 on the annual accounts of credit institutions, investment firms and management companies of collective investment undertakings (*comptes annuels des etablissements de credit, des entreprises d'investissement et des societes 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 25%. Capital losses on such shares are tax deductible. Internal transfers to and from the trading portfolio are assimilated to a realization.

Capital gains realized by Belgian resident companies (both non-SMEs and SMEs and both ordinary Belgian resident companies and qualifying credit institutions, investment enterprises and management companies of collective investment undertakings) upon the redemption of our ADSs or upon our liquidation are, in principle, subject to the same taxation regime as dividends. See "Item 10.E.—Taxation—Dividends."

Belgian resident 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.

Capital gains realized by Belgian OFPs upon the redemption of ADSs or upon our liquidation will in principle be taxed as dividends.

Other Belgian 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 the redemption of ADSs or upon our liquidation will, in principle, be subject to the same taxation regime as dividends.

Tax on Stock Exchange Transactions

Upon the issue of the ADSs (primary market), no Tax on Stock Exchange Transactions ("*taks op de beursverrichtingen*" / "*taxe sur les opérations de bourse*") is due.

The purchase and the sale and any other acquisition or transfer for consideration of ADSs (secondary market transactions) is subject to the Tax on Stock Exchange Transactions if (i) it is executed in Belgium through a professional intermediary, or (ii) deemed to be executed in Belgium, which is the case if the order is directly or indirectly made to a professional intermediary established outside of Belgium, either by private individuals with habitual residence in Belgium, or legal entities for the account of their seat or establishment in Belgium (both, a Belgian Investor).

The Tax on Stock Exchange Transactions is levied at a rate of 0.35% of the purchase price, capped at €1,600 per transaction and per party.

A separate tax is due by each party to the transaction, and both taxes are collected by the professional intermediary. However, if the intermediary is established outside of Belgium, the tax will in principle be due by the Belgian Investor, unless that Belgian Investor can demonstrate that the tax has already been paid. Professional intermediaries established outside of Belgium can, subject to certain conditions and formalities, appoint a Belgian Stock Exchange Tax Representative, which will be liable for the Tax on Stock Exchange Transactions in respect of the transactions executed through the professional intermediary. If the Stock Exchange Tax Representative would have paid the Tax on Stock Exchange Transactions due, the Belgian Investor will, as per the above, no longer be the debtor of the Tax on Stock Exchange Transactions.

No Tax on Stock Exchange Transactions is due on transactions entered into by the following parties, provided they are acting for their own account: (i) professional intermediaries described in Article 2,9° and 10° of the Belgian Law of August 2, 2002; (ii) insurance companies described in Article 2, §1 of the Belgian Law of July 9, 1975; (iii) professional retirement institutions referred to in Article 2,1° of the Belgian Law of October 27, 2006 concerning the supervision on institutions for occupational pension; (iv) collective investment institutions; (v) regulated real estate companies; and (vi) Belgian non-residents provided they deliver a certificate to their financial intermediary in Belgium confirming their non-resident status.

The EU Commission adopted on February 14, 2013 the Draft Directive on a Financial Transaction Tax, or FTT. The Draft Directive currently stipulates that once the FTT enters into force, the Participating Member States shall not maintain or introduce taxes on financial transactions other than the FTT (or VAT as provided in the Council Directive 2006/112/EC of November 28, 2006 on the common system of value added tax). For Belgium, the tax on stock exchange transactions should thus be abolished once the FTT enters into force. The Draft Directive regarding the FTT is still subject to negotiation between the Participating Member States and therefore may be changed at any time.

Annual Tax on Securities Accounts

A Law of 17 February 2021 introduced a new Belgian Annual Tax on Securities Accounts, which entered into effect on 26 February 2021. The Annual Tax on Securities Accounts is a subscription tax, levied on securities accounts and not on the holders thereof. A securities account is defined as an account on which financial instruments can be credited and debited.

The tax applies to securities accounts held both in Belgium and abroad when the account holder is a Belgian resident or when the account forms part of the assets of a Belgian establishment of a non-Belgian resident. The tax applies to natural persons residing in Belgium, as well as to companies and legal entities (subject to the tax for legal entities) that are established in Belgium.

The tax is also applicable to securities accounts held by non-Belgian residents (both natural persons and legal persons) if the securities account is held in Belgium. If the applicable double tax treaty however allocates the right to tax capital to the jurisdiction of residence, Belgium would be prevented from applying the Annual Tax on Securities Accounts to the Belgian securities accounts held by non-Belgian residents. As described above, the tax applies whether or not the account is held in Belgium if the account forms part of the assets of a Belgian establishment of a non-Belgian resident.

The Annual Tax on Securities Accounts is applicable to securities accounts of which the average value of the assets amounts to more than €1,000,000 during the reference period. In principle, this reference period starts on 1 October and ends on 30 September of the following year, except for the first reference period which starts on 26 February 2021 and ends on 30 September 2021. The aforementioned threshold is assessed on the average value of the assets in the securities account at reference points within the reference period (in principle 31 December, 31 March, 30 June and 30 September). The threshold is assessed per securities account and not per account holder.

The applicable tax rate is 0.15%, which is levied on the average value of the assets held in the securities account that exceeds the €1,000,000 threshold. It is however limited to 10% of the difference between the average value and the threshold of €1,000,000, in order to avoid that the Annual Tax on Securities Accounts would result in reducing the value of the securities account below the €1,000,000 threshold.

The Annual Tax is in principle withheld, reported and paid by the Belgian intermediary. If the intermediary is established outside of Belgium, the tax must in principle be reported and paid by the account holder, unless the account holder can demonstrate that the tax has already been reported and paid by an intermediary. Intermediaries established outside of Belgium can, subject to certain conditions and formalities, appoint a Belgian Annual Tax on Securities Accounts Representative, which will be liable for reporting and paying the Annual Tax on Securities Accounts in respect of securities accounts in scope of the Annual Tax that are held through such intermediaries. If the Annual Tax on Securities Accounts Representative would have paid the Annual

Tax on Securities Accounts due, the account holder will, as per the above, no longer be the debtor of the Annual Tax on Securities Accounts.

The Annual Tax on Securities Accounts is however not applicable to securities accounts held by certain categories of account holders active in the financial or fund sector, as listed in the relevant legislation. These exemptions do however not apply if a non-qualifying third party has a direct or indirect claim on the value of the securities account.

The relevant legislation provides for both a general anti-abuse provision, as well as specific anti-abuse provisions targeting (i) the splitting of a securities account in multiple securities accounts held at the same intermediary and (ii) the conversion of taxable financial instruments, included in a securities account, into registered financial instruments. These anti-abuse provisions apply to transactions effected as from 30 October 2020.

Prospective investors are strongly advised to seek their own professional advice in relation to the possible impact of the new Annual Tax on Securities Accounts on their own personal tax position.

Enforcement of Civil Liabilities

We are a European public company with limited liability (*Societas Europaea* or *SE*) incorporated under the laws of the Netherlands. 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 debtor is liable for the payment of the registration tax, in the proportion determined by the decision ordering payment or liquidation or determining priority for creditors made or established against it. The debtor(s) are jointly and severally liable in the event that they are ordered to pay jointly and severally. A stamp duty is payable for each original copy of an enforcement judgment rendered by a Belgian court, with a maximum of €1,450.

Dutch and Belgian civil procedure differs substantially from U.S. civil procedure in a number of respects. Insofar as the production of evidence is concerned, U.S. law and the laws of several other jurisdictions based on common law provide for pre-trial discovery, a process by which parties to the proceedings may prior to trial compel the production of documents by adverse or third parties and the deposition of witnesses. Evidence obtained in this manner may be decisive in the outcome of any proceeding. No such pre-trial discovery process exists under Dutch or Belgian law.

Subject to the foregoing and service of process in accordance with applicable treaties, investors may be able to enforce in the Netherlands or Belgium judgments in civil and commercial matters obtained from U.S. federal or state courts. However, no assurance can be given that those judgments will be enforceable. In addition, it is doubtful whether a Dutch or Belgian court would accept jurisdiction and impose civil liability in an original action commenced in the Netherlands or Belgium and predicated solely upon U.S. federal securities laws.

F. DIVIDENDS AND PAYING AGENTS

Not applicable.

G. STATEMENT BY EXPERTS

Not applicable.

H. DOCUMENTS ON DISPLAY

We are subject to the information reporting requirements of the Exchange Act applicable to foreign private issuers and under those requirements will file reports with the SEC. Those reports may be inspected without charge at the locations described below. As a foreign private issuer, we are exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as United States companies whose securities are registered under the Exchange Act. Nevertheless, we will file with the SEC an annual report containing financial statements that have been examined and reported on, with and opinion expressed by an independent registered public accounting firm.

We maintain a corporate website at *www.argenx.com*. We intend to post a link to our annual report on Form 20-F as filed with the SEC on our website promptly following it being filed with the SEC. Information

contained on, or that can be accessed through, our website does not constitute a part of this annual report. We have included our website address in this annual report solely as an inactive textual reference.

You may also review a copy of this annual report, including exhibits and any schedule filed herewith, and obtain copies of such materials at prescribed rates, at the SEC's Public Reference Room in Room 1580, 100 F Street, NE, Washington, D.C. 20549-0102. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains a website (*www.sec.gov*) that contains reports, proxy and information statements and other information regarding registrants, such as argenx SE, that file electronically with the SEC.

With respect to references made in this annual report to any contract or other document of argenx SE, such references are not necessarily complete and you should refer to the exhibits attached or incorporated by reference to this annual report for copies of the actual contract or document.

I. SUBSIDIARY INFORMATION

Not applicable.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The financial risks are management centrally. The Company coordinates the access to national and international financial markets and considers and manages continuously the financial risks concerning the Company's activities. These relate to the financial markets risk, credit risk, liquidyt risk and currency risk. there are no other important risks, such as interest rate risk on borrowings, as the Company has no financial debt. We do not buy or trade financial instruments for speculative purposes. For additional information on general risk factors, please see the section of this annual report titles "Item 3.D. – Risk Factors."

Capital risk

The Company manages its capital to ensure that it will be able to continue as a going concern. The capital structure of the Company consists of equity attributed to the holders of equity instruments of the Company, such as capital, reserves and accumulated losses as mentioned in the consolidated statements of changes in equity. The Company makes the necessary adjustments in the light of changes in the economic circumstances, risks associated to the different assets and the projected cash needs of the current and projected research activities. On December 31, 2020, cash and cash equivalents amounted to €991.6 million and total capital amounted to €2,062.9 million. The current cash situation and the anticipated cash generation are the most important parameters in assessing the capital structure. The Company's objective is to maintain the capital structure at a level to be able to finance its activities for at least twelve months. Cash income from existing and new partnerships is taken into account and, if needed and possible, the Company can issue new shares or enter into financing agreements.

Credit risk

Credit risk refers to the risk that a counterparty will default on its contractual obligations resulting in financial loss to the Company. The Company has adopted a policy of only dealing with creditworthy counterparties and obtaining sufficient collateral, where appropriate, as a means of mitigating the risk of financial loss from defaults. Concentrations in credit risk are determined based on an analysis of counterparties and their importance on the overall outstanding contractual obligations at year end.

The Company has a limited number of license and 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.

The Companies applied the IFRS 9 simplified approach to measuring expected credit losses which uses a lifetime expected loss allowance for all receivables. To measure the expected credit losses, receivables have been grouped based on credit risk characteristics and the days past due. The provision for expected credit losses was not significant given that there have been no credit losses over the last three years and the high quality nature of our customers.

Cash and cash equivalents and current financial assets are invested with several highly reputable banks and financial institutions. The Company holds its cash and cash equivalents mainly with different banks which are independently rated with a minimum rating of 'A-'. The Company also holds short term investment funds in the form of money market funds with a recommended investment horizon of 6 months or shorter but with a low historical volatility. These money market funds are highly liquid investments, can be readily convertible into a known amount of cash. Since they are a basket of funds there is no individual credit risk involved. The average credit rating of the underlying instruments for the investment funds is BBB or higher.

Liquidity risk

The Company manages liquidity risk by maintaining adequate reserves, by continuously monitoring forecast and actual cash flows, and by matching the maturity profiles of financial assets and liabilities.

The Company's main sources of cash inflows are obtained through capital increases and collaboration agreements. This cash is invested in savings accounts, term accounts and short term investment funds in the form of money market funds. These money market funds represent the majority of the Company's available sources of liquidity however since all of these are immediately tradable and convertible in cash they have a limited impact on the liquidity risk.

Interest rate risk

The only variable interest-bearing financial instruments are cash and cash equivalents and current financial investments. Changes in interest rates may cause variations in tnerest income and expense resulting from short-term interest-bearing assts. Management does not expect the short-term interest rates to decrease significantly in the immediate foreseeable future, which limits the interest exposure on our cash and cash equivalents and current financial investments.

For the year ended December 31, 2020, if applicable interest rates would increase/decrease by 25 basis points, this would have a positive/negative impact of €1.5 million (compared to €2.0 million for the year ended December 31, 2019 and €0.3 million for the year ended December 31, 2018).

Foreign exchange risk

The Company undertakes transactions denominated in foreign currencies; consequently, exposures to exchange rate fluctuations arise. The Company is mainly exposed to the U.S. Dollar, Japanse yen, British pound and Swiss franc. To limit this risk, the Company attempts to align incoming and outgoing cash flows in currencies other than EUR.

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

	At December 31,		
(in thousands of €)	**2020**	**2019**	**2018**
USD	1,053,803	821,916	312,831
JPY	215	488	—
GBP	39	4	2
CHF	94	1	4

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:	**For:**
$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)	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, 2020. 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, 2020, our Chief Executive Officer and Chief Financial Officer have concluded that the disclosure controls and procedures, in accordance with Exchange Act Rule 13a-15(e), are (i) effective at the 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 the 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 our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as such term is defined in Rule 13a-15(f) and Rule 15d-15(f) under the Exchange Act). Our internal control over financial reporting is a process designed, under the supervision of our Chief Executive Officer and Chief Financial Officer, to provide reasonable assurance regarding the reliability of financial reporting and preparation of financial statements for external reporting purposes in accordance with IFRS, as issued by the IASB.

Our internal control over financial reporting includes policies and procedures that pertain to the maintenance of records that, in reasonable detail, accurately and fairly, reflect transactions and dispositions of assets, provide reasonable assurance that transactions are recorded in the manner necessary to permit the preparation of financial statements in accordance with IFRS, and that receipts and expenditures are only carried out in accordance with the authorization of our management and directors, and provide reasonable assurance regarding the prevention or timely detection of any unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect all misstatements. Moreover, projections of any evaluation of the effectiveness of internal control to future periods are subject to a risk that controls may become inadequate because of changes in conditions and that the degree of compliance with the policies or procedures may deteriorate.

Our management has assessed the effectiveness of internal control over financial reporting based on the Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in 2013. Based on this assessment, our management has concluded that our internal control over financial reporting as of December 31, 2020 was effective.

The effectiveness of internal control over financial reporting as of December 31, 2020 has been audited by Deloitte Accountants B.V., our independent registered public accounting firm. Their audit report, including their opinion on management's assessment of internal control over financial reporting, is included in our audited consolidated financial statements included in this annual report.

Changes in Internal Control Over Financial Reporting

During the period covered by this annual report, we have not made any change to our internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 16. RESERVED

Not applicable.

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

Our board of directors has determined that Werner Lanthaler qualifies as an audit committee financial expert as defined by SEC rules and has the requisite financial sophistication under the applicable rules and regulations of the NASDAQ Stock Market. Dr. Lanthaler is independent under Rule 10A-3 of the Exchange Act.

ITEM 16B. CODE OF ETHICS

We adopted a Code of Business Conduct and Ethics, or the Code of Conduct, that is applicable to all of our employees and directors. The Code of Conduct is available on our website at *www.argenx.com*. The audit and compliance 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 2020 and 2019. Our accountants billed the following fees to us for professional services in each of those fiscal years:

Fees	Year Ended December 31, 2020	2019
	in thousands of €	
Audit Fees	€ 808	€ 730
Audit-Related Fees	165	159
All Other Fees	—	—
Total	**€ 973**	**€ 889**

"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 2020 and 2019, "Audit-Related Fees" also include fees billed for assurance and audit-related services regarding our public offerings on Nasdaq.

"All Other Fees" are any additional amounts billed for products and services provided by the principal accountant. No other fees were billed by Deloitte Accountants B.V. for the fiscal years ended December 31, 2020 and 2019.

Audit and Compliance Committee's Pre-Approval Policies and Procedures

The audit and compliance 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 and compliance 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 and compliance committee, it requires specific pre-approval by the audit and compliance committee. The payment for any proposed services in excess of pre-approved cost levels requires specific pre-approval by the audit and compliance committee.

Pursuant to its pre-approval policy, the audit and compliance committee may delegate its authority to pre-approve services to the chairperson of the Audit and Compliance 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 and compliance committee may not delegate its responsibilities to pre-approve services to the management.

The audit and compliance 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-47 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	Incorporated by Reference			
		Schedule/ Form	File Number	Exhibit	File Date (mm/dd/yyyy)
1.1	Articles of Association (English translation), as amended	Form F-1/A	333-217417	3.1	05/04/2017
1.2	Rules for the Board of Directors	Form F-1	333-217417	3.2	04/21/2017
2.1	Form of Deposit Agreement	Form F-1/A	333-217417	4.1	05/16/2017
2.2	Form of American Depositary Receipt (included in Exhibit 2.1)				
2.3#	Description of Share Capital				
4.1	Leases dated April 1, 2016 between argenx BVBA and Bio-Incubator Gent 2 NV	Form F-1	333-217417	10.1	04/21/2017
4.2**	Patent License Agreement, dated February 15, 2012, between the registrant and The Board of Regents of the University of Texas System, as amended	Form F-1	333-217417	10.2	04/21/2017
4.3†	Form of Indemnification Agreement between the registrant and each of its executive officers and directors	Form F-1	333-217417	10.3	04/21/2017
4.4†	argenx option plan and form of option agreement and notice of option grant thereunder	Form F-1	333-221984	10.4	12/11/2017
4.5**	Collaboration License Agreement, dated December 2, 2018, between the registrant, argenx BVBA and Cilag GmbH International	Form 20-F	001-38097	4.5	03/26/2019
4.6	Investment Agreement, dated December 2, 2018, between the registrant and Johnson & Johnson Innovation – JJDC, Inc.	Form 20-F	001-38097	4.6	03/26/2019

4.7# **	Collaboration and License Agreement, dated January 6, 2021, between the registrant and Zai Auto Immune (Hong Kong) Limited
8.1#	List of subsidiaries of the registrant
12.1#	Certification by the Principal Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
12.2#	Certification by the Principal Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
13.1*	Certification by the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
13.2*	Certification by the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
15.1#	Consent of Deloitte Accountants B.V.
101.INS#	XBRL Instance Document
101.SCH#	XBRL Taxonomy Extension Schema Document
101.CAL#	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF#	XBRL Taxonomy Extension Definition Linkbase Document

101.LAB#	XBRL Taxonomy Extension Label Linkbase Document
101.PRE#	XBRL Taxonomy Extension Presentation Linkbase Document

Filed herewith.

* Furnished herewith.

† Indicates a management contract or any compensatory plan, contract or arrangement.

** Confidential treatment status has been granted as to certain portions thereto, which portions are omitted and filed separately with the U.S. Securities and Exchange Commission.

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

Date: March 30, 2021

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, 2020, 2019 and 2018

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of argenx SE

Opinion on the Financial Statements

We have audited the accompanying consolidated statements of financial position of argenx SE and subsidiaries (the "Company") as of December 31, 2020, 2019 and 2018, the related consolidated statements of profit and loss and other comprehensive income, cash flows, and changes in equity, for each of the three years in the period ended December 31, 2020, 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, 2020, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2020, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 30, 2021, expressed an unqualified opinion on the Company's internal control over financial reporting.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Trade and Other Payables – research and development cost accruals — Refer to Note 15 to the financial statements

Critical Audit Matter Description

The Company recognizes costs of EUR 52.6 million, as specified in Note 15 to the financial statements, incurred for clinical trial activities as research and development expenses based on evaluation of its vendors' progress toward completion of specific tasks. Vendors' progress during 2020 may be impacted by the effects of the Covid-19 pandemic when compared to original planning. Payment timing may differ significantly from the period in

which the costs are recognized as expense, resulting in research and development cost accruals recognized within Trade and Other Payables in the Statement of Financial Position.

Quantification of the research progress and the translation of the progress to the research and development cost accruals requires judgment, because the progress is not directly observable. In estimating the vendors' progress toward completion of specific tasks, the Company therefore uses data such as patient enrollment, clinical site activations and vendor information of actual costs incurred. This data is obtained through reports from or discussions with Company personnel and outside service providers as to the progress or state of completion of trials, or the completion of services. Costs are expensed over the service period the services are provided. Costs for services provided that have not yet been paid are recognized as accruals. Research and development cost accruals also directly impact the revenue recognized from collaboration agreements, given the Company records revenue based on the percentage of completion method, whereby research and development cost accruals are used as key input value.

We identified the research and development cost accruals as a critical audit matter due to the number of ongoing clinical trial activities and the subjectivity involved in estimating research and development cost accruals and as auditing the research and development cost accruals involves judgement in evaluating the progress of the research and development activities relative to the costs incurred.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the research and development cost accruals included the following, among others:

- We tested controls over the appropriateness of the recording of the research and development accruals reflecting the progress of the clinical trials, including the monthly review meetings between the finance department and clinical research personnel.
- We read selected research and collaboration agreements, as well as amendments thereto, to evaluate whether the progress of the clinical trials reflects all relevant contractual elements.
- We considered publicly available information (such as press releases and investor presentations) and board of directors' materials regarding the status of clinical trial activities and compared this information to the judgements applied in recording the accruals and prepaid expenses.
- For a selection of contracts, we compared the amount of accruals at the end of the prior period to current year activity and evaluated the accuracy of the Company's estimation methodology.
- We performed confirmation procedures related to the progress of the projects for significant vendors to test the research and development cost input calculations.
- We made selections of specific amounts recognized as research and development expense as well as those recognized as accrued expenses and performed the following procedures:
    - Evaluated management's estimate of the vendor's progress based on inquiries with Company clinical operations personnel, specifically taking into account potential impact on the vendor's progress as a result of the Covid-19 pandemic.
    - Reconciled the related statement of work, purchase order, or other supporting documentation to management's estimate (such as communications between the Company and vendors).

Compared to prior year we have not included the critical audit matter related to Revenue and Deferred Revenue, as this critical audit matter adressed the initial accounting treatment of the Cilag GmbH International collaboration and license agreement.

/s/ Deloitte Accountants B.V.

Rotterdam, the Netherlands
March 30, 2021

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

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of argenx SE

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of argenx SE and subsidiaries (the "Company") as of December 31, 2020, based on criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control — Integrated Framework (2013) issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2020 of the Company and our report dated March 30, 2021, expressed an unqualified opinion on those financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Deloitte Accountants B.V.

Rotterdam, the Netherlands

March 30, 2021

ARGENX SE

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

(in thousands of €)	Note	As of December 31, 2020	2019	2018
ASSETS				
Current assets				
Cash and cash equivalents	12	€ 991,609	€ 331,282	€ 281,040
Restricted cash — current		—	—	1,692
Research and development incentive receivables — current		377	261	301
Financial assets — current	11	635,359	1,004,539	283,529
Prepaid expenses		22,747	9,022	2,995
Inventories	9	20,532	—	—
Trade and other receivables	10	5,687	28,115	2,886
Total current assets		**1,676,311**	**1,373,219**	**572,443**
Non-current assets				
Other non-current assets	7	6,383	3,226	252
Research and development incentive receivables — non-current		16,840	8,566	4,883
Deferred tax asset	8	12,255	—	—
Property, plant and equipment	6	9,494	8,167	824
Intangible assets	5	136,410	40,161	56
Total non-current assets		**181,382**	**60,120**	**6,015**
TOTAL ASSETS		**€ 1,857,693**	**€ 1,433,339**	**€ 578,458**

The accompanying notes form an integral part of these consolidated financial statements.

(in thousands of €)	Note	As of December 31, 2020	2019	2018
EQUITY AND LIABILITIES				
Equity	13			
Equity attributable to owners of the parent				
Share capital		€ 4,757	€ 4,276	€ 3,597
Share premium		2,058,123	1,308,539	673,454
Accumulated losses		(861,491)	(332,568)	(169,603)
Other reserves		162,984	70,499	30,947
Total equity		**€ 1,364,373**	**€ 1,050,746**	**€ 538,395**
Deferred tax liabilities		**1,212**	**—**	**—**
Non-current liabilities				
Provisions for employee benefits		128	64	7
Lease liabilities — non-current		5,035	4,540	—
Deferred revenue — non-current	16	219,248	218,032	—
Total non-current liabilities		**224,411**	**222,636**	**7**
Current liabilities				
Lease liabilities — current		2,833	1,974	—
Trade and other payables	15	224,262	85,301	37,072
Tax liabilities		2,850	344	823
Deferred revenue — current	16	37,754	72,338	2,161
Total current liabilities		**267,699**	**159,957**	**40,056**
Total liabilities		**€ 492,110**	**€ 382,593**	**€ 40,063**
TOTAL EQUITY AND LIABILITIES		**€ 1,857,695**	**€ 1,433,339**	**€ 578,458**

The accompanying notes form an integral part of these consolidated financial statements.

ARGENX SE

CONSOLIDATED STATEMENTS OF PROFIT AND LOSS AND OTHER COMPREHENSIVE INCOME

(in thousands of € except for shares and EPS)	Note	Year Ended December 31, 2020	2019	2018
Revenue	16	€ 36,425	€ 69,783	€ 21,482
Other operating income	17	18,109	12,801	7,749
Total operating income		**54,534**	**82,584**	**29,231**
Research and development expenses	19	(325,479)	(197,665)	(83,609)
Selling, general and administrative expenses	20	(149,367)	(64,569)	(27,471)
Total operating expenses		**(474,846)**	**(262,234)**	**(111,080)**
Change in fair value on non-current financial assets	7	2,544	1,096	—
Operating loss		**€ (417,769)**	**€ (178,554)**	**€ (81,849)**
Financial income/(expense)	23	(1,414)	14,275	3,694
Exchange gains/(losses)	23	(106,956)	6,066	12,308
Loss before taxes		**€ (526,139)**	**€ (158,213)**	**€ (65,847)**
Income tax expense	24	€ (2,784)	€ (4,752)	€ (794)
Loss for the year and total comprehensive loss		**€ (528,923)**	**€ (162,965)**	**€ (66,641)**
Loss for the year and total comprehensive loss attributable to:				
Owners of the parent		**€ (528,923)**	**€ (162,965)**	**€ (66,641)**
Weighted average number of shares outstanding		45,410,442	38,619,121	33,419,356
Basic and diluted loss per share (in €)	25	(11.65)	(4.22)	(1.99)

The accompanying notes form an integral part of these consolidated financial statements.

ARGENX SE

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands of €)	Note	Year Ended December 31, 2020	2019	2018
CASH FLOWS (USED IN) / FROM OPERATING ACTIVITIES				
Operating result		€ **(417,769)**	€ **(178,554)**	€ **(81,849)**
Adjustments for non-cash items				
Amortization of intangible assets	5	215	38	19
Depreciation of property, plant and equipment	6	3,214	2,128	474
Provisions for employee benefits		65	57	(18)
Expense recognized in respect of share-based payments	14	84,479	39,552	19,183
Fair value gains on non-current financial assets at fair value through profit or loss	7	(2,544)	(1,096)	—
		€ **(332,340)**	€ **(137,875)**	€ **(62,191)**
Movements in current assets/liabilities				
(Increase)/decrease in trade and other receivables	10	19,767	(22,965)	(44)
(Increase)/decrease in inventories	9	(20,532)	—	—
(Increase)/decrease in other current assets		(13,840)	(5,170)	(800)
Increase/(decrease) in trade and other payables	15	45,652	47,995	21,784
Increase/(decrease) in deferred revenue – current	16	(34,585)	62,106	(8,868)
Movements in non-current assets/liabilities				
(Increase)/decrease in other non-current assets		(8,888)	(5,560)	(1,720)
(Increase)/decrease in deferred revenue – non-current	16	1,216	200,533	(1,435)
Cash flows (used in)/from operating activities		**(343,550)**	**139,064**	**(53,274)**
Interest paid		(349)	(124)	—
Income taxes paid		(2,450)	(4,356)	(565)
NET CASH FLOWS (USED IN) / FROM OPERATING ACTIVITIES		€ **(346,349)**	€ **134,584**	€ **(53,839)**
Purchase of intangible assets	5	(3,503)	(40,143)	(62)
Purchase of property, plant and equipment	6	(949)	(1,604)	(622)
(Increase)/decrease in financial assets – current	11	307,641	(708,060)	(108,229)
Interest received		7,061	5,469	1,371
NET CASH FLOWS (USED IN) / FROM INVESTING ACTIVITIES		€ **310,250**	€ **(744,338)**	€ **(107,542)**
Principal elements of lease payments	22	(2,230)	(1,353)	—
Proceeds from issue of new shares, gross amount	13	731,546	678,936	255,721
Issue costs paid	13	(551)	(22,999)	(14,655)
Exchange gain from currency conversion on proceeds from issue of new shares		62	—	1,354
Proceeds from exercise of stock options	13	19,070	4,775	2,251
NET CASH FLOWS (USED IN) / FROM FINANCING ACTIVITIES		€ **747,897**	€ **659,359**	€ **244,671**
NET INCREASE (DECREASE) IN CASH & CASH EQUIVALENTS		€ **711,798**	€ **49,605**	€ **83,290**
Cash and cash equivalents at the beginning of the period		€ **331,282**	€ **281,040**	€ **190,867**
Exchange gains/(losses) on cash & cash equivalents		€ (51,471)	€ 637	€ 6,883
Cash and cash equivalents at the end of the period		€ **991,609**	€ **331,282**	€ **281,040**

The accompanying notes form an integral part of these consolidated financial statements.

ARGENX SE

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

	Attributable to owners of the parent					
(in thousands of €)	**Share capital**	**Share premium**	**Accumulated losses**	**Other reserves**	**Total equity attributable to owners of the parent**	**Total equity**
Balance at January 1, 2018	**€ 3,216**	**€ 430,518**	**€ (102,962)**	**€ 11,764**	**€ 342,536**	**€ 342,536**
Total comprehensive loss of the period			(66,641)		(66,641)	**(66,641)**
Share-based payment				19,183	19,183	**19,183**
Issue of share capital	347	255,374			255,721	**255,721**
Transaction costs for equity issue		(14,655)			(14,655)	**(14,655)**
Exercise of stock options	34	2,217			2,251	**2,251**
Balance year ended December 31, 2018	**€ 3,597**	**€ 673,454**	**€ (169,603)**	**€ 30,947**	**€ 538,395**	**€ 538,395**
Total comprehensive loss of the period			(162,965)		(162,965)	**(162,965)**
Share-based payment				39,552	39,552	**39,552**
Issue of share capital	637	678,299			678,936	**678,936**
Transaction costs for equity issue		(22,999)			(22,999)	**(22,999)**
Accounting treatment of the share subscription agreement		(24,948)			(24,948)	**(24,948)**
Exercise of stock options	42	4,733			4,775	**4,775**
Balance year ended December 31, 2019	**€ 4,276**	**€ 1,308,539**	**€ (332,568)**	**€ 70,499**	**€ 1,050,746**	**€ 1,050,746**
Total comprehensive loss of the period			(528,923)		(528,923)	**(528,923)**
Income tax benefit from excess tax deductions related to share-based payments				8,006	8,006	**8,006**
Share-based payment				84,479	84,479	**84,479**
Issue of new shares	421	731,125			731,546	**731,546**
Transaction costs for equity issue		(551)			(551)	**(551)**
Exercise of stock options	60	19,010			19,070	**19,070**
Balance year ended December 31, 2020	**€ 4,757**	**€ 2,058,123**	**€ (861,491)**	**€ 162,984**	**€ 1,364,373**	**€ 1,364,373**

Please refer to note 13 for more information on the share capital and movement in number of shares. See also note 14 for more information on the share-based payments.

The accompanying notes form an integral part of these consolidated financial statements.

ARGENX SE

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

1. General information about the company

argenx SE is a Dutch European public company with limited liability incorporated under the laws of the Netherlands. The company (COC 24435214) has its official seat in Rotterdam, the Netherlands, and its registered office is at Willemstraat 5, 4811 AH, Breda, the Netherlands. An overview of the company and its subsidiaries (the Company) are described in note 31.

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. Impacts of COVID-19 on our business

The current unprecedented challenges as a result of the COVID-19 outbreak have impacted how we operate. We have been taking, and continue to take, the necessary steps in terms of safety, risk mitigation, and financial measures to best manage through these challenging times. We have currently experienced limited impact on our financial performance and financial position, although we continue to face additional risks and challenges associated with the impact of the outbreak.

3. Significant accounting policies

The significant Company's accounting policies are summarized below.

3.1 Statement of compliance and basis of preparation

The consolidated financial statements are prepared in accordance with the International Financial Reporting Standards (IFRS), issued by the International Accounting Standards Board (IASB) and the interpretations issued by the IASB's International Financial Reporting Interpretation Committee. The consolidated financial statements provide a general overview of the Company's activities and the results achieved. They present fairly the entity's financial position, its financial performance and cash flows, on a going concern basis.

The significant accounting policies applied in the preparation of the above consolidated financial statements are set out below. All amounts are presented in thousands of euro, unless otherwise indicated, rounded to the nearest € '000.

The consolidated financial statements have been approved for issue by the Company's Board of Directors (the Board) on March 30, 2021.

3.2 Adoption of new and revised standards

New standards and interpretations applicable for the annual period beginning on January 1, 2020

New standards and interpretations for the annual period beginning on January 1, 2020 did not have any material impact on our consolidated financial statements.

New standards and interpretations issued, but not yet applicable for the annual period beginning on January 1, 2020

We have not early adopted any other standard, interpretation, or amendment that has been issued but is not yet effective;

The following new standards and amendments to standards have been issued, but are not mandatory for the first time for the financial year beginning January 1, 2020 and have been endorsed by the European Union.

Amendments to IFRS 10 and IAS 28 – Sale or Contribution of Assets between an Investor and its Associate or Joint Venture

The amendments to IFRS 10 and IAS 28 deal with situations where there is a sale or contribution of assets between an investor and its associate or joint venture. Specifically, the amendments state that gains or losses resulting from the loss of control of a subsidiary that does not contain a business in a transaction with an associate or a joint venture that is accounted for using the equity method, are recognised in the parent's profit or loss only to the extent of the unrelated investors' interests in that associate or joint venture. Similarly, gains and losses resulting from the remeasurement of investments retained in any former subsidiary (that has become an associate or a joint venture that is accounted for using the equity method) to fair value are recognised in the former parent's profit or loss only to the extent of the unrelated investors' interests in the new associate or joint venture.

These amendments are not expected to have any material impact on our consolidated financial statements.

Amendments to IFRS 3 – Reference to the Conceptual Framework

The amendments update IFRS 3 so that it refers to the 2018 *Conceptual Framework* instead of the 1989 *Framework*. They also add to IFRS 3 a requirement that, for obligations within the scope of IAS 37, an acquirer applies IAS 37 to determine whether at the acquisition date a present obligation exists as a result of past events. For a levy that would be within the scope of IFRIC 21 *Levies*, the acquirer applies IFRIC 21 to determine whether the obligating event that gives rise to a liability to pay the levy has occurred by the acquisition date. Finally, the amendments add an explicit statement that an acquirer does not recognise contingent assets acquired in a business combination.

These amendments are not expected to have any material impact on our consolidated financial statements.

Amendments to IAS 16 – Property, Plant and Equipment—Proceeds before Intended Use

The amendments prohibit deducting from the cost of an item of property, plant and equipment any proceeds from selling items produced before that asset is available for use, i.e. proceeds while bringing the asset to the location and condition necessary for it to be capable of operating in the manner intended by management. Consequently, an entity recognises such sales proceeds and related costs in profit or loss. The entity measures the cost of those items in accordance with IAS 2 *Inventories*. The amendments also clarify the meaning of 'testing whether an asset is functioning properly'. IAS 16 now specifies this as assessing whether the technical and physical performance of the asset is such that it is capable of being used in the production or supply of goods or services, for rental to others, or for administrative purposes. If not presented separately in the statement of comprehensive income, the financial statements shall disclose the amounts of proceeds and cost included in profit or loss that relate to items produced that are not an output of the entity's ordinary activities, and which line item(s) in the statement of comprehensive income include(s) such proceeds and cost. The amendments are applied retrospectively, but only to items of property, plant and equipment that are brought to the location and condition necessary for them to be capable of operating in the manner intended by management on or after the beginning of the earliest period presented in the financial statements in which the entity first applies the amendments. The entity shall recognise the cumulative effect of initially applying the amendments as an adjustment to the opening balance of retained earnings (or other component of equity, as appropriate) at the beginning of that earliest period presented.

These amendments are not expected to have any material impact on our consolidated financial statements.

Amendments to IAS 37 – Onerous Contracts—Cost of Fulfilling a Contract

The amendments specify that the 'cost of fulfilling' a contract comprises the 'costs that relate directly to the contract'. Costs that relate directly to a contract consist of both the incremental costs of fulfilling that contract (examples would be direct labour or materials) and an allocation of other costs that relate directly to fulfilling contracts (an example would be the allocation of the depreciation charge for an item of property, plant and equipment used in fulfilling the contract). The amendments apply to contracts for which the entity has not yet fulfilled all its obligations at the beginning of the annual reporting period in which the entity first applies the

amendments. Comparatives are not restated. Instead, the entity shall recognise the cumulative effect of initially applying the amendments as an adjustment to the opening balance of retained earnings or other component of equity, as appropriate, at the date of initial application.

These amendments are not expected to have any material impact on our consolidated financial statements.

3.3 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.

The results of the subsidiaries are included in the consolidated statements of profit and loss and other comprehensive income from the effective date of acquisition up to the date when control ceases to exist. 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 inter-company transactions and unrealized gains on transactions between group companies are eliminated. Unrealised losses are also eliminated unless the transaction provides evidence of an impairment of the transferred asset.

3.4 Foreign currency transactions

3.4.1 Functional and presentation currency

Items included in the consolidated financial statements of each of our entities are valued using the currency of their economic environment in which the entity operates. The consolidated financial statements are presented in euro (€), which is the Company's presentation currency.

3.4.2 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 consolidated statements 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.

3.4.3 Financial statements of foreign entities

For foreign entities using a different functional currency than euro:

- assets and liabilities for each consolidated statements of financial position presented are translated at the closing rate at the date of that statement of financial position.
- income and expenses for each statement presenting profit or loss and other comprehensive income are translated at average exchange rates (unless this average is not a reasonable approximation of the cumulative effect of the rates prevailing on the transaction dates, in which case income and expenses are translated at the rate on the dates of the transactions).
- all resulting exchange differences are recognised in other comprehensive income.

3.5 Intangible assets

3.5.1 Internally generated intangible assets

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 consolidated statements 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 and this has resulted in all development costs being recognized as an expense in the period in which they are incurred.

3.5.2 Acquired In-Process R&D, Software and Databases and Other intangible assets

Intangible assets with finite useful lives that are acquired separately related to in-process research and development projects, software and databases and other intangible assets are carried at cost less accumulated amortization and accumulated impairment losses. Intangible assets with indefinite useful lives are carried at cost less accumulated impairment losses.

Payments for acquired in-process research and development projects obtained through in-licensing arrangements are capitalized as intangible assets provided that they are separately identifiable, controlled by the Company and expected to provide future economic benefits. As the probability criterion in IAS 38 is always considered to be satisfied for separately acquired research and development assets and the amount of the payments is determinable, upfront and milestone payments to third parties for pharmaceutical products or compounds for which regulatory marketing approval has not yet been obtained are recognized as intangible assets.

Other intangible assets includes the Priority Review Voucher (“PRV”) acquired in 2020 which the Company can use to obtain the priority review by the FDA for one of its future regulatory submissions or may sell or transfer to a third party. The PRV is measured at cost and reviewed for impairment when events or circumstances indicate that the carrying value may not be recoverable. At the time the Company commits using the PRV to accelerate the review of a drug application, the intangible asset will be amortized and derecognized upon filing of the related Biologic License Application.

3.5.3 Amortization of intangible assets

Intangible assets, which comprises of acquired in-process research and development, software and databases and other intangible assets, are amortized on a straight-line basis over the estimated useful life as from the time they are available for use, or when the underlying drug candidate is approved, generally on the following basis:

- Acquired In-Process R&D – the longer of the patent protection life and the useful life of the combined product
- Software and Databases – 3 – 5 years

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.

3.5.4 Derecognition of intangible assets

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, if any, and the carrying amount of the asset, are recognized in the consolidated statements of profit and loss and other comprehensive income when the asset is derecognized.

3.6 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 impairment losses.

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, if any, and the carrying amount of the asset and is recognized in the consolidated statements of profit or loss and other comprehensive income.

3.7 Inventories

Inventories are carried at cost or net realisable value, whichever is lowest. Cost is determined using the first-in, first-out method. Cost comprises of costs of purchase, costs of conversion and other costs incurred in bringing the inventories to their present location and condition.

If the expected sales price less completion costs to execute sales (net realizable value) is lower than the carrying amount, a write-down is recognised for the amount by which the carrying amount exceeds its net realisable value.

Included in inventory are products which could, besides commercial activities, be used in preclinical and clinical programs as well as in non-reimbursed Early Access Programs. These products are charged to research & development expenses or selling, general and administrative expenses, respectively, when dedicated to this channel.

We capitalize inventory costs associated with products prior to the regulatory approval of these products, or for inventory produced in new production facilities, when it is highly probable that the pre-approval inventories will be saleable. The determination to capitalize is based on the particular facts and circumstances relating to the expected regulatory approval of the product or production facility being considered. The assessment of whether or not the product is considered highly probable to be saleable is made on a quarterly basis and includes, but is not limited to, how far a particular product or facility has progressed along the approval process, any known safety or efficacy concern, potential labelling restrictions and other impediments.

Previously capitalized costs related to pre-launch inventories could be required to be written down upon a change in such judgement or due to a denial or delay of approval by regulatory bodies, a delay in commercialization or other potential factors, which will be recorded to research and development expenses.

3.8 Leases

As of January 1, 2019, the Company has changed its accounting policy for leases where the Company is the lessee.

3.8.1 Accounting policy until December 31, 2018

Leases of property, plant and equipment where the Company, as lessee, had substantially all the risks and rewards of ownership were classified as finance leases. Finance leases were capitalised at the lease's inception at the fair value of the leased property or, if lower, the present value of the minimum lease payments. The corresponding rental obligations, net of finance charges, were included in other short-term and long-term payables. Each lease payment was allocated between the liability and finance cost. The finance cost was charged to the profit or loss over the lease period so as to produce a constant periodic rate of interest on the remaining balance of the liability for each period. The property, plant and equipment acquired under finance leases was depreciated over the asset's useful life or over the shorter of the asset's useful life and the lease term if there is no reasonable certainty that the Company will obtain ownership at the end of the lease term.

Leases in which a significant portion of the risks and rewards of ownership were not transferred to the Company as lessee were classified as operating leases. Operating lease payments were recognized as an expense on a straight-line basis over the lease term, except where another systematic basis was more representative of the time pattern in which economic benefits from the leased asset are consumed.

The Company has adopated IFRS 16 on January 1, 2019. The Company elected to apply the modified retrospective approach for the transition, which foresees that prior period figures remain as reported under the previous standard IAS 17, and the cumulative effect of applying IFRS 16 is recognized as an adjustment to the opening balance of equity as of the date of initial application (i.e., the beginning of the year 2019). On adoption of IFRS 16, the Company recognized lease liabilities in relation to leases which had previously been classified as 'operating leases' under IAS 17. These liabilities were measured at the present value of the remaining lease payments and discounted using the Company's incremental borrowing rate as of January 1, 2019. The Company's weighted average incremental borrowing rate applied to these lease liabilities on January 1, 2019 was 1.32%.

The differences between our total operating lease commitments as reported in note 5.7 of our consolidated financial statements of December 31, 2018 and the total lease liabilities recognized in our statement of financial position as at January 1, 2019 are summarized below:

(in thousands of €)		
Operating lease commitments disclosed as at December 31, 2018	**€**	**3,004**
Less: discounting effect using the lessee's incremental borrowing rate of the date of initial application	€	(126)
Less: short-term leases recognized on a straight-line basis as expense	€	(88)
Lease liability recognized as at January 1, 2019	**€**	**2,790**
of which are:		
Current lease liabilities	€	1,078
Non-current lease liabilities	€	1,712

The cumulative effect of adopting IFRS 16 to the consolidated statements of financial position as of January 1, 2019 is as follows:

(in thousands of €)		
Property, plant and equipment (right-of-use assets)	€	2,790
Effect on total assets	**€**	**2,790**
Lease liabilities (current and non-current)	€	2,790
Effect on total equity and liabilities	**€**	**2,790**

The Company has elected not to reassess whether a contract is, or contains, a lease at the date of initial application. Instead, for contracts entered into before the transition date, the Company relied on its assessment made applying IAS 17 and IFRIC 4 *Determining whether an Arrangement contains a Lease*.

3.8.2 Accounting policy as from January 1, 2019

As from January 1, 2019, the Company assesses whether a contract is or contains a lease, at inception of the contract. The Company recognises a right-of-use asset and a corresponding lease liability with respect to all lease arrangements in which it is the lessee, except for short-term leases (defined as leases with a lease term of 12 months or less) and leases of low value assets. For these leases, the Company recognises the lease payments as an operating expense on a straight-line basis over the term of the lease unless another systematic basis is more representative of the time pattern in which economic benefits from the leased assets are consumed.

The lease liability is initially measured at the present value of the lease payments that are not paid at the commencement date, discounted by using the rate implicit in the lease. If this rate cannot be readily determined, the lessee uses its incremental borrowing rate. The lease liability is subsequently measured by increasing the carrying amount to reflect interest on the lease liability (using the effective interest method) and by reducing the carrying amount to reflect the lease payments made. The lease liability is presented as a separate line in the consolidated statements of financial position.

The right-of-use assets comprise the initial measurement of the corresponding lease liability, lease payments made at or before the commencement day, less any lease incentives received and any initial direct costs. They are subsequently measured at cost less accumulated depreciation and impairment losses. Right-of-use assets are depreciated over the shorter period of lease term and useful life of the underlying asset. If a lease transfers ownership of the underlying asset or the cost of the right-of-use asset reflects that the Company expects to exercise a purchase option, the related right-of-use asset is depreciated over the useful life of the underlying asset. The right-of-use assets are presented in the consolidated statements of financial position under the caption “Property, plant and equipment”.

3.9 Impairment of assets

3.9.1 Financial Assets

The impairment loss of a financial asset measured at amortised cost is calculated based on the expected loss model.

For trade receivables, in the absence of a significant financing component, the allowance is measured at an amount equal to lifetime expected credit losses. Those are the expected credit losses that result from possible default events over the expected life of those trade receivables.

3.9.2 Property, plant and equipment and intangible assets

At the end of each reporting period, the Company reviews the carrying amounts of its tangible and intangible assets to determine whether there is any indication that those assets have suffered an impairment loss. If any such indication exists, the recoverable amount of the asset is estimated in order to determine the extent of the impairment loss, if any. Where it is not possible to estimate the recoverable amount of an individual asset, the Company estimates the recoverable amount of the cash-generating unit to which the asset belongs.

Intangible assets with indefinite useful lives and intangible assets not yet available for use are tested for impairment at least annually, and whenever there is an indication that the asset may be impaired.

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 the statement of profit or loss and other comprehensive income.

Where an impairment loss subsequently reverses, the carrying amount of the asset 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.

3.10 Financial instruments

Financial assets and financial liabilities are recognized in the consolidated statements of financial position when the Company becomes party to the contractual provisions of the instrument. The Company does not use currency derivatives to hedge planned future cash flows, nor does it make use of forward foreign exchange contracts. Additionally, the Company does not have financial debt at December 31, 2020.

3.10.1 Financial assets

Financial assets are initially recognized either at fair value or at transaction price. All recognized financial assets are subsequently measured at either amortized cost or fair value under IFRS 9 on the basis of both the Company's model for managing the financial assets and the contractual cash flow characteristics of the financial asset.

- A financial asset that (i) is held within a business model whose objective is to collect the contractual cash flows and (ii) has contractual cash flows that are solely payments of principal and interest on the principal amount outstanding is measured at amortized cost (net of any write down for impairment), unless the asset is designated at fair value through profit or loss (FVTPL) under the fair value option.
- A financial asset that (i) is held within a business model whose objective is achieved both by collecting contractual cash flows and selling financial assets and (ii) has contractual term that give rise on specified dates to cash flows that are solely payments of principal and interest on the principal outstanding, is measured at fair value through other comprehensive income (FVTOCI), unless the asset is designated at FVTPL under the fair value option.
- All other financial assets are measured at FVTPL.

A financial asset is classified as current when the cash flows expected to flow from the instrument mature within one year.

The Company derecognized a financial asset when the contractual rights to the cash flows from the asset expire, or the Company transfers the right to receive the contractual cash flows on the financial asset in a transaction in which substantially all the risks and rewards of ownership of the financial asset are transferred.

The Company classifies non-derivative financial assets into the following categories;

- financial asset at fair value through profit or loss (non-current financial assets, current financial assets and cash equivalents)
- financial assets at amortized cost (receivables and cash and cash equivalents)

Financial assets at fair value through profit or loss

Financial assets are designated at fair value through profit or loss if the Company manages such investments and makes purchases and sales decisions based on their fair value in accordance with the Company's investment strategy. Attributable transaction costs are recognised in the consolidated statements

of profit or loss and other comprehensive income as incurred. Financial assets at fair value through profit or loss are measured at fair value, and changes therein, which take into account any dividend income, are recognized in the consolidated statements of profit or loss and other comprehensive income.

3.10.1.1 Non-current financial assets

The Company holds investments in non-current financial assets, which based on IFRS 9, are designated as financial assets at fair value through profit or loss, which qualify for level 3 fair value measurement based on current market prices. If the market for a financial asset is not active (and for unlisted securities), the Company established fair value by using valuation techniques.

3.10.1.2 Current financial assets

Current financial assets include financial assets measured at fair value through profit or loss and comprise of money market funds and term accounts that have an initial maturity equal or less than 12 months, but exceeding 3 months.

3.10.1.3 Cash equivalents measured at fair value through profit or loss

Cash equivalents measured at fair value through profit or loss may comprise of term accounts that have an initial maturity of equal or less than 3 months and money market funds that are readily convertible to cash and are subject to insignificant risk of changes in value. These financial assets are used by the Company in the management of the short-term commitments.

Financial assets at amortized cost

3.10.1.4. Receivables

Trade and other receivables are designated as financial assets measured at amortized cost. They are initially measured either at fair value or at transaction price, in the absence of a significant financing component.

All receivables are subsequently measured at amortized cost, which generally corresponds to nominal value less expected credit loss provision.

Receivables mainly comprise trade and other receivables and current and non-current research and development incentive receivables. These research and development incentive receivables relate to refunds resulting from research and development incentives on research and development expenses in Belgium and are credited to the consolidated statements of profit or loss and other comprehensive income under the line “Other operating income” when the relevant expenditure has been incurred and there is a reasonable assurance that the research and development incentives are receivable.

3.10.1.5 Cash

Cash are financial assets measured at amortized cost and comprise of cash balances and savings accounts.

3.10.1.6 Cash equivalents measured at amortized costs

Cash equivalents measured at amortized cost comprise of term accounts that have an initial maturity of less than 3 months that are subject to an insignificant risk of changes in values. The financial assets are used by the Company in the management of short-term commitments.

Cash and cash equivalents exclude restricted cash, which is presented in the consolidated statements of financial position under the line “Restricted cash – current” and “Other non-current assets”.

3.10.2 Financial Liabilities

Financial liabilities are initially measured at their transaction price. Subsequent to initial recognition, financial liabilities are measured at amortized cost.

Financial liabilities mainly comprise of trade and other liabilities.

Trade and other liabilities are comprised of liabilities that are due less than one year from the balance sheet date and are in general not interest bearing and settled on an ongoing basis during the financial year. They also include accrued expense related to the Company's research and development costs.

3.11 Shareholder's equity

An equity instrument is any contract that evidences a residual interest in the assets of an entity after deducting all of its liabilities. Equity instruments issued by the Company are recognized at the proceeds received, net of direct issue costs.

The Company has never distributed any dividends to its shareholders. As of December 31, 2020, no profits were available for distribution.

3.12 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 an outflow of resources embodying economic benefits will be required to settle the obligations, 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).

3.13 Retirement benefits

3.13.1 Defined contribution plans

Contributions to defined contribution pension plans are recognized as an expense in the consolidated statements of profit or loss and other comprehensive income as incurred.

3.13.2 Defined benefit plans

For defined retirement benefit plans, the cost of providing benefits is determined using the projected unit credit method, with actual valuations being carried out at the end of each annual reporting period. Remeasurement, comprising actuarial gains and losses, the effect of the changes to the asset ceiling (if applicable) and the return on plan assets (excluding interest), is reflected immediately in the consolidated statements of financial position with a charge or credit recognized in other comprehensive income in the period in which they occur. Remeasurement recognized in other comprehensive income is reflected immediately in retained earings and will not be reclassified to profit or loss. Past service cost is recognized in the consolidated statements of profit or loss and other comprehensive income in the period of a plan amendment. Net interest is calculated by applying the discount rate at the beginning of the period to the net defined benefit liability or asset.

Defined benefit costs are categorized as follows: service costs (including current service cost, past service cost, as well as gains and losses on curtailments and settlements), net interest expenses or income, and remeasurement.

The retirement benefit obligation recognized in the consolidated statements of financial position represents the actual deficit or surplus in the defined benefit plans. Any surplus resulting from this calculation is limited to the present value of any economic benefits available in the form of refunds from the plans or a reduction in future contribution to the plans. A liability for a termination benefit is recognized at the earlier of when we can no longer withdraw the offer of the termination benefit and when we recognize any related restructuring costs.

3.14 Short-term employee benefits

Short-term employee benefits include payables and accruals for salaries and bonuses to be paid to the employees of the Company. They are recognized as expenses for the period in which employees perform the corresponding services.

3.15 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 acceptance date.

The fair value determined at the acceptance date of the equity-settled share-based payments is expensed on a straight-line basis over the vesting period, based on the Company's estimate of equity instruments that will eventually vest, with a corresponding increase in equity. At the end of each reporting period, the Company revises its estimate of the number of equity instruments expected to vest. The impact of the revision of the original estimates, if any, is recognized in the consolidated statements of profit or loss and other comprehensive income such that the cumulative expense reflects the revised estimate, with a corresponding adjustment to the equity-settled share-based payment reserve.

3.16 Deferred revenue

Current and non-current deferred revenue relates to cash received from collaboration & license agreements 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.

3.17 Income taxes

Income tax in the consolidated statements of profit or loss and other comprehensive income represents the sum of the current tax and deferred tax.

The current tax 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 as it excludes items of income or expense that are taxable or deductible in other years and items that are never taxable or deductible. The Company's liability for current tax is calculated using tax rates that have been enacted or substantively enacted by the end of the reporting period.

Deferred tax is recognized on temporary differences between the carrying amounts of assets and liabilities in the consolidated financial statements and the corresponding tax basis used in the computation of taxable profit. Deferred tax assets are recognized to the extent that it is probable that future taxable profits will be available against which those deductible temporary differences can be utilized. 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 offset if there is a legally enforceable right to offset current tax liabilities and assets, and they relate to income taxes levied by the same tax authority on the same taxable entity, or on different taxable entities which intend either to settle current tax liabilities and assets on a net basis, or to realize the assets and settle the liabilities simultaneously.

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.

3.18 Revenue and other operating income recognition

3.18.1 Collaborations and license agreements

Revenues to date have consisted principally of milestones, license fees, non-refundable upfront fees and research and development service fees in connection with collaboration and license agreements.

The Company recognizes revenue when the customer obtains control of promised goods or services, in an amount that reflects the consideration that the Company expects to receive in exchange for those goods and services. In order to determine revenue recognition for agreements that the Company determines to be in the scope of IFRS 15, following five steps are performed:

1. *Identify the contracts*

In its current collaboration and license agreements, the Company is mainly licensing its intellectual property and/or providing research and development services, which might include a cost sharing mechanism and/or in the future, selling its products to collaborative partner entities. Revenue is generated through these arrangements via upfront payments, milestone payments based on clinical and regulatory criteria, research and development service fees and future sales based milestones and sales based royalties. In some cases the collaboration and license agreements also include an equity subscription component. If this is the case, the Company analyses if the criteria to combine contracts, as set out by IFRS 15, are met.

2. Identify performance obligations

Depending on the type of the agreement, there can be one or more distinct performance obligations under IFRS 15. This is based on an assessment of whether the promises in an agreement are capable of being distinct and are distinct from the other promises to transfer goods and/or services in the context of the contract.

The Company has assessed that there is one single performance obligation in our material ongoing collaboration and license agreements, being the transfer of a license combined with performance of research and development services.

This is because the Company considers the performance obligations cannot be distinct in the context of the contract as the license has no stand-alone value without the Company being further involved in the research and development collaboration and that there is interdependence between the license and the research and development services to be provided.

3. Determine the transaction price

Our material ongoing collaboration and license agreements include non-refundable upfront payments or license fees; milestone payments, the receipt of which is dependent upon the achievement of certain clinical, regulatory or commercial milestones; royalties on sales and research and development service fees.

3.1 Non-refundable upfront payments or license fees

If the license to the Company’s intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable upfront fees allocated to this license at the point in time the license is transferred to the customer and the customer has the right to use the license.

For all our material ongoing collaboration and license agreements, the Company considers the performance obligations related to the transfer of the license as not distinct from the other promises to transfer goods and/or services; the Company utilizes judgement to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time. If over time, revenue is then recognized based on a pattern that best reflects the transfer of control of the service to the customer.

3.2 Milestone payments other than sales based milestones

A milestone payment, being a variable consideration, is only included in the transaction price to the extent it is highly probable that a significant reversal in the amount of cumulative revenue recognition will not occur when the uncertainty associated with the variable consideration is subsequently resolved. The Company estimates the amount to be included in the transaction price upon achievement of the milestone event. The transaction price is then allocated to each performance obligation on a stand-alone selling price

basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each reporting period, the Company re-evaluates the probability of achievement of such milestones and any related constraint, and, if necessary, adjusts the estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue and earnings in the period of adjustment.

3.3 Research and development service fees

Our material ongoing collaboration and license agreements may include reimbursement or cost sharing for research and development services. R&D services are performed and satisfied over time given that the customer simultaneously receives and consumes the benefits provided by us. Such costs reimbursements received are recognized in revenues when costs are incurred and agreed by the parties.

3.4 Sales based milestone payments and royalties

Our material ongoing collaboration and license agreements include sales based royalties, including commercial milestone payments based on the level of sales, and the license has been deemed to be the predominant item to which the royalties and commercial milestone payments relate. Related revenue is recognized as the subsequent underlying sales occur.

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 basis. As our ongoing license and collaboration arrangements only contain one single performance obligation, the transaction price is entirely allocated to this single performance obligation.

5. Recognize revenue

Revenue is recognized when the customer obtains control of the goods and/or services as provided in the collaboration and license agreements. The control can be transferred over time or at a point in time – which results in the recognition of revenue over time or at a point in time.

As our ongoing license and collaboration arrangements only contain one single performance obligation which is, as the customer simultaneously receive the benefits provided by the Company’s performance, satisfied over time, the Company recognizes revenue over time.

The recognition of revenue over time is based on a pattern that best reflects the satisfaction of the related performance obligation, applying the input method. The input method estimates the satisfaction of the performance obligation as the percentage of total collaboration costs that are completed each period compared to the total estimated collaboration costs.

Research and development service fees are recognized as revenue when costs are incurred and agreed by the parties as the Company is acting as a principal in the scope of its stake of the research and development activities of its ongoing collaboration and license agreements.

3.18.2 Grants, research and development incentives and payroll tax rebates

Because it carries out extensive research and development activities, the Company benefits from various grants, research and development incentives and payroll tax rebates from certain governmental agencies. These grants, research and development incentives and payroll tax rebates generally aim to partly reimburse approved expenditures incurred in research and development efforts of the Company and are credited to the consolidated statements of profit and loss and other comprehensive income, under the line “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.

3.19 Segment reporting

Segment results include revenue and expenses directly attributable to a segment and the relevant portion of revenue and expenses that can be allocated on a reasonable basis to a segment. Segment assets and liabilities comprise those operating assets and liabilities that are directly attributable to the segment or can be allocated to the segment on a reasonable basis. Segment assets and liabilities do not include income tax items.

The Company manages its activities and operates as one business unit which is reflected in its organizational structure and internal reporting. The Company does not distinguish in its internal reporting different segments, neither business nor geographical segments. The chief operating decision-maker is the Board of Directors.

4. Critical accounting judgements and key sources of estimation uncertainty

In the application of the Company's accounting policies, which are described above, the Company is required to make judgments, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period or in the period of the revision and future periods if the revision affects both current and future periods.

The following areas are areas where key assumptions concerning the future, and other key sources of estimation uncertainty at the end of the reporting period, have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year.

Critical estimates in applying accounting policies

Research and development cost accruals

The Company recognizes costs of €52.6 million, as specified in note 15 to the financial statements, incurred for clinical trial activities and manufacturing of drug products, as research and development expenses based on an evaluation of its vendors' progress toward completion of specific tasks. Timing of payment may differ significantly from the period in which the costs are recognized as expense, resulting in clinical trial accruals recognized within "Trade and other payables" in the consolidated statements of financial position.

Quantification of the research progress and the translation of the progress to these accruals requires estimates, because the progress is not directly observable. In estimating the vendors' progress toward completion of specific tasks, the Company therefore uses non-financial data such as patient enrollment, clinical site activations and vendor information of actual costs incurred. This data is obtained through reports from or discussions with Company personnel and outside service providers as to the progress or state of completion of trials, or the completion of services. Costs are expensed over the service period the services are provided. Costs for services provided that have not yet been paid are recognized as accrued expenses. Research and development cost accruals directly impact the revenue recognized, given the satisfaction of the single performance obligation is measured using the input method.

5. Intangible assets

(in thousands of €)	Acquired In-Process R&D	Software & databases	Other Intangibles	Total
Cost				
On January 1, 2018	€ **—**	€ **99**	€ **—**	€ **99**
Additions	—	62	—	62
Disposals	—	(2)	—	(2)
On December 31, 2018	**—**	**159**	**—**	**159**
Additions	39,881	262	—	40,143
On December 31, 2019	**39,881**	**421**	**—**	**40,302**
Additions	13,236	2,503	80,725	96,464
On December 31, 2020	€ **53,117**	€ **2,924**	€ **80,725**	€ **136,766**
Amortization and impairment				
On January 1, 2018	€ **—**	€ **(86)**	€ **—**	€ **(86)**
Amortization	—	(19)	—	(19)
Disposals	—	2	—	2
On December 31, 2018	**—**	**(103)**	**—**	**(103)**
Amortization	—	(38)	—	(38)
On December 31, 2019	**—**	**(141)**	**—**	**(141)**
Amortization	—	(215)	—	(215)
On December 31, 2020	€ **—**	€ **(356)**	€ **—**	€ **(356)**
Carrying Amount				
On December 31, 2018	€ —	€ 56	€ —	€ 56
On December 31, 2019	39,881	280	—	40,161
On December 31, 2020	€ 53,117	€ 2,568	€ 80,725	€ 136,410

The Company performed an annual impairment review on the intangible assets not yet available for use. This review did not result in the recognition of an impairment charge.

As of December 31, 2020, there are no commitments to acquire additional intangible assets, except as set forth in note 29. No intangible assets are pledged as security for liabilities nor are there any intangible assets whose title is restricted.

6. Property, plant and equipment

(in thousands of €)	IT, office and lab equipment	Right-of-use assets Buildings	Right-of-use assets Vehicles	Leasehold improvements	Lease equipment (1)	Total
Cost						
On January 1, 2018	**€ 2,389**	**€ —**	**€ —**	**€ —**	**€ —**	**€ 2,389**
Additions	370	—	—	—	253	623
Disposals	(47)	—	—	—	—	(46)
On December 31, 2018	**2,712**	**—**	**—**	**—**	**253**	**2,965**
Adoption of IFRS 16	—	2,338	452	—	—	2,790
Additions	765	4,553	525	808	29	6,680
On December 31, 2019	**3,477**	**6,891**	**977**	**808**	**282**	**12,435**
Additions	597	2,718	875	352	—	4,542
Disposals	(90)	—	—	—	—	(90)
On December 31, 2020	**€ 3,984**	**€ 9,609**	**€ 1,852**	**€ 1,160**	**€ 282**	**€ 16,887**
Depreciation and impairment						
On January 1, 2018	**€ (1,713)**	**€ —**	**€ —**	**€ —**	**€ —**	**€ (1,713)**
Depreciation	(463)	—	—	—	(11)	(474)
Disposals	46	—	—	—	—	46
On December 31, 2018	**(2,130)**	**—**	**—**	**—**	**(11)**	**(2,141)**
Depreciation	(460)	(1,315)	(233)	(92)	(28)	(2,128)
On December 31, 2019	**(2,590)**	**(1,315)**	**(233)**	**(92)**	**(39)**	**(4,269)**
Depreciation	(468)	(1,981)	(386)	(351)	(28)	(3,214)
Disposals	90	—	—	—	—	90
On December 31, 2020	**€ (2,968)**	**€ (3,296)**	**€ (619)**	**€ (443)**	**€ (67)**	**€ (7,393)**
Carrying Amount						
On December 31, 2018	€ 582	€ —	€ —	€ —	€ 242	€ 824
On December 31, 2019	887	5,576	744	716	243	8,167
On December 31, 2020	€ 1,016	€ 6,313	€ 1,233	€ 717	€ 215	€ 9,494

(1) The Company has elected not to reassess whether a contract is, or contains, a lease at the date of initial application. Instead, for contracts entered into before the transition date, the Company relied on its assessment made applying IAS 17 and IFRIC 4 *Determining whether an Arrangement contains a Lease.*

There are no commitments to acquire property, plant and equipment. Furthermore, no items of property, plant and equipment are pledged. See note 22 for information for leases where the Company is a lessee.

7. Other non-current assets

Other non-current assets consisted of non-current restricted cash and financial assets held at fair value through profit or loss.

	Year Ended December 31,		
(in thousands of €)	2020	2019	2018
Restricted Cash - non-current	€ 1,243	€ 630	€ 251
Non-current financial assets held at fair value through profit or loss	5,140	2,596	1
Total other non-current assets	**€ 6,383**	**€ 3,226**	**€ 252**

Non-current restricted cash on December 31, 2020 was mainly composed of deposit guarantees paid under the lease agreements for the laboratory and offices of the Company.

Non-current financial assets held at fair value through profit or loss is comprised of the profit share in AgomAb Therapeutics NV. In March 2019, the Company entered into a license agreement with AgomAb Therapeutics NV for the use of HGF-mimetic SIMPLE Antibodies™, developed under the Company's Innovative Access Program. In exchange for granting this license, the Company received a profit share in AgomAb Therapeutics NV.

In March 2019, AgomAb Therapeutics NV secured €21.0 million in a Series A financing round. The Company used the post-money valuation of this Series A financing round and the number of outstanding shares in determining the fair value of the profit sharing instrument and the revaluation of this instrument. This instrument is designated as financial asset held at fair value through profit or loss which qualify for level 3 fair value measurement currently based upon the Series A financing round valuation.

Fair value changes on non-current financial assets with fair value through profit of loss are recognized in the consolidated statements of profit and loss and other comprehensive income in line "Change in fair value on non-current financials assets".

The table below illustrates these non-current financials assets at fair value through profit or loss as of December 31, 2020, 2019 and 2018.

	Year Ended December 31,		
(in thousands of €)	**2020**	**2019**	**2018**
Cost at January 1	**€ 1,499**	**€ —**	**€ —**
Acquisitions of the year	—	1,499	—
Cost at December 31	**€ 1,499**	**€ 1,499**	**€ —**
Fair value adjustments at January 1	**€ 1,097**	**€ —**	**€ —**
Fair value adjustment of the year	2,544	1,097	—
Fair value adjustment at December 31	**€ 3,641**	**€ 1,097**	**€ —**
Net book value at December 31	**€ 5,140**	**€ 2,596**	**€ —**

8. Deferred Taxes

The amount of deferred tax assets and liability by type of temporary difference can be detailed as follows:

	Year Ended December 31, 2020		
(in thousands of €)	**Assets**	**Liabilities**	**Net**
Deferred tax assets / (liabilities)			
Accruals and allowances	€ 1,750	€ —	€ 1,750
Income tax benefit from excess tax deductions related to share-based payments	10,889	—	10,889
Property, plant and equipment	—	(136)	(136)
Intangible assets	—	(1,460)	(1,460)
Netting by taxable entity	(384)	384	—
Net deferred tax assets / (liabilities)	**€ 12,255**	**€ (1,212)**	**€ 11,043**

The change in net deferred taxes recorded in the consolidated statement of financial position can be detailed as follows:

(in thousands of €)	Deferred tax assets	Deferred tax liabilities
Balance at January 1, 2020	**€ —**	**€ —**
Recognized in profit or loss	7,311	(1,212)
Recognized in equity	5,073	—
Effects of change in foreign exchange rate	(129)	—
Balance at December 31, 2020	**€ 12,255**	**€ (1,212)**

9. Inventories

	Year Ended December 31,		
(in thousands of €)	2020	2019	2018
Raw materials and consumables	€ 15,164	€ —	€ —
Inventories in process	5,368	—	—
Finished goods	—	—	—
Total inventories	**€ 20,532**	**€ —**	**€ —**

On December 31, 2020, inventories amounted to €20.5 million and related to pre-launch efgartigimod-inventory, capitalized subsequent to the announcement of the topline data from the pivotal ADAPT trial of efgartigimod. As of December 31, 2020, no inventory write-downs were recorded.

10. Trade and other receivables

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

	Year Ended December 31,		
(in thousands of €)	2020	2019	2018
Trade receivable	€ 234	€ 22,580	€ 214
Interest receivable	809	2,081	556
Other receivable	4,644	3,454	2,116
	€ 5,687	**€ 28,115**	**€ 2,886**

The carrying amounts of trade and other receivables approximate their respective fair values.

Other receivables mainly included accrued income from subsidy projects and VAT receivables.

Please also refer to note 26 for more information on the financial instruments.

11. Financial assets — current

These current financial assets relate to term accounts with an initial maturity longer than 3 months but less than 12 months and money market funds that do not qualify as cash equivalents.

	Year Ended December 31,		
(in thousands of €)	2020	2019	2018
Money market funds	€ 106,177	€ 715,773	€ 283,529
Term accounts	529,182	288,766	—
	€ 635,359	**€ 1,004,539**	**€ 283,529**

On December 31, 2020, the current financial assets included $717.1 million held in USD, which could generate a foreign currency exchange gain or loss in our financial results in accordance with the fluctuations of the EUR/USD exchange rate as the Company's functional currency is EUR.

Please also refer to note 26 for more information on the financial instruments.

12. Cash and cash equivalents

(in thousands of €)	Year Ended December 31, 2020	2019	2018
Money market funds	€ 699,447	€ —	€ —
Term accounts	50,001	227,551	217,451
Cash and bank balances	242,161	103,731	63,589
	€ 991,609	**€ 331,282**	**€ 281,040**

Cash and cash equivalents may comprise of cash and bank balances, saving accounts, term accounts with an original maturity not exceeding 3 months and money market funds that are readily convertible to cash and are subject to an insignificant risk of changes in value.

Cash positions are invested with preferred financial partners, which are mostly considered to be high quality financial institutions with sound credit ratings to reduce credit risk.

On December 31, 2020, the cash and cash equivalents included $576.1 million held in USD, which could generate a foreign currency exchange gain or loss in our financial results in accordance with the fluctuations of the EUR/USD exchange rate as the Company's functional currency is EUR.

Please also refer to note 26 for more information on the financial instruments.

13. Share capital and share premium

On December 31, 2020, the Company's share capital was represented by 47,571,283 shares. All shares were issued, fully paid up and of the same class. The table below summarizes our capital increases, as a result of offerings and the exercise of stock options under the Company's Employee Stock Option Plan.

Roll forward of number of shares outstanding:

Number of shares outstanding on January 1, 2018	**32,180,641**
Exercise of stock options	319,671
U.S. third public offering on Nasdaq on September 18, 2018	3,475,000
Number of shares outstanding on December 31, 2018	**35,975,312**
Exercise of stock options	419,317
Share subscription from Johnson & Johnson Innovation Inc.	1,766,899
Global public offering on Euronext and Nasdaq on November 7, 2019	4,000,000
Over-allotment option exercised by underwriters on November 8, 2019	600,000
Number of shares outstanding on December 31, 2019	**42,761,528**
Exercise of stock options	602,463
Global public offering in Euronext and Nasdaq on May 28, 2020	3,658,515
Over-allotment option exercised by underwriters on May 29, 2020	548,777
Number of shares outstanding on December 31, 2020	**47,571,283**

On May 12, 2020 at the annual general meeting, the shareholders of the Company approved the authorization to the Board to issue:

- A maximum of 10% of the then-outstanding share capital for a period of 18 months
- A maximum of 10% of the then-outstanding share capital for a period till December 31, 2020

On December 31, 2020, an amount of €427,974.7, represented by 4,279,747 shares, still remained available under the authorized capital .

14. 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 stock options to purchase ordinary shares at an exercise price as mentioned below per ordinary share.

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. 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 regular stock options granted vest, in principle, as follows:

- 1/3rd of the regular 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 regular 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.

The sign-on stock options granted vest, in principle, as follows:

- 1/4rd of the stock options granted will vest on the first anniversary of the granting of the stock options, and
- 1/36th of the remaining 3/4th of the stock options granted will vest on the last day of each of the 36 months following the month of the first anniversary of the granting of the stock options.

In order to prefinance the taxes that are paid upon the grant of stock options, Belgian employees have the ability, in exchange for the taxes due upon the grant of the stock options, to transfer the economic benefits related to part of those stock options to a third party. As of December 31, 2020, the economic benefits of 126,982 stock options, for which accelerated vesting applies, were transferred to a third party.

No other conditions are attached to the stock options.

The following share-based payment arrangements were in existence during the current and prior years and which are exercisable at the end of each period presented:

Expiry date	Exercise price per stock options (in €)	Outstanding stock options on December 31, 2020	2019	2018
2020	€ 3.95	—	7,210	18,200
2023	2.44	165,693	211,769	294,400
2024	2.44	100,086	102,696	144,703
2024	3.95	6,238	6,238	6,895
2024	7.17	294,167	335,067	407,061
2025	11.44	21,500	39,000	39,000
2025	10.34	950	3,000	3,000
2025	9.47	114,232	185,832	226,323
2026	11.38	45,000	45,000	50,415
2026	11.47	127,252	219,791	257,616
2026	14.13	176,426	258,746	315,102
2027	18.41	102,479	108,613	114,019
2027	21.17	460,701	565,798	628,292
2023	80.82	85,077	94,100	94,600
2028	80.82	49,532	73,100	75,450
2023	86.32	325,661	366,260	369,760
2028	86.32	381,317	402,714	491,815
2024	113.49	111,174	111,690	—
2029	113.49	163,410	299,560	—
2024	135.75	195,452	204,430	—
2029	135.75	692,914	717,455	—
2025	119.53	19,000	—	—
2030	119.53	123,700	—	—
2025	196.15	131,770	—	—
2030	196.15	325,150	—	—
2025	200.22	32,100	—	—
2030	200.22	175,200	—	—
2030	247.60	31,200	—	—
2025/2030 (1)	€ 247.60	908,362	—	—
		5,365,743	**4,358,069**	**3,536,651**

(1) In December 2020, the Company granted options for which the beneficiaries had a 60-day period to choose between a contractual term of five or ten years.

	2020		2019		2018	
	Number of stock options	Weighted average exercise price	Number of stock options	Weighted average exercise price	Number of stock options	Weighted average exercise price
Outstanding at January 1	4,358,069	€ 63.75	**3,536,651**	€ 33.42	**2,862,216**	€ 11.54
Granted	1,797,652	217.35	1,365,172	128.52	1,040,475	85.37
Exercised	(602,463)	31.67	(419,317)	11.35	(319,671)	7.02
Forfeited	(187,515)	139.34	(124,437)	88.92	(46,369)	30.44
Outstanding at December 31	**5,365,743**	116.43	**4,358,069**	63.75	**3,536,651**	33.42
Exercisable at December 31	**2,833,680**	€ 53.17	**2,203,476**	€ 22.59	**1,859,315**	€ 9.62

The weighted average share price at the date of exercise of options exercised during the year ended December 31, 2020 was €207.43, compared to €110.99 during the year ended December 31, 2019 and €66.93 during the year ended December 31, 2018. The weighted average remaining contractual life of the stock options outstanding amounted to 7.08 years on December 31, 2020 compared to 7.27 years on December 31, 2019 and 7.82

years on December 31, 2018. The table below shows the weighted average remaining contractual life for each range of exercise price:

Exercise price (in €)	Outstanding on December 31, 2020	Weighted average remaining contractual life (in years)
2.44 - 3.95	272,017	3.08
7.17 - 9.47	408,399	4.24
10.34 - 14.13	371,128	5.62
18.41 - 21.17	563,180	6.87
80.82 - 86.32	841,587	5.46
113.49 - 135.75	1,305,650	7.64
196.15 - 247.60	1,603,782	9.29

The fair market value of the stock options has been determined based on the Black and Scholes model using the following unobservable assumptions:

- The expected volatility, determined on the basis of the implied volatility of the share price over the expected life of the option.
- The expected option life, calculated as the estimated duration until exercise, taking into account the specific features of the plans.

Below is an overview of the parameters used in relation to the determination of the fair value of the grants during 2020:

Stock options granted in	April 2020	June 2020	Oct 2020	Dec 2020
Number of options granted	142,700	550,090	196,500	908,362
Fair value of options (in EUR)	€ 62.31 - 120.63	€ 68.01 - 105.65	€ 74.24 - 127.68	€ 119.26 - 124.67
Share price (in EUR)	€ 126.50 - 205.60	€ 183.20 - 229.20	€ 209.00 - 239.20	€ 247.4
Exercise price (in EUR)	€ 119.53	€ 196.15	€ 200.22	€ 247.6
Expected volatility	44.44 - 64.77 %	43.46 - 52.19 %	44.17 - 52.71 %	53.00 - 53.51 %
Expected option life (in years)	4 - 6.68	4 - 6.68	4 - 6.68	6.15 - 6.68 (1)
Risk-free interest rate	(0.32) - (0.18) %	(0.43) - (0.28) %	(0.51) - (0.34) %	(0.42) - (0.40) %
Expected dividends	— %	— %	— %	— %

(1) In December 2020, the Company granted a total of 908,362 stock options. The beneficiary can choose between a contractual term of five or ten years. The expected option life ranges between 6.15 and 6.68 years. This estimate will be reassessed once the acceptance period of 60 days has passed and the beneficiaries will have made a choice between a contractual term of five or ten years. The total fair value of the grant would range from €84.5 million (100% of the stock options with a contractual term of five years) to €110.3 million (100% of the stock options with a conctractual term of ten years).

Below is an overview of the parameters used in relation to the determination of the fair value of grants during 2019:

Stock options granted in	June 2019	Nov 2019	Dec 2019
Number of options granted	423,487	19,800	921,885
Average Fair value of options (in EUR)	€ 63.45	€ 57.69	€ 41.40 - 66.39
Share price (in EUR)	€ 123.20	€ 126.40	€ 130.1 - 150.7
Exercise price (in EUR)	€ 113.49	€ 113.49	€ 135.75
Expected volatility	45.25 %	44.14	43.80 - 44.11 %
Average Expected option life (in years)	8.59	6.50	4 - 6.5
Risk-free interest rate	0.07 %	(0.05)	(0.57) - (0.24) %
Expected dividends	— %	—	— %

Below is an overview of the parameter used in relation to the determination of the fair value of grants during 2018:

Stock options granted in	June 2018	Dec 2018
Number of options granted	178,900	861,575
Fair value of options (in EUR)	€ 32.12	€ 39.85
Share price (in EUR)	€ 72.00	€ 82.20
Exercise price (in EUR)	€ 80.82	€ 86.32
Expected volatility	45.50 %	46.19 %
Average expected option life (in years)	7.36	7.83
Risk-free interest rate	0.72 %	0.77 %
Expected dividends	— %	— %

The total share-based payment expense recognized in the consolidated statement of comprehensive income totaled €84.5 million for the year ended December 31, 2020, compared to €39.6 for the year ended December 31, 2019 and €19.2 million for the year ended December 31, 2018.

15. Trade and other payables

	Year Ended December 31,		
(in thousands of €)	2020	2019	2018
Trade payables	€ 168,140	€ 58,429	€ 24,152
Short-term employee benefits	56,122	26,872	12,920
	€ 224,262	**€ 85,301**	**€ 37,072**

Trade payables correspond primarily to clinical and manufacturing activities and include accrued expenses related to these activities.

As of December 31, 2020, the trade payables include accruals amounting to €52.6 million related to accruals from clinical manufacturing organizations for the manufacturing of drug products and from clinical research organisations.

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

16. Revenue

The following table summarizes details of revenues for the year ended December 31, 2020, 2019 and 2018 by collaboration agreement and by category of revenue: upfront payments, milestone payments and research and development service fees.

(in thousands of €)	Year Ended December 31, 2020	2019	2018
Upfront payments	**€ 30,348**	**€ 22,360**	**€ 8,635**
Janssen	29,818	20,056	—
AbbVie	497	761	8,455
Agomab	—	1,499	—
Other	33	44	180
Milestone payments	**3,021**	**28,085**	**11,440**
Janssen	2,333	1,569	—
AbbVie	671	26,494	10,510
Other	17	22	930
Research and development service fees	**3,056**	**19,338**	**1,407**
Janssen	2,807	18,968	—
Other	249	370	1,407
Total revenue	**€ 36,425**	**€ 69,783**	**€ 21,482**

For the years ended December 31, 2020, 2019 and 2018, the majority of the revenue was generated under the agreements with Janssen and AbbVie, each as described below.

The table below summarizes the changes in deferred revenue – current and deferred revenue -non-current for the year ended December 31, 2020, 2019 and 2018.

(in thousands of €)	Janssen	AbbVie	Other	Total
On January 1, 2018	**€ —**	**€ 12,376**	**€ 344**	**€ 12,720**
Received				
Milestone	—	8,633	883	9,516
Revenue recognition				
Upfront	—	(8,455)	(180)	(8,635)
Milestone	—	(10,510)	(930)	(11,440)
On December 31, 2018	**—**	**2,045**	**116**	**2,161**
Received				
Upfront	288,060			288,060
Milestone	22,535	26,560		49,095
Revenue recognition				
Upfront	(20,056)	(761)	(44)	(20,861)
Milestone	(1,569)	(26,494)	(22)	(28,085)
On December 31, 2019	**288,971**	**1,350**	**50**	**290,371**
Received				
Milestone	—	—	—	—
Revenue recognition				
Upfront	(29,818)	(497)	(33)	(30,348)
Milestone	(2,333)	(671)	(17)	(3,021)
On December 31, 2020	**€ 256,819**	**€ 182**	**€ (0)**	**€ 257,001**

Below are summaries of the key collaborations.

AbbVie

In April 2016, the Company entered into a collaboration agreement with AbbVie S.À.R.L. (AbbVie) to develop and commercialize ARGX-115 (ABBV-151). Under the terms of the collaboration agreement, the Company

was responsible for conducting and funding all ARGX-115 (ABBV-151) research and development activities up to completion of IND enabling studies.

The Company granted AbbVie an exclusive option, for a specified period following completion of IND enabling studies, to obtain a worldwide, exclusive license to the ARGX-115 (ABBV-151) program to develop and commercialize products. The Company received an upfront, nonrefundable, non-creditable payment of $40 million (€35.1 million as of the date the payment was received) from AbbVie for the exclusive option to license ARGX-115 (ABBV-151). The Company achieved two preclinical milestones, each of which triggered a $10.0 million payment (€8.9 million based on the exchange rate in effect as of the date the first milestone payment was received, and €8.7 million based on the exchange rate in effect as of the date the second milestone payment was received).

In August 2018, AbbVie exercised its option and has assumed certain development obligations, being solely responsible for all research, development and regulatory costs relating to ARGX-115 based products. In March 2019, the Company achieved the first development milestone upon initiation of a first-in-human clinical trial, triggering a $30.0 million payment. Subject to the continuing progress of ARGX-115 (ABBV-151) by AbbVie, the Company is eligible to receive development, regulatory and commercial milestone payments in aggregate amounts of up to $110 million, $190 million and $325 million, respectively, as well as tiered royalties on sales at percentages ranging from the mid-single digits to the lower teens, subject to customary reductions.

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

With regard to its collaboration with AbbVie, the Company concluded as follows:

- There is one single performance obligation under IFRS 15, that being the transfer of a license combined with performance of research and development activities. The Company concluded that the license is not distinct in the context of the contract.
- The transaction price of these two agreements is currently composed of a fixed part, that being an upfront license fee, and a variable part, being milestone payments and cost reimbursements of research and development activities delivered. Milestone payments are only included in the transaction price to the extent it is highly probable that a significant reversal in the amount of cumulative revenue recognition will not occur when the uncertainty associate with the variable consideration is subsequently resolved. We estimate the amount to be included in the transaction price upon achievement of the milestone event. Sales-based milestones and sales-based royalties are a part of the Company's arrangements but are not yet included in its revenues.
- The transaction price has been allocated to the single performance obligation and revenues have been recognized over the estimated service period based on a pattern that reflects the transfer of the license and progress to complete satisfaction of the research and development activities. This is because we considered that there is a transformational relationship between the license and the research and development activities to be delivered.
- The Company has chosen an input model to measure the satisfaction of the single performance obligation that considers percentage of costs incurred for these programs that are completed each period (percentage of completion method).
- Cost reimbursements received are recognized in revenues when costs are incurred and agreed by the parties, as the Company is acting as a principal in the scope of its stake of the research and development activities of its ongoing license and collaboration agreements.

Janssen

In December 2018, the Company entered into a collaboration agreement with Cilag GmbH International, an affiliate of Janssen, to jointly develop and commercialize cusatuzumab. The Company has granted Janssen a license to the cusatuzumab program to develop, manufacture and commercialize products. For the U.S., the granted

commercialization license is co-exclusive with argenx, while outside the U.S., the granted license is exclusive. Janssen and argenx will assume certain development obligations, and will be jointly responsible for all research, development and regulatory costs relating to the products. argenx will be eligible to receive potentially up to $1.3 billion in development, regulatory and sales milestones, in addition to tiered royalties, ranging from the low double digits to the high teens. Janssen will be responsible for commercialization worldwide. argenx retains the option to participate in commercialization efforts in the US, where the companies have agreed to share royalties on a 50/50 basis, and outside the U.S., Janssen will pay sales royalties ranging from the low double digits to the high teens to argenx.

Under the terms of the agreement, Janssen committed to an upfront payment of $500 million consisting of a license payment of $300 million and a $200 million equity investment in the Company by subscribing to 1,766,899 new shares at a price of €100.02 per share, including an issuance premium. The agreement became effective in January 2019 following expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act. In December 2019, the Company achieved the first development milestone, triggering a $25.0 million payment.

With regard to this collaboration with Janssen, the Company concluded as follows:

- There is one single performance obligation under IFRS 15, that being the transfer of a license combined with performance of research and development activities. The Company concluded that the license is not distinct in the context of the contract.

- The Company concluded that the share premium that Janssen paid above the closing price on the day of entering into the investment agreement (being December 2, 2018) was paid because of the existing obligations to deliver development services under the terms of the collaboration agreement, and is therefore to be considered to be part of the overall consideration received.

- The transaction price of these two agreements is currently composed of a fixed part, that being an upfront license fee, and a variable part, being milestone payments and cost reimbursements of research and development activities delivered. Milestone payments are only included in the transaction price to the extent it is highly probable that a significant reversal in the amount of cumulative revenue recognition will not occur when the uncertainty associate with the variable consideration is subsequently resolved. We estimate the amount to be included in the transaction price upon achievement of the milestone event. Sales-based milestones and sales-based royalties are a part of the Company’s arrangements but are not yet included in its revenues.

- The transaction price has been allocated to the single performance obligation and revenues have been recognized over the estimated service period based on a pattern that reflects the transfer of the license and progress to complete satisfaction of the research and development activities. This is because we considered that there is a transformational relationship between the license and the research and development activities to be delivered.
- The Company has chosen an input model to measure the satisfaction of the single performance obligation that considers percentage of costs incurred for these programs that are completed each period (percentage of completion method).
- Cost reimbursements received are recognized in revenues when costs are incurred and agreed by the parties, as the Company is acting as a principal in the scope of its stake of the research and development activities of its ongoing license and collaboration agreements.

17. Other operating income

	Year Ended December 31,		
(in thousands of €)	**2020**	**2019**	**2018**
Grants	€ 1,226	€ 2,289	€ 1,842
Research and development incentives	8,875	4,818	2,151
Payroll tax rebates	8,008	5,694	3,756
	€ 18,109	**€ 12,801**	**€ 7,749**

17.1 Grants

The grant income is related to grants received from the Flanders Innovation and Entrepreneurship Agency. No conditions related to the above government grants were unfulfilled, nor were there any material contingencies related thereon at the date of the approval of these consolidated financial statements.

17.2 Research and development incentives

The Company has accounted for a tax receivable of €8.9 million in the year ended December 31, 2020, compared to €4.8 and €2.2 million in the year ended December 31, 2019 and December 31, 2018, respectively, following a research and development tax incentive scheme in Belgium according to which the incentive will be refunded after a five year period, if not offset against the current tax payable over the period.

17.3 Payroll tax rebates

The Company accounted for €8.0 million payroll tax rebates in the year ended December 31, 2020, compared to €5.7 and €3.8 million in the year ended December 31, 2019 and December 31, 2018, respectively, as a reduction in withholding income taxes for its highly qualified personnel employed in its research and development department.

18. Segment reporting

The Company operates from the Netherlands, Belgium, the United States of America and Japan. Revenues are generated by external customers with their main registered office geographically located as shown in the table below. In prior periods this has been presented based on the geographical location of the contracting entity.

	Revenue from external customers		
	Year ended December 31,		
(in thousands of €)	2020	2019	2018
Denmark	€ 299	€ 436	€ 1,136
Belgium	—	1,499	—
United States	36,126	67,848	18,964
Other	—	—	1,382
Total	**€ 36,425**	**€ 69,783**	**€ 21,482**

The non-current assets of the Company, with the exception of the deferred tax assets, are geographically located as shown in the table below:

	Non-current assets		
	Year ended December 31,		
(in thousands of €)	2020	2019	2018
Netherlands	€ 1	€ 1	€ 1
Belgium	163,224	56,777	5,967
United States	3,872	3,058	47
Japan	2,030	284	—
Total	**€ 169,127**	**€ 60,120**	**€ 6,015**

19. Research and development expenses

(in thousands of €)	Year Ended December 31, 2020	2019	2018
Personnel expense	€ 75,121	€ 45,733	€ 26,519
External research and development expenses	228,438	137,050	48,859
Materials and consumables	3,099	2,027	1,464
Depreciation and amortization	2,472	1,641	494
Other expenses	16,349	11,214	6,273
	€ 325,479	**€ 197,665**	**€ 83,609**

20. Selling, general and administrative expenses

(in thousands of €)	Year Ended December 31, 2020	2019	2018
Personnel expense	€ 94,251	€ 40,082	€ 18,292
Consulting fees	42,459	16,343	5,472
Supervisory board	4,243	2,792	1,088
Other Expenses	8,414	5,352	2,619
	€ 149,367	**€ 64,569**	**€ 27,471**

21. Personnel expenses

The personnel expenses mentioned in note 19 and 20 above are as follows:

(in thousands of €)	Year Ended December 31, 2020	2019	2018
Short-term employee benefits—Salaries	€ 65,516	€ 32,866	€ 18,617
Short-term employee benefits—Social Security	7,848	3,555	2,213
Post-employment benefits	1,072	748	441
Termination benefits	849	644	96
Share-based payment	80,644	37,208	18,527
Employer social security contributions stock options	13,443	10,794	4,918
	€ 169,372	**€ 85,815**	**€ 44,812**

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:

Average Number of FTE	Year Ended December 31, 2020	2019	2018
Research and development	213.0	121.6	76.1
Selling, general and administrative	119.5	56.3	27.6
	332.5	**177.9**	**103.7**

22. Leases

The statement of financial position shows the following amounts relating to leases:

In thousands of €	Year Ended December 31, 2020	Year Ended December 31, 2019
Right-of-use assets		
Buildings	€ 6,313	€ 5,576
Vehicles	1,233	744
Equipment	215	243
	€ 7,760	**€ 6,563**
Lease liabilities		
Current	€ 2,833	€ 1,974
Non-current	5,035	4,540
	€ 7,868	**€ 6,514**

Additions to the right-of-use assets amounted to €3.6 million for the year ended December 31, 2020.

The table below shows a maturity analysis of the lease liabilities as on December 31, 2020:

(in thousands of €)	Less than 1 year	1-3 years	3-5 years	More than 5 years	Total contractual cash flows	Carrying amount
Lease liabilities	€ 3,043	€ 4,085	€ 1,171	€ —	€ 8,299	€ 7,868

The consolidated statements of profit or loss and other comprehensive income shows the following amounts relating to leases:

In thousands of €	Year Ended December 31, 2020	2019	2018
Depreciation charges			
Buildings	€ 1,981	€ 1,315	€ —
Vehicles	386	233	—
Equipment	28	28	11
	€ 2,395	**€ 1,576**	**€ 11**
Interest expense (included in finance cost)	€ 176	€ 105	€ —
Expense relating to short-term leases	231	123	—
Expense relating to leases of low-value assets that are not shown above as short-term leases	5	5	—

The total cash outflow for leases in 2020 was €2.6 million.

The Company did not enter into any lease agreement with variable lease payments or residual value guarantees. The Company has leases that include extension options. These options provide flexibility in managing the leased assets and align with the Company's business needs. The Company exercises judgement in deciding whether it is reasonably certain that the extension options will be exercised.

23. Financial result and exchange gains/(losses)

(in thousands of €)	Year Ended December 31, 2020	2019	2018
Interest income	€ 4,517	€ 7,874	€ 1,371
Net gain on current financial assets held at fair value through profit or loss and cash equivalents	1,173	6,525	2,323
Financial income	**€ 5,690**	**€ 14,399**	**€ 3,694**
Net loss on current financial assets held at fair value through profit or loss and cash equivalents	€ (6,755)	€ —	€
Other financial expense	(349)	(124)	—
Financial expense	**€ (7,104)**	**€ (124)**	**€ —**
Realized exchange gains/(losses)	€ (400)	€ (338)	€ 1,355
Unrealized exchange gains/(losses)	(106,556)	6,404	10,953
Exchange gains/(losses)	**€ (106,956)**	**€ 6,066**	**€ 12,308**

The exchange losses of €107.0 million for the year ended December 31, 2020 were primarily attributable to unrealized exchange rate gains on our cash and cash equivalents and current financial assets position in USD due to the unfavorable fluctuation of the USD exchange rate over the period.

24. Income tax expense

The income tax expense for the year can be reconciled to the accounting loss as follows:

(in thousands of €)	Year Ended December 31, 2020	2019	2018
Loss before taxes	€ 526,139	€ 158,213	€ 65,847
Income tax calculated at 25%	131,535	39,553	16,462
Effect of expenses not deductible in determining taxable results	(11,478)	(7,701)	(3,934)
Effect of stock issue expenses that are not deductible in determining taxable results	11,775	5,750	3,716
Effect of concessions	6,804	572	430
Effect of tax losses carried forward not recognized	(100,771)	(11,670)	(5,511)
Effect of different tax rates in jurisdictions in which the company operates	(168)	(52)	(15)
Deferred tax asset other than loss carryforwards not recognized	(39,516)	(27,341)	(11,968)
(Underprovided)/overprovided in prior years	(857)	(3,876)	
Other	(108)	13	26
Income tax expense recognized in the consolidated statement of profit and loss	**€ (2,784)**	**€ (4,752)**	**€ (794)**

The tax rate used for the 2020, 2019 and 2018 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 €141.9 million on December 31, 2020, comparefd to €40.0 million on December 31, 2019. Deferred tax have been measured using the effective rate that will apply in Belgium and the Netherlands (25%). The Company has unused tax losses carried forward for an amount of €567.8 million on December 31, 2020, compared to €160 million on December 31, 2019, of which €1.4 million and €7.2 million will expire in 2028 and 2029, respectively. This, combined with other temporary differences, resulted in a net deferred tax asset position. Due to the uncertainty surrounding the Company's ability to realize taxable profits in the near future, the Company did not recognize any deferred tax assets, with the exception of those further detailed in note 10.

Income taxes were directly recognized in the income statement can be detailed as follows:

(in thousands of €)	Year Ended December 31, 2020	2019	2018
Current year	€ 6,871	€ 4,752	794
Income tax prior years	1,547	—	—
Current tax expense	**8,418**	**4,752**	**794**
Originating and reversal of temporary differences	(5,634)	—	—
Deferred tax expense / (income)	**(5,634)**	**—**	**—**
Total tax expense	**€ 2,784**	**€ 4,752**	**€ 794**

25. Loss per share

(in thousands of €)	Year Ended December 31, 2020	2019	2018
Loss of the year	€ (528,923)	€ (162,965)	€ (66,641)
Weighted average number of shares outstanding	45,410,442	38,619,121	33,419,356
Basic and diluted loss per share (in €)	**€ (11.65)**	**€ (4.22)**	**€ (1.99)**

Earnings/losses per ordinary share are calculated by dividing the loss for the period by the weighted average number of ordinary shares during the year.

As the Company reported a net loss in 2020, 2019 and 2018, stock options have an anti-dilutive effect rather than a dilutive effect. As such, there is no difference between basic and diluted earnings/losses per ordinary share.

26. Financial risk management

The financial risks are managed centrally. The Company coordinates the access to national and international financial markets and considers and manages continuously the financial risks concerning the Company's activities. These relate to the financial markets risk, credit risk, liquidity risk and currency risk. There are no other important risks, such as interest rate risk on borrowings, as the Company has no financial debt. The Company does not buy or trade financial instruments for speculative purposes.

Categories of financial assets and liabilities:

(in thousands of €)	Measurement category	Carrying amount Year Ended December 31, 2020	2019	2018
Financial assets — non-current	FVTPL	€ 5,140	€ 2,596	€ 1
Research and development incentive receivables — non-current	Amortised cost	16,840	8,566	4,883
Restricted cash — non-current	Amortised cost	1,243	630	251
Trade and other receivables	Amortised cost	5,687	28,115	2,886
Financial assets—current	FVTPL	635,359	1,004,539	283,529
Research and development incentive receivables — current	Amortised cost	377	261	301
Restricted cash — current	Amortised cost	—	—	1,692
Cash and bank balances	Amortised cost	242,161	103,731	63,589
Cash equivalents	FVTPL	699,447	—	—
Cash equivalents	Amortised cost	50,001	227,551	217,451
Trade and other payables	Amortised cost	224,262	85,301	37,072

The carrying amounts of trade and other payables are considered to be the same as their fair values, due to their short-term nature.

Financial assets held at fair value through profit or loss

Financial assets held at fair value through profit or loss consisted of equity instruments of listed and non-listed companies and money market funds.

The Company has no restrictions on the sale of these equity instruments and the assets are not pledged under any of its liabilities. These instruments are classified as financial assets held at fair value through profit or loss which qualify for:

- Level 1 fair value measurement with respect to current financial assets and cash equivalents based upon the closing price (net asset value) of such securities at each reporting date.
- Level 3 fair value measurement with respect to non-current financial assets.

The market price of these financial instruments might face fluctuations and might be affected by a variety of factors, such as the global economic situation. Current financial assets and cash equivalents include collective investment funds nominated in € and $ of which the underlying investments include bonds and other international debt securities. Based on the average credit rating of the underlying instruments, amongst others, these investments are either classified as current financial assets or cash equivalents.

The maximum exposure to credit risk is the carrying amount at reporting date.

The Company carried the following assets at fair value on December 31, 2020, 2019 and 2018 respectively:

	At December 31, 2020		
(in thousands of €)	**Level 1**	**Level 2**	**Level 3**
Non-current financial assets	€ —	€ —	€ 5,140
Current financial assets	635,359	—	—
Cash Equivalents	699,447	—	—
Assets carried at fair value	€ **1,334,806**	€ **—**	€ **5,140**

	At December 31, 2019		
(in thousands of €)	**Level 1**	**Level 2**	**Level 3**
Non-current financial assets	€ —	€ —	€ 2,596
Current financial assets	1,004,539	—	—
Assets carried at fair value	€ **1,004,539**	€ **—**	€ **2,596**

	At December 31, 2018		
(in thousands of €)	**Level 1**	**Level 2**	**Level 3**
Non-current financial assets	€ —	€ —	€ 1
Current financial assets	283,529	—	—
Assets carried at fair value	€ **283,529**	€ **—**	€ **1**

During the disclosed calendar year no transfers occurred between the applicable categories.

In March 2019, the Company entered into a license agreement with AgomAb Therapeutics NV for the use of HGF-mimetic SIMPLE Antibodies™, developed under the Company's Innovative Access Program. In exchange for granting this license, the Company received a profit share in AgomAb Therapeutics NV. The profit share has been designated as a non-current financial asset held at fair value through profit or loss. Since AgomAb Therapeutics NV is a private company, the valuation of the profit share is based on level 3 assumptions.

Capital risk

The Company manages its capital to ensure that it will be able to continue as a going concern. The capital structure of the Company consists of equity attributed to the holders of equity instruments of the Company, such as capital, reserves and accumulated losses as mentioned in the consolidated statement of changes in equity. The Company makes the necessary adjustments in the light of changes in the economic circumstances, risks associated to the different assets and the projected cash needs of the current and projected research activities. On December 31, 2020, cash and cash equivalents amounted to €991.6 million and total capital amounted to €2,062.9 million. The current cash situation and the anticipated cash generation are the most important parameters in assessing the capital structure. The Company's objective is to maintain the capital structure at a level to be able to finance its activities for

at least twelve months. Cash income from existing and new partnerships is taken into account and, if needed and possible, the Company can issue new shares or enter into financing agreements.

Credit risk

Credit risk refers to the risk that a counterparty will default on its contractual obligations resulting in financial loss to the Company. The Company has adopted a policy of only dealing with creditworthy counterparties and obtaining sufficient collateral, where appropriate, as a means of mitigating the risk of financial loss from defaults. Concentrations in credit risk are determined based on an analysis of counterparties and their importance on the overall outstanding contractual obligations at year end.

The Company has a limited number of license and 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.

The Company applied the IFRS 9 simplified approach to measuring expected credit losses which uses a lifetime expected loss allowance for all receivables. To measure the expected credit losses, receivables have been grouped based on credit risk characteristics and the days past due. The provision for expected credit losses was not significant given that there have been no credit losses over the last three years and the high quality nature of our customers.

Cash and cash equivalents and current financial assets are invested with several highly reputable banks and financial institutions. The Company holds its cash and cash equivalents mainly with different banks which are independently rated with a minimum rating of ‘A-’. The Company also holds short term investment funds in the form of money market funds with a recommended investment horizon of 6 months or shorter but with a low historical volatility. These money market funds are highly liquid investments, can be readily convertible into a known amount of cash. Since they are a basket of funds there is no individual credit risk involved. The average credit rating of the underlying instruments for the investment funds is “BBB-“ or higher.

Liquidity risk

The Company manages liquidity risk by maintaining adequate reserves, by continuously monitoring forecast and actual cash flows, and by matching the maturity profiles of financial assets and liabilities.

The Company’s main sources of cash inflows are obtained through capital increases and collaboration agreements. This cash is invested in savings accounts, term accounts and short term investment funds in the form of money market funds. These money market funds represent the majority of the Company’s available sources of liquidity however since all of these are immediately tradable and convertible in cash they have a limited impact on the liquidity risk.

Interest rate risk

The only variable interest-bearing financial instruments are cash and cash equivalents and current financial investments. Changes in interest rates may cause variations in interest income and expense resulting from short-term interest-bearing assts. Management does not expect the short-term interest rates to decrease significantly in the immediate foreseeable future, which limits the interest exposure on our cash and cash equivalents and current financial investments.

For the year ended December 31, 2020, if applicable interest rates would increase/decrease by 25 basis points, this would have a positive/negative impact of €1.5 million (compared to €2.0 million for the year ended December 31, 2019 and €0.3 million for the year ended December 31, 2018).

Foreign exchange risk

The Company undertakes transactions denominated in foreign currencies; consequently, exposures to exchange rate fluctuations arise. The Company is mainly exposed to the U.S. Dollar, Japanse yen, British pound and

Swiss franc. To limit this risk, the Company attempts to align incoming and outgoing cash flows in currencies other than EUR.

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

	At December 31,		
(in thousands of €)	**2020**	**2019**	**2018**
USD	1,053,803	821,916	312,831
JPY	215	488	—
GBP	39	4	2
CHF	94	1	4

On December 31, 2020, if the USD/EUR exchange rate would have increased/decreased by 10%, this would have had a negative/positive impact of €95.80 million, compared to €74.72 million and €28.44 million on December 31, 2019 and December 31, 2018, respectively. On December 31, 2020, if the exchange rate for other currencies would have increased/decreased by 10% , this would have had no significant impact.

27. Related party transactions

27.1 Relationship and transactions with subsidiaries

See note 31 for an overview of the consolidated companies of the group, which are all wholly-owned subsidiaries of argenx SE.

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.

27.2 Relationship and transactions with key personnel

The Company’s key management personnel consists of the members of the management team and the members of the board of directors.

Remuneration of key management personnel

On December 31, 2020, the executive committee consisted of 9 members: Chief Executive Officer, Chief Operating Officer, Chief Financial Officer, Chief Scientific Officer, General Counsel, Chief Medical Officer, Vice President Corporate Development and Strategy, Global Head of Quality Assurance and Global Head of Human Resources. They provide their services on a full-time basis.

On December 31, 2020, the board of directors consisted of 8 members: Peter Verhaeghe, Don deBethizy, Pamela M. Klein, David L. Lacey, Werner Lanthaler, A.A. Rosenberg, James M. Daly and Tim Van Hauwermeiren.

Only the Chief Executive Officer is a member of both the management team and the board of directors. The Chief Executive Officer does not receive any special remuneration for his board membership, as this is part of his total remuneration package in his capacity as member of the management team.

The remuneration package of the members of key management personnel comprises:

(in thousands of €, except for the number of stock options)	Year Ended December 31, 2020	2019	2018
Remuneration of key management personnel			
Short-term benefits for executive team members as a group			
Gross salary	€ 2,842	€ 2,527	€ 2,505
Variable pay	1,322	975	1,078
Employer social security	659	813	528
Other short term benefits	137	122	125
Termination Benefits	337	470	—
Post-employment benefits for executive team members as a group	141	144	153
Cost of stock options granted in the year for executive team members as a group	37,493	21,847	13,363
Employer social security cost related to stock options	9,811	9,160	2,793
Total benefits for key management personnel	**52,742**	**36,058**	**20,544**
Numbers of stock options granted in the year			
Executive team as a group	334,900	405,000	460,700
Remuneration of non-executive directors			
Board fees and other short-term benefits for directors	355	378	355
Cost of stock options granted in the year for non-executive directors	8,384	4,330	3,271
Total benefits for non-executive board members	**8,739**	**4,708**	**3,626**
Numbers of stock options granted in the year			
Non-executive directors	70,000	70,000	85,000

Other

No loans, quasi-loans or other guarantees were given by the Company or any of its subsidiaries to members of the board of directors or the executive team. We have not entered into transactions with our key management personnel, other than as described above with respect to remuneration arrangements relating to the exercise of their mandates as members of the executive team and the board of directors.

28. Contingencies

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

29. Commitments

At balance sheet date, there were no commitments signed for the acquisition of property, plant and equipment. In January 2021, the Company entered into a binding lease commitment related to the envisioned relocation to a newly built office in Zwijnaarde, Belgium. Included in the binding lease commitment is a rent free period for 6 months following the completion of the building. The total future cash outflows related to this lease are as follows:

(in thousands of €)	Less than 1 year	1-3 years	3-5 years	More than 5 years	Total contractual cash flows
Lease commitments not commenced	€ —	€ 282	€ 3,382	€ 13,247	€ 16,912

In February 2019, and as amended in September 2020, the Company entered into a global collaboration and license agreement with Halozyme Therapeutics, Inc. Under the terms of the agreement, the Company will pay $12.5 million per target for future target nominations and potential future payments of up to $160.0 million per selected target subject to achievement of specified development, regulatory and sales-based milestones and up to $40.0 million subject to the achievement of additional, specified sales-based milestones. This amount represents the maximum amount that would be paid if all milestones would be achieved but excludes variable royalty payments based on unit sales. In 2019, the Company exercised the option to nominate an additional target (triggering a $10.0 million development milestone payment) and initiated a Phase 1 clinical trial using Halozyme's proprietary

ENHANZE® drug delivery technology (triggering a $5.0 million development milestone payment). In 2020, the Company initiated a Phase 3 clinical trial using Halozyme's proprietary ENHANZE® drug delivery technology (triggering a $15.0 million development milestone payment).

The Company's manufacturing commitments with Lonza, its drug substance manufacturing contractor, relate to the ongoing execution of the biologic license application (BLA) services for efgartigimod and its manufacturing activities related to the potential future commercialisation. In December 2018, the Company signed its first commercial supply agreement with Lonza related to the reservation of commercial drug substance supply capacity for efgartigimod. In the aggregate, the Company has outstanding commitments for efgartigimod under the first commercial supply agreement of €114.0 million.

30. Audit fees

The following auditors' fees were expensed in the income statement:

Fees	Year Ended December 31, 2020	2019	2018
		in thousands of €	
Audit fees (1)	€ 808	€ 730	€ 648
Audit-related fees	165	159	143
Tax and other services (2)	—	—	—
Total	**€ 973**	**€ 889**	**€ 791**

(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 by the Deloitte network.

31. Overview of consolidation scope

The parent company argenx SE is domiciled in the Netherlands. The Company, argenx SE, has two subsidiaries, argenx BV and argenx IIP BV, based in Belgium. argenx BV has three subsidiary, argenx US, Inc., based in the United States of America, argenx Japan KK, based in Japan and argenx Switzerland SA, based in Switzerland. Details of the Company's consolidated entities at the end of the reporting period are as follows:

Name	Registration number	Country	Participation	Main activity
argenx SE	COC 24435214	The Netherlands	100.00 %	Holding company
argenx BV	0818292196	Belgium	100.00 %	Biotechnical research on drugs and pharma processes
argenx IIP BV	0751809485	Belgium	100.00 %	Biotechnical research on drugs and pharma processes
argenx US, Inc.	36-4880497	USA	100.00 %	Pharmaceuticals and pharmacy supplies merchant wholesalers
argenx Switzerland, SA	CH-660.3.799.020-7	Switzerland	100.00 %	Pharmaceuticals and pharmacy supplies merchant wholesalers
argenx Japan KK	0104-01-145183	Japan	100.00 %	Pharmaceuticals and pharmacy supplies merchant wholesalers

32. Events after the balance sheet date

On January 6, 2021, argenx and Zai Lab announced a Strategic Collaboration for efgartigimod in Greater China, expected to allow the Company to more rapidly advance new potential indications into clinical development

each year and grants Zai Lab the exclusive rights to develop and commercialize efgartigimod in Greater China. Zai Lab will recruit Chinese patients to argenx's registrational trials for the development of efgartigimod and will allow argenx to accelerate efgartigimod development by initiating multiple Phase 2 proof-of-concept trials in new autoimmune indications.

Under the terms of the agreement, the Company will receive up to $175 million in collaboration payments, comprised of a $75 million upfront payment in the form of 568,182 newly issued Zai Lab shares calculated at a price of $132 per share, $75 million as guaranteed non-creditable, non-refundable payment, and an additional $25 million milestone payment upon approval of efgartigimod in the U.S. The Company is also eligible to receive tiered royalties (mid-teen to low twenties on a percentage basis) based on annual net sales of efgartigimod in Greater China.

In January 2021, the Company entered into a binding lease commitment in relation to the envisioned relocation to a newly built office for an annual base rent of €1.7 million which would be operational in the second quarter of 2023, and has an initial term of 10.5 years. Included in the binding lease commitment is a rent free period for 6 months following the completion of the building.

On February 5, 2021, argenx SE announced the closing of their global offering of 3,125,000 of its ordinary shares through a global offering which consisted of (i) a public offering of 1,608,000 ADSs in the U.S. and certain other countries outside the European Economic Area (EEA) at a price of $320.00 per ADS, before underwriting discounts and commissions, and offering expenses; and (ii) a concurrent private placement of 1,517,000 ordinary shares in the European Economic Area at a price of €265.69 per share, before underwriting discounts and commissions, and offering expenses. On February 4, 2021, the underwriters of the offering exercised their over-allotment option to purchase 468,750 additional ADSs in full. As a result, the Company received €954.8 million in gross proceeds from the offering, decreased by €46.8 million of underwriter discounts and commissions, and offering expenses, of which €46.5 million is expected to be deducted from equity. The total net cash proceeds from the offering amounted to €908.0 million.

Table of Contents

(This page has been left blank intentionally.)

DESCRIPTION OF SHARE CAPITAL

As of December 31, 2019, argenx SE (the "company," "argenx," "we," "us," and "our") had two classes of securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): our Ordinary Shares and our American Depositary Shares ("ADSs").

The following description is a summary of certain information relating to our share capital, certain provisions of our articles of association and Dutch law. Because this description is a summary, it may not contain all of the information important to you. Accordingly, this description is qualified entirely by reference to articles of association, which is incorporated by reference to Exhibit 1.1 to our Form F-1 filed with the Securities and Exchange Commission (the "SEC") on May 4, 2017 (our "Articles of Association").

The following description includes comparisons of certain provisions of our articles of association and Dutch law applicable to us and the Delaware General Corporation Law, or the DGCL, the law under which many publicly listed companies in the United States are incorporated. Because such statements are summaries, they do not address all aspects of Dutch law that may be relevant to us and our shareholders or all aspects of Delaware law which may differ from Dutch law, and they are not intended to be a complete discussion of the respective rights.

General

We were incorporated on April 25, 2008, as a private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*) under Dutch law. On May 28, 2014, we converted into a public company with limited liability (*naamloze vennootschap*) under Dutch law pursuant to a notarial deed of conversion and amendment. On April 26, 2017, we converted 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.

We are registered with the trade register of the Dutch Chamber of Commerce under number 24435214. Our corporate seat is in Rotterdam, the Netherlands, and our registered office is at Willemstraat 5, 4811 AH, Breda, the Netherlands.

Our ordinary shares are listed on Euronext Brussels under ISIN Code NL0010832176 under the symbol "ARGX." The ADSs are listed on the Nasdaq Global Select Market ("Nasdaq") under the symbol "ARGX."

Under Dutch law, a company's authorized share capital sets out the maximum amount and number of shares that it may issue without amending its articles of association.

Our Articles of Association provide for an authorized share capital in the amount of €9.0 million divided into 90 million shares, each with a nominal value of €0.10. All issued and outstanding shares have been fully paid up and the shares are held in dematerialized form. Our share capital consists of ordinary shares, each with a nominal value of €0.10. Our shares are not separated into classes. As of December 31, 2019, our issued and paid-up share capital amounted to €4,276,152.80 represented by 42,761,528 ordinary shares with a nominal value of €0.10, each representing an identical fraction of our share capital. As of December 31, 2019, neither we nor any of our subsidiaries held any of our own shares.

Issue of Shares

Our Articles of Association provide that shares may be issued or rights to subscribe for our shares may be granted pursuant to a resolution of the shareholders at the General Meeting, or alternatively, by our board of directors if so designated by the shareholders at the General Meeting. A resolution of the shareholders at the General Meeting to issue shares, to grant rights to subscribe for shares or to designate our board of directors as the corporate body of the company authorized to do so can only take place at the proposal of our board of directors with the consent of the majority of the non-executive directors. Shares may be issued or rights to subscribe for shares may be granted by resolution of our board of directors, if and insofar as our board of directors is designated to do so by the shareholders

at the General Meeting. Designation by resolution of the shareholders at the General Meeting cannot be withdrawn unless determined otherwise at the time of designation. The scope and duration of our board of directors' authority to issue shares or grant rights to subscribe for shares (such as granting stock options or issuing convertible bonds) is determined by a resolution of the shareholders at the General Meeting and relates, at the most, to all unissued shares in the company's authorized capital at the relevant time. The duration of this authority may not exceed a period of five years. Designation of our board of directors as the body authorized to issue shares or grant rights to subscribe for shares may be extended by a resolution of the shareholders at the General Meeting for a period not exceeding five years in each case. The number of shares that may be issued is determined at the time of designation.

No shareholders' resolution or board of directors resolution is required to issue shares pursuant to the exercise of a previously granted right to subscribe for shares. A resolution of our board of directors to issue shares and to grant rights to subscribe for shares can only be taken with the consent of the majority of the non-executive directors. One of the items on the agenda of the EGM is the renewal of this authorization.

On May 8, 2018, the shareholders at the General Meeting renewed the designation of our board of directors as the corporate body competent to grant option rights to subscribe for shares under the argenx Employee Stock Option Plan and to limit or exclude preemption rights of shareholders for such shares with the prior consent of the majority of the non-executive directors for a period of 18 months. One of the items on the agenda of this General Meeting was to propose to renew the designation of our board of directors as the corporate body competent to grant option rights to subscribe for shares under the argenx Employee Stock Option Plan and to limit or exclude preemption rights of shareholders for such shares with the prior consent of the majority of the non executive directors for a period of 18 months.

On May 7, 2019, the shareholders at the General Meeting renewed the authorization to our board of directors to issue shares and grant rights to subscribe for shares and to limit or exclude preemption rights of shareholders for such shares with the prior consent of the majority of the non-executive directors for a period of 18 months. In its resolution, the shareholders at the General Meeting restricted the competency of our board of directors under this second authorization as regards the issue of shares and the grant of rights to subscribe for shares to a maximum of 20% of our total issued and outstanding share capital as at the day of that meeting. As of the date hereof, no use has been made of this authorization, so that the full amount still is available to issue new shares. The primary purpose of this authorization is to allow the board of directors the general flexibility to issue additional shares as and when the need may arise or an opportunity would present itself, including to issue shares and grant rights to subscribe for shares and to limit or exclude preemption rights of shareholders for such shares for the purpose of the admission to listing and trading of new ordinary shares on Nasdaq. While there is no current intention to benefit any specific person with this second authorization to restrict the preemption rights of the existing shareholders, when using this authorization the board will be able to restrict the preemption rights in whole or in part, including for the benefit of specific persons.

Preemptive Rights

Dutch law and the Articles of Association give shareholders preemptive rights to subscribe on a pro rata basis for any issue of new shares or, upon a grant of rights, to subscribe for shares. Holders of shares have no preemptive rights upon (1) the issue of shares against a payment in kind (being a contribution other than in cash); (2) the issue of shares to our employees or the employees of a member of our group; and (3) the issue of shares to persons exercising a previously granted right to subscribe for shares.

A shareholder may exercise preemptive rights during a period of at least two weeks from the date of the announcement of the issue of shares. Pursuant to the Articles of Association, the shareholders at the General Meeting may restrict or exclude the preemptive rights of shareholders. A resolution of the shareholders at the General Meeting to restrict or exclude the preemptive rights or to designate our board of directors as our body authorized to do so, may only be adopted on the proposal of our board of directors with the consent of the majority of the non-executive directors. A resolution of the shareholders at the General Meeting to exclude or restrict preemptive rights, or to authorize our board of directors to exclude or restrict preemptive rights, requires a majority of at least two-thirds of the votes cast, if less than 50% of our issued and outstanding share capital is present or represented at the General Meeting.

With respect to an issuance of shares pursuant to a resolution of our board of directors, the preemptive rights of shareholders may be restricted or excluded by resolution of our board of directors if and insofar as our board of directors is designated to do so by the shareholders at the General Meeting. A resolution of our board of directors to restrict or exclude preemptive rights can only be taken with the consent of the majority of the non-executive directors.

The designation of our board of directors as the body competent to restrict or exclude the preemptive rights may be extended by a resolution of the shareholders at the General Meeting for a period not exceeding five years in each case. Designation by resolution of the shareholders at the General Meeting cannot be withdrawn unless determined otherwise at the time of designation. On May 8, 2018, the shareholders at the General Meeting renewed the designation of our board of directors as the corporate body competent to grant option rights to subscribe for shares under the argenx Employee Stock Option Plan and to limit or exclude preemption rights of shareholders for such shares with the prior consent of the majority of the non-executive directors for a period of 18 months. One of the items on the agenda of this General Meeting was to propose to renew the designation of our board of directors as the corporate body competent to grant option rights to subscribe for shares under the argenx Employee Stock Option Plan and to limit or exclude preemption rights of shareholders for such shares with the prior consent of the majority of the non executive directors for a period of 18 months. On May 7, 2019, the shareholders at the General Meeting renewed the designation of our board of directors as the corporate body competent to issue additional shares and grant rights to subscribe for shares and to limit or exclude preemption rights of shareholders for such shares with the prior consent of the majority of the non-executive directors for a period of 18 months. In its resolution, the shareholders at the General Meeting restricted the competency of our board of directors under this second authorization as regards the issue of shares and the grant of rights to subscribe for shares to a maximum of 20% of our total issued and outstanding share capital as at the day of that meeting. The purpose of this authorization is to allow the board of directors the general flexibility to issue additional shares as and when the need may arise or an opportunity would present itself, including to issue shares and grant rights to subscribe for shares and to limit or exclude preemption rights of shareholders for such shares for the purpose of the admission to listing and trading of new ordinary shares on Nasdaq. While there is no current intention to benefit any specific person with this authorization to restrict the preemption rights of the existing shareholders, when using this authorization the board will be able to restrict the preemption rights in whole or in part, including for the benefit of specific persons. The board's ability to restrict the preemption rights in whole or in part could be used as a potential anti-takeover measure.

Under the DGCL, stockholders of a Delaware corporation have no preemptive rights to subscribe for additional issues of stock or to any security convertible into such stock unless, and to the extent that, such rights are expressly provided for in the corporation's certificate of incorporation.

Acquisition of Shares by the Company

We may not subscribe for our own shares on issue. We may acquire fully paid-up shares at any time for no consideration or, if:

- our shareholders' equity less the payment required to make the acquisition, does not fall below the sum of called-up and paid-in share capital and any statutory reserves;
- we and our subsidiaries would thereafter not hold shares or hold a pledge over shares with an aggregate nominal value exceeding 50% of our issued share capital; and
- our board of directors has been authorized thereto by the shareholders at the General Meeting.

As part of the authorization, the shareholders at the General Meeting must specify the number of shares that may be repurchased, the manner in which the shares may be acquired and the price range within which the shares may be acquired. A resolution of our board of directors to repurchase shares can only be taken with the consent of the majority of the non-executive directors.

Shares held by us in our own share capital do not carry a right to any distribution. Furthermore, no voting rights may be exercised for any of the shares held by us or our subsidiaries unless such shares a are subject to the right of usufruct or to a pledge in favor of a person other than us or its subsidiaries and the voting rights were vested in the

pledgee or usufructuary before us or its subsidiaries acquired such shares. Neither we nor our subsidiaries may exercise voting rights in respect of shares for which we or our subsidiaries have a right of usufruct or a pledge.

Reduction of Share Capital

The shareholders at the General Meeting may, upon a proposal of our board of directors with the consent of the majority of the non-executive directors, resolve to reduce the issued share capital by cancelling shares or by amending the Articles of Association to reduce the nominal value of the shares.

Only shares held by us or shares for which we hold the depositary receipts may be cancelled. A resolution of the shareholders at the General Meeting to reduce the number of shares must designate the shares to which the resolution applies and must lay down rules for the implementation of the resolution. A resolution to reduce the issued share capital requires a majority of at least two-thirds of the votes cast, if less than 50% of our issued and outstanding share capital is present or represented at the General Meeting.

Articles of Association and Dutch Law

Set forth below is a summary of relevant information concerning our share capital and material provisions of our Articles of Association and applicable Dutch law. This summary does not constitute legal advice regarding those matters and should not be regarded as such.

Amendment of Articles of Association

The shareholders at the General Meeting may resolve to amend the Articles of Association, at the proposal of our board of directors, with the consent of the majority of the non-executive directors. A resolution by the shareholders at the General Meeting to amend the Articles of Association requires a simple majority of the votes cast in a meeting in which at least half of our issued and outstanding capital is present or represented, or at least two-thirds of the votes cast, if less than half of our issued and outstanding capital is present or represented at that meeting.

Changing the rights of any of the shareholders will require the Articles of Association to be amended.

Company's Shareholders' Register

Subject to Dutch law, we must keep our shareholders' register accurate and up-to-date. Our board of directors keeps our shareholders' register and records names and addresses of all holders of shares, showing the date on which the shares were acquired, the date of the acknowledgement by or notification of us as well as the amount paid on each share. The register also includes the names and addresses of those with a right of usufruct (*vruchtgebruik*) in shares belonging to another or a pledge in respect of such shares.

Corporate Objectives

Our corporate objectives are: (a) to exploit, including all activities relating to research, development, production, marketing and commercial exploitation; biological, chemical or other products, processes and technologies in the life sciences sector in general, and more specifically in the diagnostic, pharmaceutical, medical, cosmetic, chemical and agricultural sector; (b) to design and develop instruments which may be used in medical diagnosis and affiliated areas; (c) the worldwide distribution of, sale of and rendering services relating to our products and subsidiaries directly to customers as well as through third parties; (d) to incorporate, to participate in any way whatsoever, to manage, to supervise, to operate and to promote enterprises, businesses and companies; (e) to render advice and services to businesses and companies with which we form a group and to third parties; (f) to finance businesses and companies; (g) to borrow, to lend and to raise funds, including the issue of bonds, promissory notes or other securities or evidence of indebtedness as well as to enter into agreements in connection with the aforementioned; (h) to render guarantees, to bind us and to pledge our assets for obligations of the companies and enterprises with which we form a group and on behalf of third parties; (i) to obtain, alienate, manage and exploit registered property and items of property in

general; (j) to trade in currencies, securities and items of property in general; (k) to develop and trade in patents, trademarks, licenses, know-how and other industrial property rights; and (l) to perform any and all activities of industrial, financial or commercial nature, as well as everything pertaining the foregoing, relating thereto or conductive thereto, all in the widest sense of the word.

Limitation on Liability and Indemnification Matters

Under Dutch law, our board of directors and certain other officers may be held liable for damages in the event of improper or negligent performance of their duties. They may be held jointly and severally liable for damages to our company and to third parties for infringement of the Articles of Association or of certain provisions of the Dutch Civil Code. In certain circumstances, they may also incur additional specific civil and criminal liabilities. Directors and certain other officers are insured under an insurance policy taken out by us against damages resulting from their conduct when acting in the capacities as such directors or officers. In addition, our Articles of Association provide for indemnification of our directors, including reimbursement for reasonable legal fees and damages or fines based on acts or failures to act in their duties. No indemnification shall be given to a member of our board of directors if a Dutch court has established, without possibility for appeal, that the acts or omissions of such indemnified person that led to the financial losses, damages, suit, claim, action or legal proceedings resulted from either an improper performance of his or her duties as a director or an officer of our company or an unlawful or illegal act, and only to the extent that his or her financial losses, damages and expenses are covered by an insurance and the insurer has settled these financial losses, damages and expenses (or has indicated that it would do so). Furthermore, such indemnification will generally not be available in instances of willful (*opzettelijk*), intentionally reckless (*bewust roekeloos*) or seriously culpable (*ernstig verwijtbaar*) conduct unless Dutch law provides otherwise.

Shareholders' Meetings and Consents

General Meeting

General meetings of shareholders are held at the place where the company has its official seat or at Schiphol Airport (municipality of Haarlemmermeer), the Netherlands. The annual General Meeting shall be held on the second Tuesday of the month of May on the hour and at the place mentioned in the convening notice. If such a date is not a business day, the annual General Meeting shall be held the first following business day. Additional extraordinary General Meetings may also be held whenever considered appropriate by our board of directors. Pursuant to Dutch law, one or more shareholders and others entitled to attend a General Meeting, who jointly represent at least one-tenth of the issued capital, may request our board of directors to convene a General Meeting. If our board of directors has not taken the steps necessary to ensure that a General Meeting will be held within the relevant statutory period after the request, the requesting persons may, at his/her/their request, be authorized by court in preliminary relief proceedings to convene a General Meeting. The court shall disallow the application if it does not appear that the applicants have previously requested our board of directors to convene a General Meeting and our board of directors has not taken the necessary steps so that the General Meeting could be held within six weeks after the request.

General meetings of shareholders can be convened by a notice, which shall include an agenda stating the items to be discussed, including for the annual General Meeting, among other things, the adoption of the annual accounts, appropriation of our profits and proposals relating to the composition of our board of directors, including the filling of any vacancies in our board of directors. In addition, the agenda shall include such items as have been included therein by our board. The agenda shall also include such items requested by one or more shareholders, and others entitled to attend General Meetings, representing at least 3% of the issued share capital. Requests must be made in writing and received by our board of directors at least 60 days before the day of the convocation of the meeting. No resolutions shall be adopted on items other than those which have been included in the agenda. In accordance with the Dutch Corporate Governance Code, or DCGC, a shareholder may include an item on the agenda only after consulting our board of directors in that respect. If one or more shareholders intends to request that an item be put on the agenda that may result in a change in the company's strategy, our board of directors may invoke a response time of a maximum of 180 days until the day of the General Meeting.

The General Meeting is presided over by the chairperson or, if he is absent, by the vice chairperson of the board of directors. If the chairperson and the vice chairperson are absent, the non-executive directors present at the meeting shall appoint one of them to be chairperson. Board members may attend a General Meeting. In these meetings, they have an advisory vote. The chairperson of the meeting may decide at its discretion to admit other persons to the meeting.

The external auditor of the company shall attend the General Meeting in which the annual accounts are discussed.

In connection with our General Meetings, ADS holders will not be treated as our shareholders and will not have shareholder rights.

Admission and Registration

All shareholders, and each usufructuary and pledgee to whom the right to vote on our shares accrues, are entitled, in person or represented by a proxy authorized in writing, to attend and address the General Meeting and exercise voting rights pro rata to their shareholding. Shareholders may exercise their rights if they are the holders of our shares on the record date as required by Dutch law, which is currently the 28th day before the day of the General Meeting, and they or their proxy have notified us of their intention to attend the General Meeting in writing or by any other electronic means that can be reproduced on paper ultimately at a date set for that purpose by our board of directors which date may not be earlier than the seventh day prior to the General Meeting, specifying such person's name and the number of shares for which such person may exercise the voting rights and/or meeting rights at such General Meeting. The convocation notice shall state the record date and the manner in which the persons entitled to attend the General Meeting may register and exercise their rights.

Quorum and Voting Requirements

Each ordinary share confers the right on the holder to cast one vote at the General Meeting. Shareholders may vote by proxy. The voting rights attached to any shares held by us are suspended as long as they are held in treasury. Nonetheless, the holders of a right of usufruct (*vruchtgebruik)* in shares belonging to another and the holders of a right of pledge in respect of ordinary shares held by us are not excluded from any right they may have to vote on such ordinary shares, if the right of usufruct (*vruchtgebruik*) or the right of pledge was granted prior to the time such ordinary share was acquired by us. We may not cast votes in respect of a share in respect of which there is a right of usufruct (*vruchtgebruik*) or a right of pledge. Shares which are not entitled to voting rights pursuant to the preceding sentences will not be taken into account for the purpose of determining the number of shareholders that vote and that are present or represented, or the amount of the share capital that is provided or that is represented at a General Meeting.

In accordance with Dutch law and generally accepted business practices, our Articles of Association do not provide quorum requirements generally applicable to the General Meeting. 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. Decisions of the General Meeting are taken by an absolute majority of votes cast, except where Dutch law or the Articles of Association provide for a qualified majority or unanimity.

Board Members

Election of Board Members

Under our Articles of Association, our directors are appointed by the shareholders at the General Meeting upon proposal by our board of directors.

Duties and Liabilities of Directors

Under Dutch law, our board of directors is collectively responsible for our general affairs. Pursuant to our Articles of Association, our board of directors shall divide its duties among its members, with our day-to-day management entrusted to the executive directors. The non-executive directors supervise the management of the executive directors and the general affairs of our company and the business connected with it and provide the executive directors with advice. In addition, both the executive directors and the non-executive directors must perform such duties as are assigned to them pursuant to the Articles of Association. The division of tasks within our board of directors is determined (and amended, if necessary) by our board of directors. Each director has a duty to properly perform the duties assigned to him or her and to act in our corporate interest. Under Dutch law, the corporate interest extends to the interests of all corporate stakeholders, such as shareholders, creditors, employees and other stakeholders.

Dividends and Other Distributions

Amount Available for Distribution

Pursuant to Dutch law and the Articles of Association, the distribution of profits will take place following the adoption of our annual accounts, from which we will determine whether such distribution is permitted. We may only make distributions to the shareholders, whether from profits or from its freely distributable reserves, only insofar as its shareholders' equity exceeds the sum of the paid-up and called-up share capital plus the reserves required to be maintained by Dutch law.

The shareholders at the General Meeting may determine which part of our profits will be added to the reserves in consideration of our reserves and dividends policy. The remaining part of the profits after the addition to the reserves will be at the disposal of the shareholders at the General Meeting. Distributions of dividends will be made pro rata to the nominal value of each share.

Subject to Dutch law and the Articles of Association, our board of directors, with the consent of the majority of the non-executive directors, may resolve to distribute an interim dividend if it determines such interim dividend to be justified by our profits. For this purpose, our board of directors must prepare an interim statement of assets and liabilities. Such interim statement shall show our financial position not earlier than on the first day of the third month before the month in which the resolution to make the interim distribution is announced. An interim dividend can only be paid if (a) an interim statement of assets and liabilities is drawn up showing that the funds available for distribution are sufficient, and (b) our shareholders' equity exceeds the sum of the paid-up and called-up share capital plus the reserves required to be maintained by Dutch law.

Our board of directors, with the consent of the majority of the non-executive directors, may resolve that we make distributions to shareholders from one or more of our freely distributable reserves, other than by way of profit distribution, subject to the due observance of our policy on reserves and dividends. Any such distributions will be made pro rata to the nominal value of each share.

Dividends and other distributions shall be made payable not later than the date determined by our board. Claims to dividends and other distributions not made within five years from the date that such dividends or distributions became payable, will lapse and any such amounts will be considered to have been forfeited to us (*verjaring*).

We do not anticipate paying any cash dividends for the foreseeable future.

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.

Annual Accounts and Semi-Annual Accounts

Our financial year is the calendar year. Within four months after the end of our financial year, our board of directors must prepare the annual accounts. It must make them available for inspection by the shareholders at our office. The annual accounts must be accompanied by an auditors' statement, an annual report, a report by our board of directors and certain other information required under Dutch law (Section 2 Title 9 of the DCC). The annual accounts, the annual report, the other information required under Dutch law (Section 2 Title 9 of the DCC) and the auditors' statement must be made available to shareholders for review from the day of the notice convening the annual General Meeting. All members of our board of directors must sign the annual accounts and if a member does not sign, the reasons for this must be stated. The annual accounts must be adopted by the General Meeting. Within two months after the end of the first six months of the financial year, our board of directors must prepare semi-annual accounts and make them publicly available. If the semi-annual accounts are audited or reviewed, the independent auditor's report must be made publicly available together with the semi-annual accounts.

Dissolution and Liquidation

argenx SE may only be dissolved by a resolution of the shareholders at a General Meeting upon a proposal made by our board of directors with the consent of the majority of the non-executive directors. If a resolution to dissolve argenx SE is to be put to the shareholders at a General Meeting, this must in all cases be stated in the notice convening the General Meeting. If the shareholders at a General Meeting resolve to dissolve argenx SE, the members of our board of directors will be charged with the liquidation of the business of argenx SE. During liquidation, the provisions of the Articles of Association will remain in force as far as possible.

A resolution by the shareholders at a General Meeting to dissolve argenx SE requires a two-thirds majority of the votes cast if less than half the issued and outstanding share capital is represented at the meeting.

Any surplus remaining after settlement of all debts and liquidation costs will be distributed to the shareholders in proportion to the nominal value of their shareholdings.

Public Offer

In accordance with Directive 2004/25/EC, each European Union member state should ensure the protection of minority shareholders by obliging any person that acquires control of a company to make an offer to all the holders of that company's voting securities for all their holdings at an equitable price.

The Directive 2004/25/EC applies to all companies governed by the laws of a European Union member state of which all or some voting securities are admitted to trading on a regulated market in one or more European Union member states. The laws of the European Union member state in which a company has its registered office will determine the percentage of voting rights that is regarded as conferring control over that company.

In accordance with Section 5:70 of the Dutch Financial Supervision Act (*Wet op het financieel toezicht*), or the DFSA, any person—whether acting alone or in concert with others—who, directly or indirectly, acquires a controlling interest in a company will be obliged to launch a mandatory public offer for all our outstanding shares. A controlling interest is deemed to exist if a (legal) person is able to exercise, alone or acting in concert, at least 30% of the voting rights in the General Meeting. An exception is made for, amongst others, shareholders who—whether alone or acting in concert with others—(i) had an interest of at least 30% of our voting rights before our shares were first admitted to trading on Euronext Brussels and who still have such an interest after such first admittance to trading, and (ii) reduce their holding to below 30% of the voting rights within 30 days of the acquisition of the controlling interest provided that (a) the reduction of their holding was not effected by a transfer of shares to an exempted party and (b) during such period such shareholders or group of shareholders did not exercise their voting rights.

The rules under the DFSA regarding mandatory public offers apply to us because the company has its statutory seat in the Netherlands. However, as the shares are not admitted to trading on a regulated market in the Netherlands but are admitted to trading on Euronext Brussels and the ADSs are admitted to trading on Nasdaq, the Dutch Decree

on public offers (*Besluit openbare biedingen Wft*) will only apply in relation to matters relating to information to be provided to trade unions and employees and company law matters, including the convocation of a General Meeting in the event of a public offer and a position statement by our board of directors. In case of a mandatory public offer, the provisions regarding the offered consideration and the bid procedure will be governed by Belgian law pursuant to article 4§1, 3° of the Belgian law dated April 1, 2007 on public takeover bids. Pursuant to article 53 of the implementing Royal Decree, a mandatory public offer on our shares must be launched at a price equal to the higher of (i) the highest price paid by the offeror or persons acting in concert with it for the acquisition of shares during the last 12 months and (ii) the weighted average trading prices during the last 30 days before the obligation to launch a mandatory public offer was triggered. The price can be in cash or in securities. However, if the securities that are offered as consideration are not liquid securities that are traded on a regulated market or if the offeror or persons acting in concert with it have acquired shares for cash in the last 12 months, a cash alternative has to be offered.

No takeover bid has been instigated by third parties in respect of our equity during the previous financial year and the current financial year.

Squeeze Out Procedures

Pursuant to Section 92a, Book 2, Dutch Civil Code, a shareholder who for his own account holds at least 95% of our issued share capital may initiate proceedings against our minority shareholders jointly for the transfer of their shares to the claimant. The proceedings are held before the Dutch Enterprise Chamber of the Amsterdam Court of Appeal (*Ondernemingskamer van het Gerechtshof te Amsterdam*), or the Enterprise Chamber, and can be instituted by means of a writ of summons served upon each of the minority shareholders in accordance with the provisions of the Dutch Code of Civil Procedure (*Wetboek van Burgerlijke Rechtsvordering*). The Enterprise Chamber may grant the claim for squeeze out in relation to all minority shareholders and will determine the price to be paid for the shares, if necessary after appointment of one or three experts who will offer an opinion to the Enterprise Chamber on the value to be paid for the shares of the minority shareholders. Once the order to transfer becomes final before the Enterprise Chamber, the person acquiring the shares shall give written notice of the date and place of payment and the price to the holders of the shares to be acquired whose addresses are known to him. Unless the addresses of all of them are known to the acquiring person, such person is required to publish the same in a daily newspaper with a national circulation.

In addition, pursuant to Section 359c, Book 2 of the Dutch Civil Code, following a public offer, a holder of at least 95% of our issued share capital and voting rights has the right to require the minority shareholders to sell their shares to it. Any such request must be filed with the Enterprise Chamber within three months after the end of the acceptance period of the public offer. Conversely, pursuant to article 2:359d of the Dutch Civil Code each minority shareholder has the right to require the holder of at least 95% of our issued share capital and voting rights to purchase its shares in such case. The minority shareholder must file such claim with the Enterprise Chamber within three months after the end of the acceptance period of the public offer.

Market Abuse Rules

As of July 3, 2016, setting aside previously applicable national legislation in the European Union member states, the Market Abuse Regulation (Regulation (EU) No 596/2014), or MAR, provides for specific rules intended to prevent market abuse, such as prohibitions on insider trading, divulging inside information and tipping and market manipulation. The company, the members of our board of directors and other insiders and persons performing or conducting transactions in the company's financial instruments, as applicable, are subject to the insider trading prohibition, the prohibition on divulging inside information and tipping and the prohibition on market manipulation. In certain circumstances, the company's investors may also be subject to market abuse rules.

Inside information is any information of a precise nature relating (directly or indirectly) to us, or to our shares or other financial instruments, which information has not been made public and which, if it were made public, would be likely to have a significant effect on the price of the shares or the other financial instruments or on the price of related derivative financial instruments.

Pursuant to the MAR, a person is prohibited to possess inside information and use that information by acquiring or disposing of, for its own account or for the account of a third party, directly or indirectly, our shares and other financial instruments to which that information relates (which is considered to be insider dealing). The use of inside information by cancelling or amending an order concerning our shares or other financial instruments to which the information relates where the order was placed before the person concerned possessed the inside information, is also prohibited. In addition, a person is also prohibited to recommend another person to engage in insider dealing, or induce another person to engage in insider dealing, which arises where the person possesses inside information and (a) recommends, on the basis of that information, that another person acquires or disposes of our shares or other financial instruments to which that information relates, or induces that person to make such an acquisition or disposal or (b) recommends, on the basis of that information, that another person cancels or amends an order concerning our shares or other financial instruments to which that information relates, or induces that person to make such a cancellation or amendment.

The company is under an obligation to make any inside information immediately public. However, the company may, on its own responsibility, delay the publication of inside information if it can ensure the confidentiality of the information. Such deferral is only possible if the publication thereof could damage the company's legitimate interests and if the deferral does not risk misleading the market. If the company wishes to use this deferral right it needs to inform the Belgian Financial Services and Markets Authority thereof after the information is disclosed to the public and provide a written explanation of how the conditions for deferral were met, immediately. The company is subject to Belgian law and MAR regarding the publication of inside information.

Directors, other persons discharging managerial responsibilities and persons closely associated with them are covered by the MAR notification obligations. Directors and other persons discharging managerial responsibilities as well as persons closely associated with them, must notify the AFM of every transaction conducted on their own account relating to the shares or debt instruments of the company, or to derivatives or other financial instruments linked to those shares or debt instruments. Notification must be made within three working days after the date of the transaction. Under MAR, no notification of a transaction needs to be made until transactions in a calendar year by that director, persons discharging managerial responsibilities or persons closely associated with them exceed a threshold of €5,000 (without netting). Once the threshold has been reached, all transactions will need to be notified, regardless of amount and wherever concluded.

Non-compliance with these reporting obligations could lead to criminal penalties, administrative fines and cease-and-desist orders (and the publication thereof), imprisonment or other sanctions.

Transparency Directive

We are a European public company with limited liability (*Societas Europaea* or *SE*) incorporated and existing under the laws of the Netherlands. The Netherlands is our home European Union member state (*lidstaat van herkomst*) for the purposes of Directive 2004/109/EC, or the Transparency Directive as amended by Directive 2010/73/EU, as a consequence of which we will be subject to the DFSA in respect of certain ongoing transparency and disclosure obligations. In addition, as long as our shares are listed on Euronext Brussels and the ADSs on Nasdaq, we are required to disclose any regulated information which has been disclosed pursuant to the DFSA as well in accordance with the Belgian Act of May 2, 2007, the Belgian Royal Decree of November 14, 2007 and Nasdaq listing rules.

We must publish our annual accounts within four months after the end of each financial year and our half-yearly figures within two months after the end of the first six months of each financial year. Within five calendar days after adoption of our annual accounts, we must file our adopted annual accounts with the AFM.

Pursuant to the DFSA, we will be required to make public without delay any change in the rights attaching to our shares or any rights to subscribe our shares.

Dutch Financial Reporting Supervision Act

Pursuant to the Dutch Financial Reporting Supervision Act (*Wet toezicht financiële verslaggeving*), the DFRSA, the AFM supervises the application of financial reporting standards by companies whose official seat is in the Netherlands and whose securities are listed on a regulated Dutch or foreign stock exchange.

Pursuant to the DFRSA, the AFM has an independent right to (i) request an explanation from us regarding its application of the applicable financial reporting standards if, based on publicly known facts or circumstances, it has reason to doubt the our financial reporting meets such standards and (ii) recommend to us that we make available further explanations and files these with the AFM. If we do not comply with such a request or recommendation, the AFM may request that the Enterprise Chamber order us to (a) provide an explanation of the way we have applied the applicable financial reporting standards to our financial reports or (b) prepare our financial reports in accordance with the Enterprise Chamber's instructions.

Our Obligations and Obligations of our Shareholders and Directors to Notify Holders of Shares and Voting Rights

Pursuant to chapter 5.3 of the DFSA, any person who, directly or indirectly, acquires or disposes of an actual or potential capital interest or voting rights in the company must immediately give written notice to the AFM of such acquisition or disposal if, as a result of such acquisition or disposal, the percentage of capital interest and/or voting rights held by such person reaches, exceeds or falls below the following thresholds: 3%, 5%, 10%, 15%, 20%, 25%, 30%, 40%, 50%, 60%, 75% and 95%.

For the purpose of calculating the percentage of capital interest or voting rights, the following interests must be taken into account: (i) shares and/or voting rights directly held (or acquired or disposed of) by any person; (ii) shares or voting rights held (or acquired or disposed of) by such person's controlled entities or by a third party for such person's account; (iii) voting rights held (or acquired or disposed of) by a third party with whom such person has concluded an oral or written voting agreement; (iv) voting rights acquired pursuant to an agreement providing for a temporary transfer of voting rights in consideration for a payment; (v) shares which such person, or any controlled entity or third party referred to above, may acquire pursuant to any option or other right to acquire shares; (vi) shares which determine the value of certain cash settled financial instruments such as contracts for difference and total return swaps; (vii) shares that must be acquired upon exercise of a put option by a counterparty; and (viii) shares which are the subject of another contract creating an economic position similar to a direct or indirect holding in those shares.

Controlled entities (*gecontroleerde ondernemingen*) within the meaning of the DFSA do not themselves have notification obligations under the DFSA as their direct and indirect interests are attributed to their (ultimate) parent. If a person who has a 3% or larger interest in the company's share capital or voting rights ceases to be a controlled entity it must immediately notify the AFM and all notification obligations under the DFSA will become applicable to such former controlled entity.

Special rules apply to the attribution of shares and/or voting rights which are part of the property of a partnership or other form of joint ownership. A holder of a pledge or right of usufruct in respect of shares can also be subject to notification obligations, if such person has, or can acquire, the right to vote on the shares. The acquisition of (conditional) voting rights by a pledgee or beneficial owner may also trigger notification obligations as if the pledgee or beneficial owner were the legal holder of the shares and/or voting rights.

Furthermore, when calculating the percentage of capital interest a person is also considered to be in possession of shares if (i) such person holds a financial instrument the value of which is (in part) determined by the value of the shares or any distributions associated therewith and which does not entitle such person to acquire any shares, (ii) such person may be obliged to purchase shares on the basis of an option, or (iii) such person has concluded another contract whereby such person acquires an economic interest comparable to that of holding a share.

Under the DFSA, we are required to notify the AFM promptly of any change of 1% or more in our issued and outstanding share capital or voting rights since the previous notification. Other changes in our issued and outstanding share capital or voting rights must be notified to the AFM within eight days after the end of the quarter in which the change occurred. If a person's capital interest or voting rights reaches, exceeds or falls below the above-mentioned

thresholds as a result of a change in our issued and outstanding share capital or voting rights, such person is required to make a notification not later than on the fourth trading day after the AFM has published our notification as described above.

Every holder of 3% or more of our share capital or voting rights who, in relation to its previous notification, reaches, exceeds or falls below any of the above mentioned thresholds as a consequence of a different composition by means of an exchange or conversion into shares or the exercise of rights pursuant to an agreement to acquire voting rights, must notify the AFM at the latest within four trading days.

Furthermore, each director must notify the AFM of each change in the number of shares he or she holds and of each change in the number of votes he or she is entitled to cast in respect of our issued and outstanding share capital, immediately after the relevant change.

The AFM does not issue separate public announcements of the notifications. It does, however, keep a public register of and publishes all notifications made pursuant to the DFSA at its website (www.afm.nl). Third parties can request to be notified automatically by email of changes to the public register in relation to a particular company's shares or a particular notifying party.

Non-compliance with these notification obligations is an economic offence and may lead to criminal prosecution. The AFM may impose administrative penalties for non-compliance, and the publication thereof. In addition, a civil court can impose measures against any person who fails to notify or incorrectly notifies the AFM of matters required to be notified. A claim requiring that such measures be imposed may be instituted by us, or by one or more of our shareholders who alone or together with others represent at least 3% of our issued and outstanding share capital of or voting rights. The measures that the civil court may impose include:

- an order requiring the person with a duty to disclose to make the appropriate disclosure;
- suspension of the right to exercise the voting rights by the person with a duty to disclose for a period of up to three years as determined by the court;
- voiding a resolution adopted by the shareholders at the General Meeting, if the court determines that the resolution would not have been adopted but for the exercise of the voting rights of the person with a duty to disclose, or suspension of a resolution adopted by the shareholders at the General Meeting until the court makes a decision about such voiding; and
- an order to the person with a duty to disclose to refrain, during a period of up to five years as determined by the court, from acquiring shares or voting rights in the company.

Shareholders are advised to consult with their own legal advisors to determine whether the notification obligations apply to them.

Short Positions

Net Short Position

Pursuant to European Union regulation No. 236/2012, each person holding a net short position attaining 0.2% of our issued share capital of must report it to the AFM. Each subsequent increase of this position by 0.1% above 0.2% will also have to be reported. Each net short position equal to 0.5% of our issued share capital and any subsequent increase of that position by 0.1% will be made public via the AFM short selling register. To calculate whether a natural person or legal person has a net short position, their short positions and long positions must be set off. A short transaction in a share can only be contracted if a reasonable case can be made that the shares sold can actually be delivered, which requires confirmation of a third party that the shares have been located. The notification shall be made no later than 15:30 CET on the following trading day.

Gross Short Position

Furthermore, each person holding a gross short position in relation to our issued share capital that reaches, exceeds or falls below one of the following thresholds: 3%, 5%, 10%, 15%, 20%, 25%, 30%, 40%, 50%, 60%, 75% and 95%, must immediately give written notice to the AFM.

If a person's gross short position reaches, exceeds or falls below one of the abovementioned thresholds as a result of a change in our issued share capital, such person is required to make a notification not later than on the fourth trading day after the AFM has published our notification in the public register of the AFM.

The AFM keeps a public register of the short selling notifications. Shareholders are advised to consult with their own legal advisors to determine whether any of the above short selling notification obligations apply to them.

Group Structure

argenx SE is the top entity in our group. argenx SE is the sole shareholder of argenx BVBA, a private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*) incorporated under the laws of Belgium, having its registered seat in Zwijnaarde, Belgium. argenx BVBA is the sole shareholder of argenx US, Inc., a Delaware corporation, and argenx Japan KK, based in Japan.

argenx SE has no other direct or indirect subsidiaries.

argenx SE holds a small minority stake of 1% in Bird Rock Bio, a company incorporated under the laws of Delaware with its registered seat in La Jolla, CA, United States.

Comparison of Dutch Corporate Law, our Articles of Association and Board By-Laws and U.S. Corporate Law

The following comparison between Dutch corporation law, which applies to us, and Delaware corporation law, the law under which many publicly listed corporations in the United States are incorporated, discusses additional matters not otherwise described in this exhibit. Because these statements are summaries, they do not address all aspects of Dutch law that may be relevant to us and our shareholders or all aspects of Delaware law which may differ from Dutch law, and they are not intended to be a complete discussion of the respective rights.

Shareholder Rights

ADS holders are not treated as our shareholders and will not have shareholder rights. ADS holder rights are limited to those under the deposit agreement.

Voting Rights

The Netherlands. In accordance with Dutch law and our Articles of Association, each issued ordinary share confers the right to cast one vote at the General Meeting. Each holder of ordinary shares may cast as many votes as it holds shares. Shares that are held by us or our direct or indirect subsidiaries do not confer the right to vote.

Shareholders may exercise their rights at a General Meeting if they are the holders of our shares on the record date as required by Dutch law, which is currently the 28th day before the day of the General Meeting, and they or their proxy have notified us of their intention to attend the General Meeting in writing or by any other electronic means that can be reproduced on paper ultimately at a date set for that purpose by our board of directors (which date was for the previous General Meetings set on the seventh day prior to the relevant General Meeting), specifying such person's name and the number of shares for which such person may exercise the voting rights and/or meeting rights at such General Meeting. The record date and the manner in which shareholders can register and exercise their rights will be set out in the notice of the meeting.

Delaware. Under the Delaware General Corporation Law, each stockholder is entitled to one vote per share of stock, unless the certificate of incorporation provides otherwise. In addition, the certificate of incorporation may

provide for cumulative voting at all elections of directors of the corporation, or at elections held under specified circumstances. Either the certificate of incorporation or the bylaws may specify the number of shares or the amount of other securities that must be represented at a meeting in order to constitute a quorum, but in no event will a quorum consist of less than one third of the shares entitled to vote at a meeting.

Stockholders as of the record date for the meeting are entitled to vote at the meeting, and the board of directors may fix a record date that is no more than 60 nor less than 10 days before the date of the meeting, and if no record date is set then the record date is the close of business on the day next preceding the day on which notice is given, or if notice is waived then the record date is the close of business on the day next preceding the day on which the meeting is held. The determination of the stockholders of record entitled to notice or to vote at a meeting of stockholders shall apply to any adjournment of the meeting, but the board of directors may fix a new record date for the adjourned meeting.

Shareholder Proposals

The Netherlands. Pursuant to our Articles of Association, extraordinary General Meetings will be held whenever our board of directors deems such to be necessary. Pursuant to Dutch law, one or more shareholders, who jointly represent at least one-tenth of the issued capital may request our board of directors to convene a General Meeting. If our board of directors has not taken the steps necessary to ensure that a General Meeting could be held within the relevant statutory period after the request, the requesting persons may, at his/her/their request, be authorized by Court in preliminary relief proceedings to convene a General Meeting. The court shall disallow the application if it does not appear that the applicants have previously requested our board of directors to convene a General Meeting and our board of directors has not taken the necessary steps so that the General Meeting could be held within six weeks after the request.

Also, the agenda for a General Meeting shall include such items requested by one or more shareholders, and others entitled to attend General Meetings, representing at least 3% of the issued share capital, except where the articles of association state a lower percentage. Our Articles of Association do not state such lower percentage. Requests must be made in writing and received by our board of directors at least 60 days before the day of the convocation of the meeting. In accordance with the DCGC, a shareholder shall exercise the right of putting an item on the agenda only after consulting our board of directors in that respect. If one or more shareholders intends to request that an item be put on the agenda that may result in a change in the company's strategy, our board of directors may invoke a response time of a maximum of 180 days until the day of the General Meeting.

Delaware. Delaware law does not specifically grant stockholders the right to bring business before an annual or special meeting. However, if a Delaware corporation is subject to the SEC's proxy rules, a stockholder who owns at least $2,000 in market value, or 1% of the corporation's securities entitled to vote, may propose a matter for a vote at an annual or special meeting in accordance with those rules.

Action by Written Consent

The Netherlands. Our Articles of Association do not provide for the possibility that shareholders' resolutions can also be adopted in writing without holding a meeting of shareholders. Although permitted by Dutch law, for a listed company, this method of adopting resolutions is not feasible.

Delaware. Although permitted by Delaware law, publicly listed companies do not typically permit stockholders of a corporation to take action by written consent.

Appraisal Rights

The Netherlands. The concept of appraisal rights is not known as such under Dutch law.

However, pursuant to Dutch law a shareholder who for his own account contributes at least 95% of our issued share capital may initiate proceedings against our minority shareholders jointly for the transfer of their shares to the claimant. The proceedings are held before the Enterprise Chamber. The Enterprise Chamber may grant the claim for squeeze out in relation to all minority shareholders and will determine the price to be paid for the shares, if necessary after appointment of one or three experts who will offer an opinion to the Enterprise Chamber on the value to be paid for the shares of the minority shareholders. Once the order to transfer becomes final before the Enterprise Chamber, the person acquiring the shares shall give written notice of the date and place of payment and the price to the holders of the shares to be acquired whose addresses are known to him. Unless the addresses of all of them are known to the acquiring person, such person is required to publish the same in a daily newspaper with a national circulation.

Furthermore, in accordance with the Directive (EU) 2017/1132 of the European Parliament and the Council of June 14, 2017 on cross-border mergers of limited liability companies, Dutch law provides that, to the extent that the acquiring company in a cross-border merger is organized under the laws of another European Union member state, a shareholder of a Dutch disappearing company who has voted against the cross-border merger may file a claim with the Dutch company for compensation. Such compensation to be determined by one or more independent experts. The shares of such shareholder that are subject to such claim will cease to exist as of the moment of entry into effect of the cross-border merger.

Payment by the acquiring company is only possible if the resolution to approve the cross-border merger by the corporate body of the other company or companies involved in the cross-border merger includes the acceptance of the rights of the shareholders of the Dutch company to oppose the cross-border merger.

Delaware. The Delaware General Corporation Law provides for stockholder appraisal rights, or the right to demand payment in cash of the judicially determined fair value of the stockholder's shares, in connection with certain mergers and consolidations.

Shareholder Suits

The Netherlands. In the event a third party is liable to a Dutch company, only the company itself can bring a civil action against that party. The individual shareholders do not have the right to bring an action on behalf of the company. Only in case cause for the liability of a third party to the company also constitutes a tortious act directly against a shareholder such shareholder has an individual right of action against such third party in its own name. The Dutch Civil Code provides for the possibility to initiate such actions collectively. A foundation or an association whose objective is to protect the rights of a group of persons having similar interests can institute a collective action. The collective action itself cannot result in an order for payment of monetary damages but may only result in a declaratory judgment (*verklaring voor recht*). In order to obtain compensation for damages, the foundation or association and the defendant may reach—often on the basis of such declaratory judgment—a settlement. A Dutch court may declare the settlement agreement binding upon all the injured parties with an opt-out choice for an individual injured party. An individual injured party may also itself institute a civil claim for damages.

Delaware. Under the Delaware General Corporation Law, a stockholder may bring a derivative action on behalf of the corporation to enforce the rights of the corporation. An individual also may commence a class action suit on behalf of himself and other similarly situated stockholders where the requirements for maintaining a class action under Delaware law have been met. A person may institute and maintain such a suit only if that person was a stockholder at the time of the transaction which is the subject of the suit. In addition, under Delaware case law, the plaintiff normally must be a stockholder at the time of the transaction that is the subject of the suit and throughout the duration of the derivative suit. Delaware law also requires that the derivative plaintiff make a demand on the directors of the corporation to assert the corporate claim before the suit may be prosecuted by the derivative plaintiff in court, unless such a demand would be futile.

Repurchase of Shares

The Netherlands. Under Dutch law, a company such as ours may not subscribe for newly issued shares in its own capital. Such company may, however, subject to certain restrictions of Dutch law and its Articles of Association,

acquire shares in its own capital. We may acquire fully paid shares in our own capital at any time for no valuable consideration. Furthermore, we may repurchase fully paid shares in our own capital if (i) such repurchase would not cause our shareholders' equity to fall below an amount equal to the sum of the paid-up and called-up part of the issued share capital and the reserves we are required to maintain pursuant to applicable law, (ii) we (including our subsidiaries) would thereafter not hold shares or hold a pledge over shares with an aggregate nominal value exceeding 50% of our issued share capital and (iii) our board of directors has been authorized thereto by the shareholders at the General Meeting.

An authorization by the shareholders at the General Meeting to our board of directors for the repurchase of shares can be granted for a maximum period of 18 months. Such authorization must specify the number and class of shares that may be acquired, the manner in which these shares may be acquired and the price range within which the shares may be acquired.

No authorization of the shareholders at the General Meeting is required if ordinary shares are acquired by us with the intention of transferring such ordinary shares to our employees under an applicable employee stock purchase plan.

Delaware. Under the Delaware General Corporation Law, a corporation may purchase or redeem its own shares unless the capital of the corporation is impaired or the purchase or redemption would cause an impairment of the capital of the corporation. A Delaware corporation may, however, purchase or redeem out of capital any of its preferred shares or, if no preferred shares are outstanding, any of its own shares if such shares will be retired upon acquisition and the capital of the corporation will be reduced in accordance with specified limitations.

Anti-takeover Provisions

The Netherlands. Under Dutch law, various protective measures are possible and permissible within the boundaries set by Dutch law and Dutch case law. We have adopted several provisions that may have the effect of making a takeover of our company more difficult or less attractive, including requirements 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.

Delaware. In addition to other aspects of Delaware law governing fiduciary duties of directors during a potential takeover, the Delaware General Corporation Law also contains a business combination statute that protects Delaware companies from hostile takeovers and from actions following the takeover by prohibiting some transactions once an acquirer has gained a significant holding in the corporation.

Section 203 of the Delaware General Corporation Law prohibits "business combinations," including mergers, sales and leases of assets, issuances of securities and similar transactions by a corporation or a subsidiary with an interested stockholder that beneficially owns 15% or more of a corporation's voting stock, within three years after the person becomes an interested stockholder, unless:

- the transaction that will cause the person to become an interested stockholder is approved by the board of directors of the target prior to the transactions;
- after the completion of the transaction in which the person becomes an interested stockholder, the interested stockholder holds at least 85% of the voting stock of the corporation not including shares owned by persons who are directors and officers of interested stockholders and shares owned by specified employee benefit plans; or
- after the person becomes an interested stockholder, the business combination is approved by the board of directors of the corporation and holders of at least 66.67% of the outstanding voting stock, excluding shares held by the interested stockholder.

A Delaware corporation may elect not to be governed by Section 203 by a provision contained in the original certificate of incorporation of the corporation or an amendment to the original certificate of incorporation or to the bylaws of the company, which amendment must be approved by a majority of the shares entitled to vote and may not

be further amended by the board of directors of the corporation. Such an amendment is not effective until twelve months following its adoption.

Inspection of Books and Records

The Netherlands. The board of directors provides the shareholders at the General Meeting in good time with all information that the shareholders require for the exercise of their powers, unless this would be contrary to an overriding interest of us. If the board of directors invokes an overriding interest, it must give reasons.

Delaware. Under the Delaware General Corporation Law, any stockholder may inspect for any proper purpose certain of the corporation's books and records during the corporation's usual hours of business.

Removal of Board Member

The Netherlands. The shareholders at a General Meeting have the authority to suspend or remove members of our board of directors at any time, with or without cause, by means of a resolution passed by a simple majority of the votes cast. Executive directors may also be suspended by our board of directors. A suspension by our board of directors may be discontinued by the shareholders at a General Meeting at any time.

Delaware. Under the Delaware General Corporation Law, any director or the entire board of directors may be removed, with or without cause, by the holders of a majority of the shares then entitled to vote at an election of directors, except (i) unless the certificate of incorporation provides otherwise, in the case of a corporation whose board is classified, stockholders may effect such removal only for cause or (ii) in the case of a corporation having cumulative voting, if less than the entire board of directors is to be removed, no director may be removed without cause if the votes cast against his removal would be sufficient to elect him if then cumulatively voted at an election of the entire board of directors, or, if there are classes of directors, at an election of the class of directors of which he is a part.

Preemptive Rights

The Netherlands. Under Dutch law, in the event of an issuance of ordinary shares or upon a grant of rights to subscribe for ordinary shares, each shareholder will have a pro rata preemptive right in proportion to the aggregate nominal value of the ordinary shares held by such holder (with the exception of ordinary shares to be issued to employees or ordinary shares issued against a contribution other than in cash or the issue of shares to persons exercising a previously granted right to subscribe for shares). A shareholder may exercise preemptive rights during a period of at least two weeks from the date of the announcement of the issue of shares. Under our Articles of Association, the preemptive rights in respect of newly issued ordinary shares may be restricted or excluded by a resolution of the shareholders at the General Meeting upon proposal of our board of directors with the consent of the majority of the non-executive directors.

Our board of directors, with the consent of the majority of the non-executive directors, may restrict or exclude the preemptive rights in respect of newly issued ordinary shares if it has been designated as the authorized body to do so by the shareholders at the General Meeting. Such designation can be granted for a period not exceeding five years. A resolution of the shareholders at the General Meeting to restrict or exclude the preemptive rights or to designate our board of directions as the authorized body to do so requires a two-thirds majority of the votes cast, if less than one half of our issued share capital is represented at the meeting.

Delaware. Under the Delaware General Corporation Law, stockholders have no preemptive rights to subscribe for additional issues of stock or to any security convertible into such stock unless, and to the extent that, such rights are expressly provided for in the certificate of incorporation.

Dividends

The Netherlands. Pursuant to Dutch law and the Articles of Association, the distribution of profits will take place following the adoption of our annual accounts, from which we will determine whether such distribution is permitted. We may only make distributions to the shareholders, whether from profits or from its freely distributable reserves, only insofar as its shareholders' equity exceeds the sum of the paid-up and called-up share capital plus the reserves required to be maintained by Dutch law.

The shareholders at the General Meeting may determine which part of our profits will be added to the reserves in consideration of our reserves and dividends policy. The remaining part of the profits after the addition to the reserves will be at the disposal of the shareholders at the General Meeting. Distributions of dividends will be made pro rata to the nominal value of each share.

Subject to Dutch law and the Articles of Association, our board of directors, with the consent of the majority of the non-executive directors, may resolve to distribute an interim dividend if it determines such interim dividend to be justified by our profits. For this purpose, our board of directors must prepare an interim statement of assets and liabilities. Such interim statement shall show our financial position not earlier than on the first day of the third month before the month in which the resolution to make the interim distribution is announced. An interim dividend can only be paid if (a) an interim statement of assets and liabilities is drawn up showing that the funds available for distribution are sufficient, and (b) our shareholders' equity exceeds the sum of the paid-up and called-up share capital plus the reserves required to be maintained by Dutch law.

Our board of directors, with the consent of the majority of the non-executive directors, may resolve that we make distributions to shareholders from one or more of its freely distributable reserves, other than by way of profit distribution, subject to the due observance of our policy on reserves and dividends. Any such distributions will be made pro rata to the nominal value of each share.

Dividends and other distributions shall be made payable not later than the date determined by our board of directors. Claims to dividends and other distribution not made within five years from the date that such dividends or distributions became payable, will lapse and any such amounts will be considered to have been forfeited to us (*verjaring*).

Delaware. Under the Delaware General Corporation Law, a Delaware corporation may pay dividends out of its surplus (the excess of net assets over capital), or in case there is no surplus, out of its net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year (provided that the amount of the capital of the corporation is not less than the aggregate amount of the capital represented by the issued and outstanding stock of all classes having a preference upon the distribution of assets). In determining the amount of surplus of a Delaware corporation, the assets of the corporation, including stock of subsidiaries owned by the corporation, must be valued at their fair market value as determined by the board of directors, without regard to their historical book value. Dividends may be paid in the form of ordinary shares, property or cash.

Shareholder Vote on Certain Reorganizations

The Netherlands. Under Dutch law, the shareholders at the General Meeting must approve resolutions of our board of directors relating to a significant change in the identity or the character of the company or the business of the company, which includes:

- a transfer of the business or virtually the entire business to a third party;
- the entry into or termination of a long-term cooperation of the company or a subsidiary with another legal entity or company or as a fully liable partner in a limited partnership or general partnership, if such cooperation or termination is of a far-reaching significance for the company; and
- the acquisition or divestment by the company or a subsidiary of a participating interest in the capital of a company having a value of at least one third of the amount of its assets according to its statement of financial position and explanatory notes or, if the company prepares a consolidated statement of financial

position, according to its consolidated statement of financial position and explanatory notes in the last adopted annual accounts of the company.

Under Dutch law, a shareholder who, for its own account, owns shares representing at least 95% of the nominal value of a company's issued share capital may institute proceedings against the company's other shareholders jointly for the transfer of their shares to that shareholder. The proceedings are held before the Enterprise Chamber, which may grant the claim for squeeze-out in relation to all minority shareholders and will determine the price to be paid for the shares, if necessary after appointment of experts who will offer an opinion to the Enterprise Chamber on the value of the shares.

Delaware. Under the Delaware General Corporation Law, the vote of a majority of the outstanding shares of capital stock entitled to vote thereon generally is necessary to approve a merger or consolidation or the sale of all or substantially all of the assets of a corporation. The Delaware General Corporation Law permits a corporation to include in its certificate of incorporation a provision requiring for any corporate action the vote of a larger portion of the stock or of any class or series of stock than would otherwise be required.

Under the Delaware General Corporation Law, no vote of the stockholders of a surviving corporation to a merger is needed, however, unless required by the certificate of incorporation, if (i) the agreement of merger does not amend in any respect the certificate of incorporation of the surviving corporation, (ii) the shares of stock of the surviving corporation are not changed in the merger and (iii) the number of shares of common stock of the surviving corporation into which any other shares, securities or obligations to be issued in the merger may be converted does not exceed 20% of the surviving corporation's common stock outstanding immediately prior to the effective date of the merger. In addition, stockholders may not be entitled to vote in certain mergers with other corporations that own 90% or more of the outstanding shares of each class of stock of such corporation, but the stockholders will be entitled to appraisal rights.

Limitations on the Right to Own Securities

Neither Dutch law nor our Articles of Association impose any general limitation on the right of non-residents or foreign persons to hold our securities or exercise voting rights on our securities other than those limitations that would generally apply to all shareholders.

Transfer Agent and Registrar

The transfer agent and registrar for the ADSs is The Bank of New York Mellon.

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

COLLABORATION AND LICENSE AGREEMENT

between

ARGENX BV

and

ZAI AUTO IMMUNE (HONG KONG) LIMITED

Dated as of 6 January 2021

TABLE OF CONTENTS

SCHEDULES:

COLLABORATION AND LICENSE AGREEMENT

This Collaboration and License Agreement (the "**Agreement**") is made and entered into effective as of 6 January 2021 (the "**Effective Date**") by and between argenx BV, a private limited company organized under the laws of Belgium with its principal place of business at Industriepark Zwijnaarde 7, 9052 Zwijnaarde (Ghent), Belgium ("**Licensor**"), and Zai Auto Immune (Hong Kong) Limited, a Hong Kong company, with an address at Room 2301, 23F, Island Place Tower, 510 King's Road, North Point, Hong Kong ("**Licensee**") and, solely with respect to Section 15.16 Zai Lab Limited, a China company, with an address at 4F, Bldg 1, Jinchuang Plaza 4560 Jinke Rd Shanghai, China, 201210 ("**Parent**"). Licensor and Licensee are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, Licensor Controls (as defined herein) certain intellectual property rights with respect to the Licensed Compound (as defined herein) and Licensed Products (as defined herein) in the Territory (as defined herein);

WHEREAS, the Parties wish to collaborate on the development and commercialization of the Licensed Products in the Territory, in each case in accordance with the terms and conditions set forth below, taking into account the strong wish of the Licensor to have the commercialisation of the Licensed Product start as soon as possible in the Territory; and

WHEREAS, Licensor and Licensee wish to collaborate on the development and commercialization of the Licensed Products in the Territory, in each case in accordance with the terms and conditions set forth below.

NOW, THEREFORE, in consideration of the premises and the mutual promises and conditions hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

ARTICLE 1

DEFINITIONS

Unless otherwise specifically provided herein, the following terms shall have the following meanings:

1.1. "**Accounting Standards**" means, (a) with respect to Licensee, that Licensee shall maintain records and books of accounts in accordance with United States Generally Accepted Accounting Principles (GAAP), consistently applied and (b) with respect to Licensor, that Licensor shall maintain records and books of accounts in accordance with International Financial Reporting Standards (IFRS), consistently applied.

1.2. "**Acquiring Person**" has the meaning set forth in Section 7.8.3.

1.3. "**Additional Indication**" means, with respect to Licensed Products, each indication in the Field other than the Initial Indications, including any indication in which Licensed Products may be used in combination with one or more products of the Licensee.

1.4. "**Affiliate**" means, with respect to a Person, any subsidiary or any other Person that, directly or indirectly, through one or more intermediaries, is controlled by or is under common control with such Person. For purposes of this definition, "**control**" and, with correlative meanings, the terms "**controlled by**" and "**under common control with**" means (a) the possession, directly or indirectly, of the power to direct the management or policies of a business entity, whether through the ownership of Voting Stock, by contract relating to voting rights or corporate governance, or otherwise; or (b) the ownership, directly or indirectly, of more than fifty percent (50%) of the Voting Stock or other ownership interest of a business entity (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity).

1.5. "**Agreement**" has the meaning set forth in the preamble hereto.

1.6. "**Alliance Manager**" has the meaning set forth in Section 2.11.

1.7. "**Applicable Law**" means federal, state, local, national and supra-national laws, statutes, rules, and regulations, including any rules, regulations or other requirements of the Regulatory Authorities, major national securities exchanges or major securities listing organizations, that may be in effect from time to time during the Term and applicable to a particular activity or jurisdiction hereunder.

1.8. "**Biosimilar Product**" means, with respect to a given Licensed Product in a particular jurisdiction after Regulatory Approval of such Licensed Product in such jurisdiction, a Third Party biologic product (a) whose licensing, approval, or marketing authorization relies in whole or in part on (i) a prior Regulatory Approval granted such Licensed Product or (ii) any data generated in support of a prior Regulatory Approval granted such Licensed Product, and (b) is determined by the competent Regulatory Authority of such jurisdiction to be interchangeable with the respective Licensed Product, including in terms of quality, safety, efficacy and dosing regimen.

1.9. "**Binding Forecast**" has the meaning set forth in Section 5.3;

1.10. "**Board of Directors**" has the meaning set forth in the definition of Change of Control.

1.11. "**Breaching Party**" has the meaning set forth in Section 13.2.1.

1.12. "**Bundling Sale**" has the meaning set forth in Section 8.4.7.

1.13. "**Business Day**" means a day other than a Saturday or Sunday on which banking institutions in Ghent, Belgium and Shanghai, the PRC are open for business.

1.14. "**Calendar Quarter**" means each successive period of three (3) months of the Gregorian calendar commencing on January 1, April 1, July 1 and October 1, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date, and the last Calendar Quarter shall end on the last day of the Term.

1.15. "**Calendar Year**" means each successive period of twelve (12) months of the Gregorian calendar commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the year in which the Effective Date occurs and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term.

1.16. "**Change of Control**" with respect to either Party or a Controlling Entity of such Party shall be deemed to have occurred if any of the following occurs during the Term:

1.16.1. any "person" or "group" (as defined below) (a) is or becomes the "beneficial owner" (as defined below), directly or indirectly, of shares of capital stock or other interests (including partnership interests) of such Party or its Controlling Entity then outstanding and normally entitled (without regard to the occurrence of any contingency) to vote in the election of the directors, managers or similar supervisory positions ("**Voting Stock**") of such Party or its Controlling Entity representing fifty percent (50%) or more of the total voting power of all outstanding classes of Voting Stock of such Party or its Controlling Entity or (b) has the power, directly or indirectly, to elect a majority of the members of such Party's or its Controlling Entity's board of directors, or similar governing body ("**Board of Directors**"); the Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management or policies of such entity; or

1.16.2. such Party or its Controlling Entity enters into a merger, consolidation or similar transaction with another Person (whether or not such Party is the surviving entity) and as a result of such merger, consolidation or similar transaction (a) the members of the Board of Directors of such Party or its Controlling Entity immediately prior to such transaction constitute less than a majority of the members of the Board of Directors of such Party or its Controlling Entity or such surviving Person immediately following such transaction or (b) the Persons that beneficially owned, directly or indirectly, the shares of Voting Stock of such Party or its Controlling Entity immediately prior to such transaction cease to beneficially own, directly or indirectly, shares of Voting Stock of such Party or its Controlling Entity representing at least a majority of the total voting power of all outstanding classes of Voting Stock of the surviving Person in substantially the same proportions as their ownership of Voting Stock of such Party or its Controlling Entity immediately prior to such transaction; or

1.16.3. such Party sells or transfers to any Third Party, in one (1) or more related transactions, properties or assets representing all or substantially all of such Party's assets to which this Agreement relates; or

1.16.4. the holders of capital stock of such Party or its Controlling Entity approve a plan or proposal for the liquidation or dissolution of such Party.

For the purpose of this definition of Change in Control: (a) "**person**" and "**group**" have the meanings given such terms under Section 13(d) and 14(d) of the United States Securities

Exchange Act of 1934 and the term "**group**" includes any group acting for the purpose of acquiring, holding or disposing of securities within the meaning of Rule 13d-5(b)(1) under the said Act; (b) a "**beneficial owner**" shall be determined in accordance with Rule 13d-3 under the aforesaid Act; and (c) the terms "**beneficially owned**" and "**beneficially own**" shall have meanings correlative to that of "**beneficial owner**."

1.17. "**Clinical Data**" means all Information with respect to the Licensed Compound or any Licensed Product made, collected, or otherwise generated under or in connection with a Clinical Trial, including any data (including raw data), reports, and results with respect thereto.

1.18. "**Clinical Trial**" means a Clinical Phase I Trial, Clinical Phase II Trial, or Clinical Phase III Trial, and such other tests and studies in human subjects that are required by Applicable Law, or otherwise recommended by the Regulatory Authorities, to obtain or maintain Regulatory Approvals for a Licensed Product for one (1) or more indications, including tests or studies that are intended to expand the Product Labeling for such Licensed Product with respect to such indication.

1.19. "**Clinical Phase I Trial**" means a study in humans which provides for the first administration to humans of a product, conducted in healthy volunteers or patients to obtain information on product safety, tolerability, pharmacological activity or pharmacokinetics.

1.20. "**Clinical Phase II Trial**" means a clinical study (other than a Clinical Phase I Trial) in humans of the safety, dose ranging and efficacy of a product, which is prospectively designed to generate sufficient data (if successful) to commence pivotal studies/Clinical Phase III Trials.

1.21. "**Clinical Phase III Trial**" means a controlled, and usually multicenter, clinical study in humans of the efficacy and safety of a product, which is prospectively designed to demonstrate statistically whether such product is effective and safe for use in humans in the indication being investigated in a manner sufficient to submit an application to obtain Regulatory Approval to market such product.

1.22. "**COGS**" has the meaning ascribed thereto in **Schedule 1.22**.

1.23. "**Commercialization**" means any and all activities directed to the preparation for sale of, offering for sale of, or sale of Licensed Products, including activities related to marketing, promoting, distributing, and importing such Licensed Products, and interacting with Regulatory Authorities regarding any of the foregoing. For clarity, Commercialization does not include Manufacturing. When used as a verb, "**to Commercialize**" and "**Commercializing**" means to engage in Commercialization, and "**Commercialized**" has a corresponding meaning.

1.24. "**Commercially Reasonable Efforts**" means, with respect to the performance of Development, Commercialization or other applicable activities with respect to the Licensed Products by Licensee, the carrying out of such activities using efforts and resources comparable to the efforts and resources commonly used in the biopharmaceutical industry for

products of similar market potential at a similar stage in development or product life (without regard to the particular circumstances of Licensee, including any other product opportunities of Licensee) taking into account relevant factors such as safety, regulatory issues, intellectual property issues, and reimbursement. "Commercially Reasonable Efforts" shall be determined on a jurisdiction-by-jurisdiction and indication-by-indication basis, Commercially Reasonable Efforts require, with respect to the applicable obligation, that Licensee shall **[***]**.

1.25. "**Commercial Supply Agreement**" has the meaning set forth in Section 5.3.

1.26. "**Committee**" means the JSC, the JDC, the JMC, the JCC, the JFC or another Sub-Committee (together, the "**Committees**").

1.27. "**Competing Product**" means any product that **[***]** mode of action.

1.28. "**Compliance Self-Audit**" has the meaning set forth in Section 6.10.

1.29. "**Confidential Information**" means any technical, business, or other information or data provided orally, visually, in writing or other form by or on behalf of one Party to the other Party in connection with this Agreement, whether prior to, on, or after the Effective Date, including information relating to the terms of this Agreement, the Licensed Compound or any Licensed Product, any Exploitation of the Licensed Compound or Licensed Products, any Information with respect thereto developed by or on behalf of a Party or its Affiliates, or the scientific, regulatory or business affairs or other activities of either Party. The Licensed Know-How, Product Improvements and the Regulatory Data owned by Licensor pursuant to the terms of this Agreement are deemed to be Licensor's Confidential Information and Licensee is deemed to be the receiving Party and Licensor the disclosing Party with respect thereto. The existence and terms of this Agreement, are the Confidential Information of each Party, with each Party being deemed the receiving Party of such Confidential Information.

1.30. "**Control**" means, with respect to any item of Information, Regulatory Documentation, material, Patent, or other property right, the possession of the right, whether directly or indirectly, and whether by ownership, license, covenant not to sue or otherwise (other than by operation of the license and other grants in ARTICLE 7), to grant a license, sublicense or other right (including the right to reference Regulatory Documentation) to or under such Information, Regulatory Documentation, material, Patent, or other property right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party.

1.31. "**Controlling Entity**" means, with respect to a Party, any Person that controls such Party. For purposes of this definition, "control" means (a) the possession, directly or indirectly, of the power to direct the management or policies of a business entity, whether through the ownership of Voting Stock, by contract relating to voting rights or corporate governance, or otherwise; or (b) the ownership, directly or indirectly, of fifty percent (50%) or more of the Voting Stock or other ownership interest of a business entity (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity).

1.32. "**CMO**" means a contract manufacturing organization.

1.33. "**CRO**" means a contract research organization.

1.34. "**CTA**" means an application filed with a Regulatory Authority for authorization to commence human clinical studies, including (a) a Clinical Trial Application as defined in the PRC Drug Administration Law or an equivalent in other jurisdictions, and (b) all supplements, amendments, variations, extensions and renewals thereof that may be filed with respect to the foregoing.

1.35. "**Default Notice**" has the meaning set forth in Section 13.2.1(a).

1.36. "**Development**" means with regard to the Licensed Compound and the Licensed Product all activities related to research, pre-clinical and other non-clinical testing, test method development and stability testing, toxicology, formulation, process development, Clinical Trials, statistical analysis and report writing, the preparation and submission of Drug Approval Applications, regulatory affairs with respect to any of the foregoing, including the preparation and submission of CTAs, the maintenance of a pharmacovigilance and safety database, and all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining a Regulatory Approval. For clarity, Development does not include Manufacturing. When used as a verb, "**Develop**" means to engage in Development.

1.37. "**Development Plan**" means a development plan setting forth in reasonable detail all Development activities to be performed by Licensee (a) to seek, obtain and maintain Regulatory Approvals for Licensed Products in the Territory, and (b) with respect to its responsibilities to perform Development activities for Global Trials in the Territory; which plan shall include in reasonable detail all items listed in Section 3.2.1.

1.38. "**Dollars**" or "**$**" means United States Dollars.

1.39. "**Drug Approval Application**" means an application filed with a Regulatory Authority for the approval of a pharmaceutical product to be marketed in the Territory.

1.40. "**Effective Date**" means the effective date of this Agreement as set forth in the preamble hereto.

1.41. "**EMA**" means the European Medicines Agency, and any successor agency(ies) or authority having substantially the same function.

1.42. "**Exploit**" or "**Exploitation**" means to make, have made, import, export, use, have used, sell, have sold, or offer for sale, including to Develop, Commercialize, register, modify, enhance, improve, Manufacture, have Manufactured, hold, or keep (whether for disposal or otherwise), or otherwise dispose of.

1.43. "**FcRn**" means the neonatal Fc receptor (UniProt ID: P55899).

1.44. "**FDA**" means the United States Food and Drug Administration, and any successor agency(ies) or authority having substantially the same function.

1.45. "**Field**" means all uses of the Licensed Products for any preventative or therapeutic indications, in humans and animals.

1.46. "**First Commercial Sale**" means, with respect to a given Licensed Product and a given jurisdiction, the first commercial sale for monetary value for use or consumption by the end user in an arm's length transaction of such Licensed Product to a Third Party in such jurisdiction after Regulatory Approval for such Licensed Product has been obtained in such jurisdiction. "First Commercial Sale" will not include any distribution or other sale solely for patient assistance, named patient use, compassionate use, or other patient access programs, non-registrational or registrational studies or similar programs or studies, in each case where a Licensed Product is supplied without charge or at the actual Manufacturing cost thereof (without allocation of indirect costs or any markup).

1.47. "**Global Marketing Guidelines**" has the meaning set forth in Section 6.5.

1.48. "**Global Trial**" means Development activities related to a Clinical Trial for a Licensed Product that are (a) conducted outside the Territory, or both inside and outside the Territory, and (b) are intended to support Regulatory Filings both inside and outside the Territory.

1.49. "**Global Trial Plan**" has the meaning set forth in Section 3.3.1.

1.50. "**Good Clinical Practice**" or "**GCP**" means, in respect of a Clinical Trial, the highest of the then current standards required by Applicable Law of: (a) the European Union, including Directive 2001/20/EC and guidance published by the European Commission or EMA in relation to such Directive; (b) the United States, including the provisions of Title 21 of the U.S. Code of Federal Regulations (including Parts 11, 50, 54, 56, 312, 314, 320, 601 and 610); (c) Japan; (d) the People's Republic of China; or (e) such other countries in which a Licensed Product is tested.

1.51. "**Good Laboratory Practice**" or "**GLP**" means, in respect of laboratory activities, the highest of the then current standards required by Applicable Law of: (a) the European Union, including the Directive 2004/9/EC, Directive 2004/10/EC, guidance published by the European Commission or EMA in relation to such Directives and any local laws, rules and regulations that implement such Directives and guidance; (b) the United States, including the FDA's Good Laboratory Practice regulations at 21 C.F.R. Part 58; (c) Japan; (d) the People's Republic of China; or (e) such other countries in which a Licensed Product is tested.

1.52. [***].

1.53. "**Indemnification Claim Notice**" has the meaning set forth in Section 12.3.

1.54. "**Indemnified Party**" has the meaning set forth in Section 12.3.

1.55. "**Information**" means all knowledge of a technical, scientific, business and other nature, including know-how, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and other material, Regulatory Data, and other biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols, reagents (e.g., plasmids, proteins, cell lines, assays and compounds) and biological methodology; in each case (whether or not confidential, proprietary, patented or patentable, of commercial advantage or not) in written, electronic or any other form now known or hereafter developed.

1.56. "**Initial Indications**" means the indications set out in the initial Development Plan attached hereto as **Schedule 3.2.1**.

1.57. "**In-licensing Agreements**" means the **[***]**.

1.58. "**JCC**" has the meaning set forth in Section 2.4.

1.59. "**JDC**" has the meaning set forth in Section 2.2.

1.60. "**JFC**" has the meaning set forth in Section 2.5.

1.61. "**JMC**" has the meaning set forth in Section 2.3.

1.62. "**JSC**" has the meaning set forth in Section 2.1.

1.63. "**Joint Program IP**" has the meaning set forth in Section 9.1.2(c).

1.64. "**Joint Patents**" means Patents claiming Joint Program IP.

1.65. "**Licensed Compound**" means Licensor's proprietary antibody fragment known as efgartigimod, an FcRn blocker, as more fully set forth in **Schedule 1.65**. The definition of Licensed Compound does not include any **[***]**.

1.66. "**Licensee**" has the meaning set forth in the preamble hereto.

1.67. "**Licensee Indemnitees**" has the meaning set forth in Section 12.2.

1.68. "**Licensed Know-How**" any Information that is Controlled by Licensor or any of its Affiliates as of the Effective Date or, subject to Sections 7.7.3 and 15.3.2, during the Term the practice of which is necessary or useful for, or that is actually used in, the Development or Commercialization of Licensed Compound or Licensed Products.

1.69. "**Licensed Patents**" means all Patents that (a) are owned or Controlled by Licensor or any of its Affiliates as of the Effective Date or, subject to Sections 7.7.3 and 15.3.2, at any time during the Term (including Licensor's interests in Joint Patents), and (b) (i) claim the composition of matter or a method of use of the Licensed Compound or a Licensed Product or the

Manufacture thereof, or (ii) are necessary or reasonably useful for the Development or Commercialization of the Licensed Compound or the Licensed Products in the Field in the Territory. The Licensed Patents existing at the Effective Date are listed in **Schedule 1.69**.

1.70. "**Licensed Product**" means any biopharmaceutical product containing the Licensed Compound as an active pharmaceutical ingredient, alone or in combination with one (1) or more other active ingredients (in the same formulation), in any and all forms, presentations, delivery systems, dosages, and formulations.

1.71. "**Licensed Technology**" means the Licensed Patents and the Licensed Know-How.

1.72. "**Licensor**" has the meaning set forth in the preamble hereto.

1.73. "**Licensor Indemnitees**" has the meaning set forth in Section 12.1.

1.74. "**Lonza Agreement**" means that certain Multi-Product License Agreement between Lonza Sales AG and arGEN-X N.V. (currently argenx SE) dated February 4, 2015.

1.75. "**Losses**" has the meaning set forth in Section 12.1.

1.76. "**Manufacture**" and "**Manufacturing**" means all activities related to the synthesis, making, production, processing, purifying, filling, finishing, packaging, labeling, shipping, and holding of the Licensed Compound, any Licensed Product, or any intermediate thereof, including process development, process qualification and validation, scale-up, pre-clinical, clinical and commercial production and analytic development, product characterization, stability testing, quality assurance, and quality control.

1.77. "**Net Sales**" means the gross amounts invoiced or otherwise billed (or, if not invoiced or billed, received as barter, non-cash consideration or otherwise), by Licensee, its Affiliates and sublicensees in connection with the sale, lease or other transfer for value of Licensed Products to Third Parties; less (a) amounts actually allowed or credited for **[***]** (to the extent not already reflected in or deducted from the gross amount invoiced), excluding **[***]**, (b) packing costs, insurance costs, freight out, transportation costs, VAT and import duties imposed on the transaction (c) wholesaler, cash discounts and distributor costs in amounts customary in the trade to the extent actually granted or incurred, included in the invoice, separately itemized on the invoice and not already reflected in or deducted from in the gross amount invoiced, (d) bad debt written off under Accounting Standards, **[***]** with reasonable collection efforts and added back if collected, in each case (a), (b), (c), and (d) to the extent allocable to the Licensed Products; provided that, in no event (i) shall the **[***]** (ii) shall any item of deduction be counted more than once and (iii) shall VAT be deducted for the purposes of calculating Net Sales if and to the extent such amounts are finally reimbursable to Licensee. In addition, in determining Net Sales, the following shall apply:

1.77.1. All of the foregoing deductions must be calculated in accordance with then current Accounting Standards, consistently applied, during the applicable calculation period throughout the selling, leasing or otherwise transferring party's organization.

1.77.2. Net Sales shall not include sales between or among Licensee and its Affiliates or subcontractors except if for end use.

1.77.3. Any discounts, rebates, chargebacks and other deductions will be fairly and equitably allocated to the Licensed Products, as applicable, and other products or processes of Licensee and its Affiliates or subcontractors such that a Licensed Product, as applicable, does not bear a disproportionate portion of any such deductions.

1.77.4. For purposes of calculating the Net Sales of any Licensed Products sold, leased or transferred, in exchange for consideration other than for cash in any jurisdiction, the price for such Licensed Products, as applicable, will equal the weighted average price of such Licensed Products, as applicable, that are sold for cash in such jurisdiction during the prior Calendar Year (or, if none, the average price of such Licensed Products, as applicable, that are sold for cash in the Territory during the applicable Calendar Quarter) in similar quantities.

For clarity, no deductions from Net Sales shall be made (a) for commissions paid to individuals, whether they are independent sales agents or employees or (b) for the cost of collections.

1.78. "**New Global Trial**" has the meaning set forth in Section 3.3.1(a).

1.79. "**NMPA**" means the Chinese National Medical Products Administration, and any successor agency(ies) or authority(ies) having substantially the same function.

1.80. "**Non-Breaching Party**" has the meaning set forth in Section 13.2.1.

1.81. "**Non-Cooperative Jurisdiction**" means a jurisdiction that is a jurisdiction with no taxation or a low taxation or a non-cooperative jurisdiction, all within the meaning of Article 307, §1/2 of the Belgian Income Tax Code 1992).

1.82. "**Parent**" has the meaning set forth in the preamble hereto.

1.83. "**Party**" and "**Parties**" has the meaning set forth in the preamble hereto.

1.84. "**Patents**" means (a) all national, regional and international patents and patent applications, including provisional patent applications; (b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, provisionals and continued prosecution applications; (c) any and all patents that have issued or in the future issue from the foregoing patent applications ((a) and (b)), including utility models, petty patents and design patents and certificates of invention; (d) any and all extensions or restorations secured by existing or future extension or restoration mechanisms, including revalidations,

reissues, renewals, substitutions, re-examinations and extensions (including any patent term adjustments, patent term extensions, supplementary protection certificates and the like) of the foregoing patents or patent applications ((a), (b), and (c)); and (e) any similar rights, including so-called pipeline protection or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any of such foregoing patent applications and patents.

1.85. "**Person**" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

1.86. "**Pharmacovigilance Agreement**" has the meaning set forth in Section 4.8.

1.87. "**Product Improvement**" has the meaning set forth in Section 9.1.2(a).

1.88. "**Product Infringement**" has the meaning set forth in Section 9.3.1.

1.89. "**Product Labeling**" means, with respect to a Licensed Product in a jurisdiction in the Territory, (a) the Regulatory Authority-approved full prescribing information for such Licensed Product for such jurisdiction, including any required patient information, and (b) all labels and other written, printed, or graphic matter upon a container, wrapper, or any package insert utilized with or for such Licensed Product in such jurisdiction.

1.90. "**Product Trademarks**" means the Trademark(s) designated by Licensor for use by Licensee for the Development or Commercialization of Licensed Products in the Territory in accordance with the terms of this Agreement and Licensor's global brand strategy, and any registrations thereof or any pending applications relating thereto in the Territory (excluding, in any event, any trademarks, service marks, names or logos that include any corporate name or logo of the Parties or their Affiliates).

1.91. "**Program IP**" means all Information and inventions that are conceived, discovered, developed, or otherwise made by or on behalf of either or both Parties (or their respective Affiliates or subcontractors) in the performance of activities under this Agreement, whether or not patented or patentable, and any and all Patents and other intellectual property rights with respect thereto.

1.92. "**Publication**" means any publication or presentation in relation to Development activities for Licensed Products.

1.93. "**Quality Agreement**" shall mean a quality agreement setting out further administrative, technical and quality provisions regarding the subject of such quality agreement, pertaining to Manufacture and supply of Licensed Product (for Development or Commercialization purposes or the conduct of Development activities, as applicable), GCP activities or pharmacovigilance activities including any intermediary version thereof.

1.94. [***].

1.95. "**Regulatory Approval**" means, with respect to a jurisdiction, any and all approvals, licenses, registrations, or authorizations of any Regulatory Authority necessary to Commercialize a Licensed Compound or Licensed Product in such jurisdiction, including, where applicable, (a) pricing or reimbursement approval in such jurisdiction, (b) pre- and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto), and (c) approval of Product Labeling.

1.96. "**Regulatory Authority**" means any applicable supra-national, federal, national, regional, state, provincial, or local governmental or regulatory authority, agency, department, bureau, commission, council, or other entities (e.g., the NMPA, EMA or FDA) regulating or otherwise exercising authority with respect to activities contemplated in this Agreement, including the Exploitation of the Licensed Compound or Licensed Products in the Territory.

1.97. "**Regulatory Data**" means all non-clinical data, Clinical Data and other data contained in Regulatory Documentation.

1.98. "**Regulatory Documentation**" means all (a) Regulatory Filings and Regulatory Approvals, (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes of calls and in-person meetings and official contact reports relating to any communications with any Regulatory Authority) and adverse event files, and (c) Clinical Data and data contained or relied upon in any of the foregoing, in each case ((a), (b), and (c)) relating to a Licensed Compound or Licensed Products.

1.99. "**Regulatory Exclusivity**" means, with respect to a Licensed Product in a jurisdiction in the Territory, any additional market protection, other than Patent protection, granted by a Regulatory Authority for such Licensed Product in such jurisdiction which confers an exclusive Commercialization period during which Licensee can exclusively market and sell such Licensed Product in such jurisdiction through such regulatory exclusivity right.

1.100. "**Regulatory Filings**" means any filing with any Regulatory Authority with respect to the Development, Manufacture or Commercialization of the Licensed Compound or a Licensed Product. Unless expressly provided otherwise, Regulatory Filings include CTAs and Drug Approval Applications.

1.101. "**Royalty Term**" has the meaning set forth in Section 8.4.2.

1.102. "**Segregate**" means, with respect to a Competing Product, to segregate the research, development, manufacture, and commercialization activities relating to such Competing Product from the Development, Manufacture, and Commercialization activities with respect to the Licensed Compound and the Licensed Product under this Agreement, including by ensuring that: (a) no personnel involved in performing the research, development, manufacture, and commercialization, as applicable, of such Competing Product have access to non-public plans or non-public information relating to the Development, Manufacture, and Commercialization of the

Licensed Compound or the Licensed Product or any other relevant Confidential Information of the applicable Party; and (b) no personnel involved in performing the Development, Manufacture, and Commercialization of the Licensed Compound or the Licensed Product have access to non-public plans or information relating to the research, development, manufacture, and commercialization of such Competing Product; provided, that, in either case ((a) or (b)), senior management personnel may review and evaluate plans and information regarding the research, development, manufacture, and commercialization of such Competing Product solely in connection with monitoring the progress of products and to make portfolio decision-making among product opportunities.

1.103. "**Senior Officer**" means, with respect to Licensor, its Chief Executive Officer (or its designee and direct report), and with respect to Licensee, its Chief Executive Officer (or its designee and direct report).

1.104. "**Share Issuance Agreement**" means the Share Issuance Agreement attached hereto as **Schedule 8.1**.

1.105. "**Sole Program IP**" has the meaning set forth in Section 9.1.2(b).

1.106. "**Sole Program Patents**" means Patents claiming Sole Program IP.

1.107. "**Sub-Committee**" has the meaning set forth in Section 2.6.

1.108. "**Subcontractable Affiliate**" means with regard to Licensee, any Affiliate that is controlled directly or indirectly by Licensee or Parent (as "controlled by" is defined in Section 1.4).

1.109. "**Sublicensable Affiliate**" means with regard to Licensee, any Affiliate that directly or indirectly controls Licensee or which is directly or indirectly controlled by Licensee, but expressly excluding any Affiliates under common control with Licensee (as "control", "controlled by" and "under common control with" are defined in Section 1.4).

1.110. "**Term**" has the meaning set forth in Section 13.1.

1.111. "**Territory**" means the People's Republic of China ("**PRC**"), Hong Kong, Macau and Taiwan.

1.112. "**Territory Marketing Materials**" has the meaning set forth in Section 6.5.

1.113. "**Territory-specific PoC Trials**" means any Clinical Phase I Trial and Clinical Phase II Trial for a Licensed Product that is designed to show clinical proof of concept for a new indication, and for which all or substantially all of the activities are conducted in the Territory.

1.114. "**Territory-specific Trials**" means any Clinical Trial for a Licensed Product for which all or substantially all of the activities are conducted in the Territory for

obtaining Regulatory Approval for such Licensed Product in one (1) or more indications in the Field in the Territory, excluding any Territory-specific PoC Trials.

1.115. "**Third Party**" means any Person other than Licensor, Licensee and their respective Affiliates.

1.116. "**Third Party Claims**" has the meaning set forth in Section 12.1.

1.117. "**Trademark**" means any word, name, symbol, color, designation or device or any combination thereof that functions as a source identifier, including any trademark, trade dress, brand mark, service mark, trade name, brand name, logo, business symbol or domain names, whether or not registered.

1.118. "**United States**" or "**U.S.**" means the United States of America and its territories and possessions (including the District of Columbia and Puerto Rico).

1.119. **[***]** means that certain patent license agreement **[***].**

1.120. "**Valid Claim**" means (a) a claim of an issued and unexpired Patent within the Licensed Patents (including the Joint Patents) that has not (i) irretrievably lapsed or expired, irretrievably been abandoned, or irretrievably been disclaimed; or (ii) been held invalid, unenforceable, or non-patentable by a court or other appropriate body that has competent jurisdiction, such holding being final and unappealable or unappealed within the time allowed for appeal, or (b) a claim in a pending Patent application that is included in the Licensed Patents that is being prosecuted in good faith and has been pending (from the earliest priority date) for ten (10) years or less and that has not been abandoned or finally disallowed without the possibility of appeal or re-filing of the application.

1.121. "**VAT and Indirect Taxes**" means any value added, sales, purchase, turnover or consumption tax as may be applicable in any relevant jurisdiction.

1.122. "**Voting Stock**" has the meaning set forth in the definition of Change of Control.

1.123. "**Withholding Income Tax**" has the meaning set forth in Section 8.7.2.

1.124. "**Withholding Tax**" has the meaning set forth in Section 8.7.2.

ARTICLE 2

COLLABORATION MANAGEMENT

2.1. Joint Steering Committee. Within **[***]** days following the Effective Date, the Parties shall establish a joint steering committee (the "**JSC**"). The JSC shall include senior executives of each Party. The JSC shall: (a) approve updates and amendments to the Development Plan (including timelines and budgets); (b) monitor the activities of the other Committees; (c) resolve any dispute referred to it by a Committee in accordance with Section 2.9;

and (d) perform such other functions that are expressly delegated to the JSC in this Agreement or as mutually agreed by the Parties in writing.

2.2. Joint Development Committee. Within **[***]** days following the Effective Date, the Parties shall establish a joint development committee (the "**JDC**"). JDC shall include individuals from each Party with reasonable expertise in the areas of product development, clinical development and regulatory matters. The JDC shall be the forum for discussion of all Development related activities in the Territory, and shall: (a) oversee and monitor the Development activities for Licensed Products in the Territory in accordance with the Development Plan, and review Development reports and discuss at meetings the status, progress and results of the Development activities performed by Licensee in the Territory; (b) discuss the design of **[***]** Trials that are to be performed in the Territory; (c) perform the tasks and make the decisions delegated to the JDC under ARTICLE 3 and ARTICLE 4 of this Agreement; (d) serve as a forum for exchanging and discussing Regulatory Documentation, Regulatory Data and other technical information, and discussing strategies for, and the status of, obtaining Regulatory Approvals for Licensed Products in the Territory; (e) serve as a forum for discussing status of obtaining Regulatory Approvals for Licensed Products outside the Territory and (f) perform such other functions that are expressly delegated to the JDC in this Agreement or by the JSC.

2.3. Joint Manufacturing Committee. Within **[***]** days following the Effective Date, the Parties shall establish a joint manufacturing committee (the "**JMC**"). The JMC shall include individuals from each Party with reasonable expertise in the area of biological product manufacturing. The JMC shall be the forum for discussion of all Manufacturing related activities related to the Territory, and shall: (a) oversee and coordinate the clinical and commercial supply of Licensed Products for the Territory; **[***]**; (c) discuss any Manufacturing matters with respect to the Licensed Compound and Licensed Products designated for use in the Territory; and (d) perform such other functions that are expressly delegated to the JMC in this Agreement or by the JSC.

2.4. Joint Commercialization Committee. At least **[***]** prior to the anticipated filing of the first Drug Approval Application for the first Licensed Product in the Territory, the Parties shall establish a joint commercialization committee (the "**JCC**"). The JCC shall include individuals from each Party with reasonable expertise in the areas of sales and marketing, operations, and market access. The JCC shall be the forum for discussion of all Commercialization related activities in the Territory, and shall: (a) discuss, approve and update the Commercialization Plans and any amendments thereto; (b) ensure that the Commercialization activities in the Territory are consistent with Licensor's global brand, the Global Marketing Guidelines, and the Commercialization strategy outside the Territory, (c) establish a process to review and comment on the application of the Global Marketing Guidelines to the Territory and on the Territory Marketing Materials; (d) monitor and discuss the progress of the Commercialization of Licensed Products in the Field in the Territory in accordance with the Commercialization Plans and exchange information on the Commercialization of Licensed Product outside the Territory; (e) **[***];** and (f) perform the other functions that are expressly delegated to the JCC in this Agreement or by the JSC in writing.

2.5. Joint Finance Committee. Within **[***]** days following the Effective Date, the Parties shall establish a joint finance committee (the "**JFC**"). The JFC shall include individuals from each Party with reasonable expertise in the areas of accounting, budgeting and financial reporting. The JFC shall be the forum for discussion of all finance related issues in relation to the Territory, and shall: (a) coordinate budgeting, accounting, financial reporting and other financial activities provided for in this Agreement; (b) if requested by the JSC, develop a process for the development of budgets by the Committees in order to assist in reconciling payments owed by one Party to the other in connection with Development activities, and the approval of such budgets by the JSC, including the Development budgets; and (c) perform such other functions that are expressly delegated to the JFC in this Agreement or by the JSC.

2.6. Sub-committees. From time to time, the JSC may establish and delegate duties to Sub-committees (each, a "**Sub-committee**") on an "as-needed" basis to oversee particular projects or activities. Each Sub-committee shall have the responsibility delegated to it in writing by the JSC, provided that in no event shall the authority of a Sub-committee exceed the responsibilities and authority of the JSC.

2.7. Membership of Committees. Each Committee shall be composed of an equal number of representatives appointed by each Party. Each Committee shall be initially composed of three (3) representatives of each Party until otherwise agreed by the Parties. Each Party may replace any of its Committee representatives at any time upon written notice to the other Party. Each Committee shall be co-chaired by one designated representative of each Party. The co-chairpersons of each Committee shall not have any greater authority than any other representative on the Committee.

2.8. Meetings and Minutes of Committees. Each Committee shall meet quarterly, or as otherwise agreed to by the Parties. The co-chairpersons of the Committee shall be responsible for calling meetings on no less than **[***]** notice, or upon the request of a Party on shorter notice if the other Party consents to such shorter notice (such consent not to be unreasonably withheld, conditioned or delayed). Each Party shall make all proposals for agenda items and shall provide all appropriate information with respect to such proposed items at least **[***]** in advance of the applicable meeting; provided, that under exigent circumstances requiring input by the Committee, a Party may provide its agenda items to the other Party within a shorter period of time in advance of the meeting, or may propose that there not be a specific agenda for a particular meeting, so long as the other Party consents to such later addition of such agenda items or the absence of a specific agenda for such meeting (such consent not to be unreasonably withheld, conditioned or delayed). The co-chairpersons of the Committees shall prepare and circulate for review and approval of the Parties minutes of each meeting within **[***]** after the meeting. The Parties shall agree on the minutes of each meeting promptly, but in no event later than the next meeting of the Committee.

2.8.1. Procedural Rules. Each Committee shall have the right to adopt such standing rules as shall be necessary for its work, to the extent that such rules are not inconsistent with this Agreement. A quorum of the Committee shall exist whenever there is present at a meeting at least one representative appointed by each Party. Representatives of the Parties on the

Committee may attend a meeting either in person or by telephone, video conference or similar means in which each participant can hear what is said by, and be heard by, the other participants. Representation by proxy shall be allowed.

2.8.2. Decision-making. Each Committee shall take action by consensus of the representatives present at a meeting at which a quorum exists, with each Party having a single vote irrespective of the number of representatives of such Party in attendance, or by a written resolution signed by at least one representative appointed by each Party.

2.8.3. Further Participants. Employees or consultants of either Party that are not representatives of the Parties on the Committee may attend meetings of the Committee; provided, that such attendees (a) shall not vote or otherwise participate in the decision-making process of the Committee, and (b) are bound by obligations of confidentiality and non-disclosure equivalent to those set forth in ARTICLE 10.

2.9. Dispute Resolution.

2.9.1. Escalation to the JSC. If the JDC, JMC, JCC, JFC or a Sub-Committee fails to reach consensus on any matter within its authority for a period in excess of **[***]** days following the date on which such matter was first presented to such Committee, the matter shall be referred to the JSC.

2.9.2. Dispute Resolution by Senior Officers. If the JSC fails to reach consensus on: (i) any matter referred to it by the JDC, JMC, JCC, JFC or a Sub-Committee that is within such Committee's authority, or (ii) any matter within the JSC's authority, within **[***]** following the date on which such matter was first presented to the JSC, then, unless this Agreement expressly provides otherwise, such matter shall be escalated to the Senior Officers for resolution, who shall confer in good faith on the resolution of the issue. Any final decision mutually agreed to by the Senior Officers shall be conclusive and binding on the Parties. If the Senior Officers fail to reach consensus on any matter referred to them within **[***]** after such issue was first referred to them, then, the following shall apply:

(a) such dispute shall be finally and definitively resolved by the Senior Officer of Licensee for matters within the authority of a Committee that are primarily related to the Development and Commercialization of Licensed Products in the Field in the Territory except for matters that (i) would materially adversely affect the Development or Commercialization of Licensed Compound or Licensed Product, (ii) would materially adversely affect the safety of the Licensed Compound or Licensed Product, (iii) **[***]**), or (iv) are subject to Licensor's final decision making authority pursuant to Section 2.9.2(b). For clarity, Licensee's final-decision making authority shall include any decision to finally determine Licensee's pricing strategy for the Licensed Products in the Territory, **[***];** and

(b) such dispute shall be finally and definitively resolved by the Senior Officer of Licensor for: (i) matters that would materially adversely affect the Development or Commercialization of Licensed Compound outside the Territory or would materially adversely affect the safety of the Licensed Product, provided that Licensor may not use such final decision-

making authority in a manner that would materially adversely affect the Development or Commercialization of Licensed Compound or Licensed Product in the Territory; (ii) **[***]** provided, however, that Licensor may not use its final decision-making authority to: (A) approve a trial design to which Licensee objects in good faith as not being likely to support a Regulatory Approval of the respective Licensed Product in the Territory, or (B) increase the total number of human subjects to be enrolled in such Territory-specific POC Trial beyond the number of human subjects set forth in the Development Plan for such Territory-specific POC Trial; (iv) matters relating to Manufacturing; (v) matters relating to Publications; **[***]**.

(c) provided, further, that, neither Party may exercise its final decision-making authority under Section 2.9.2(a) or Section 2.9.2(b) in a manner that would (i) negate any consent right or other right specifically allocated to the other Party under this Agreement, (ii) require the other Party to perform activities that the other Party has not agreed to perform as set forth in this Agreement, or (iii) require the other Party to perform any act that it reasonably believes to be inconsistent with any Applicable Law.

(d) except for matters expressly set forth under Section 2.9.2(a) or Section 2.9.2(b), neither Party shall have final decision-making authority for any other matter and any such remaining dispute shall be resolved pursuant to Section 15.5.2. Notwithstanding the foregoing, mutual agreement of the Parties is required for (i) any decision for Licensee to participate in a New Global Trial and (ii) any amendments to the Development Plan (including activities, timelines and budgets).

2.10. Limitations on Authority. Each Party shall retain the rights, powers, and discretion granted to it under this Agreement and no such rights, powers, or discretion shall be delegated to or vested in a Committee unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. Neither Committee shall have the power to, and neither Party shall exercise its final decision making authority in a manner that would, (a) amend, modify, or waive compliance with this Agreement, which may only be amended or modified as provided in Section 15.7 or compliance with which may only be waived as provided in Section 15.10; (b) determine any issue in a manner that would conflict with the express terms and conditions of this Agreement; or (c) make decisions outside the scope of those matters expressly delegated to it in this Agreement. For clarity, the Committees have no approval rights with respect to matters related to the Licensed Compound or Licensed Product outside the Territory or outside the Field, which matters are within Licensor's sole discretion.

2.11. Alliance Manager. Promptly after the Effective Date, each Party shall appoint an individual who is an employee of such Party and proficient in English (each, an "**Alliance Manager**") to oversee contact between the Parties for all matters between meetings of the Committees, including sharing of information regarding material Development updates of the Licensed Product that are under the purview of the Committees or for which information exchange is otherwise provided for under this Agreement, and who shall have such other responsibilities as the Parties may agree in writing. Each Party may replace its Alliance Manager at any time by notice in writing to the other Party. The Alliance Managers will attend the JSC meetings as non-voting participants.

2.12. Discontinuation of Committees. A Committee shall continue to exist until the Parties mutually agree to disband such Committee. Once a Committee has been discontinued, any requirement of Licensee to provide Information, documents or other materials to such Committee shall be deemed a requirement to provide such Information, documents or other materials to Licensor.

2.13. Expenses. Each Party shall be responsible for all travel and related costs and expenses for its members and other representatives to attend meetings of, and otherwise participate on, the Committees.

ARTICLE 3

DEVELOPMENT

3.1. General. Licensee will be responsible, under JDC oversight, for the Development activities to support the Regulatory Approval of the Licensed Product in the Field in the Territory, and will conduct the Development of the Licensed Compound and Licensed Products in accordance with the Development Plan, or as otherwise explicitly permitted under this Agreement. Licensor will be responsible, at its sole discretion, for all Development activities that are conducted outside the Territory.

3.2. Territory-specific Development.

3.2.1. Development Plan; Updates; Amendments.

(a) The Development Plan shall include all material Development activities to be performed by Licensee in the Territory for the Development of the Licensed Compound and Licensed Products, including: (i) all Territory-specific Trials and Territory-specific PoC Trials; (ii) all material Development activities to be performed by Licensee in the Territory as part of a Global Trial; (iii) a plan for preparing and submitting Regulatory Filings in the Territory and obtaining and maintaining Regulatory Approvals for Licensed Products in the Territory; (iv) all other material Development activities that are required to seek, obtain and maintain Regulatory Approvals in the Territory for the Initial Indications and any Additional Indications approved by the JSC; and (v) **[***]**.

(b) The initial Development Plan is attached hereto as **Schedule 3.2.1**. The Development Plan (including estimated timelines and estimated budgets) may be updated and amended from time to time only with the approval of the JSC, as described in this Section 3.2.1. To the extent that the initial Development Plan as of the Effective Date does not include all of the items listed in Section 3.2.1(a), the Parties will cooperate through the JSC, JDC and JFC in good faith to amend such Development Plan to include such further detail.

(c) The JDC shall review the Development Plan (including milestones and estimated timelines and estimated budgets) at least annually and prepare any recommended updates. The JDC shall submit all such updates to the JSC for review and approval.

(d) Either Party may submit a proposed update or amendment to the Development Plan to the JDC from time to time, including changes to the Territory-specific Trials and Territory-specific PoC Trials or proposal for new Territory-specific Trials and Territory-specific PoC Trials. The JDC shall discuss such proposal at its next meeting, and submit such proposal to the JSC for review and approval together with a recommendation as to whether to approve such update or amendment.

3.2.2. Development in Additional Indications.

(a) Upon the request of either Party, the JDC shall discuss the Development of Licensed Products in an Additional Indication in the Territory. The JDC shall submit such request to the JSC for review and approval together with a recommendation on whether to approve the Development in such Additional Indication.

(b) If the JSC approves the Development of Licensed Products in an Additional Indication, the JDC shall prepare an update to the Development Plan, including all material Development activities that are required to obtain Regulatory Approval in such Additional Indications, estimated milestones and estimated timelines, and submit such update to the JSC for review and approval.

3.2.3. Conduct of Development Activities; Diligence.

(a) Licensee shall use Commercially Reasonable Efforts to execute and to perform or cause to be performed, the Development activities allocated to it in the Development Plan, including Territory-specific Trials, Territory-specific PoC Trials and those parts of the Global Trials to be performed by Licensee in the Territory in accordance with the Development Plan, and shall use Commercially Reasonable Efforts to meet the timelines set out in the Development Plan. Without limiting the generality of the foregoing, Licensee shall: (i) obtain and maintain (itself or through its Affiliates or subcontractors) sufficient facilities, personnel (with appropriate qualifications and experience), equipment, materials and other resources as reasonably required to complete the Development activities allocated to it in the Development Plan; and (ii) use Commercially Reasonable Efforts to **[***].**

(b) If at any time Licensor has a reasonable basis to believe that Licensee is in material breach of its diligence obligations under this Section 3.2.3, then Licensor may so notify Licensee in writing, specifying the basis for its belief, and, without limitation to any other right or remedy available to Licensor hereunder, at Licensor's request, the Parties shall meet within **[***]** days after such notice to discuss in good faith Licensor's concerns and Licensee's Development efforts with respect to the Licensed Products in the Field in the Territory.

(c) Licensee shall conduct the Development of Licensed Products in the Field in the Territory in accordance with all Applicable Laws and GLP and GCP requirements applicable to it and consistent, from a safety perspective, with the manner in which Licensor is conducting the Development of Licensed Products outside the Territory; provided, that Licensor has provided notice to the JDC of such safety standards. The Parties will in good faith negotiate a suitable GxP Quality Agreement for the Development activities.

(d) Licensee will keep Licensor reasonably informed of all material aspects of Licensee's, its Affiliates' and sublicensees' Development of Licensed Products in the Field in the Territory. Without limiting the foregoing, subject to Applicable Law, the Parties will discuss in good faith and coordinate, through the JDC, Licensee's material Development activities for Licensed Products in the Field in the Territory, including the design and commencement of Clinical Trials and any other material Development steps. Licensee will consider in good faith Licensor's input and comments with respect thereto, and any final decision within the JDC's decision making authority shall be made in accordance with Section 2.9.2.

(e) Licensee shall perform, and shall cause its subcontractors to perform, any and all of its Development activities under this Agreement in good scientific manner, in compliance with all Applicable Law and GCP and GLP, and in accordance with the covenants set forth in Section 11.3.

(f) Neither Licensee nor its Affiliates shall, directly or indirectly, whether alone or together with a Third Party, Develop the Licensed Compound or Licensed Products outside the Territory or outside the Field.

3.3. Global Trials.

3.3.1. New Global Trials.

(a) If Licensor intends to perform a Global Trial for which activities are not contemplated by the Development Plan (a "**New Global Trial**"), it shall provide an outline of the design of such Global Trial to the JDC. The JDC will discuss in its next meeting whether and which activities of such Global Trial (e.g., the percentage of patient enrolment in the Territory) can be allocated to Licensee for performance in the Territory. If the Parties reach consensus in the JDC that part of a New Global Trial will be performed by Licensee in the Territory, the JDC will prepare an update to the Development Plan, and will submit such proposal to the JSC for review and approval.

(b) If the JSC, and after dispute resolution in accordance with 2.9.2, the Senior Officers, fail to reach unanimous agreement on the participation of Licensee in a New Global Trial, or the scope of such participation by Licensee, Licensor shall be free to perform such New Global Trial without the involvement of the Licensee, whether solely or in collaboration with any Third Party.

(c) If Licensee does not participate in a New Global Trial for a particular Licensed Product in a particular indication, **[***].** Notwithstanding the foregoing, in the event Licensee is required by the Regulatory Authority in the Territory to provide such Clinical Data for such Global Trial in support of Licensee's other Development or Commercialization activities for an indication for which Licensee has borne such share of costs, then, **[***]**.

3.3.2. Global Trial Plan; Updates; Amendments. The plan for the Global Trials may be amended from time to time by Licensor ("**Global Trial Plan**"). Licensor may update or amend the Global Trial Plan in its sole discretion, provided that: (a) Licensor may

not allocate any Development activities to be performed as part of a Global Trial to the Territory without the approval of the JSC; and (b) Licensor may not increase the number of human subjects to be enrolled in the Territory as part of a Global Trial beyond **[***]** of the total number of human subjects enrolled in such Global Trial worldwide. Licensor will regularly (if and when applicable) provide to Licensee, through the JDC, updates or amendments to the Global Trial Plan. For the avoidance of doubt, the Development activities that are to be performed by Licensee as part of a Global Trial will in any case also be included in the Development Plan, and Licensee will perform these activities in accordance with the Development Plan (as amended or updated in accordance with Sections 3.3.1(a) or 3.3.3).

3.3.3. Changes to Global Trial. If Licensor intends to make changes to a Global Trial that is part of the Development Plan or if such changes affect the Territory, including an increase of human subjects to be enrolled by Licensee as part of such Global Trial in the Territory, it shall provide a proposal of such change to the JDC. The JDC will discuss such proposed change in its next meeting, if it reaches consensus on such change to the Global Trial affecting the Territory, it will prepare an amendment to the Development Plan, and will submit such proposed amendment to the JSC for review and approval.

3.3.4. Conduct of Global Trials. Licensee will perform all Development activities that are to be performed in the Territory as part of a Global Trial in accordance with the Development Plan and Section 3.2.3; provided that Licensor shall have the right to conduct such activities as provided in Section 3.3.1(b). Licensor will perform all Development activities that are to be performed outside the Territory as part of a Global Trial in which Licensee is participating in accordance with the Global Trial Plan and in good scientific manner, in compliance with all Applicable Law and GCP and GLP, and in accordance with the covenants set forth in Section 11.3.

3.4. Sponsorship of Clinical Trials. Unless otherwise agreed upon by the Parties or required by Applicable Law, as between the Parties, **[***]**. In connection with the performance of any such Clinical Trial for which Licensor is the sponsor and Licensee, its Affiliates or sublicensees is performing in the Territory, (a) at Licensee's request, Licensor will provide reasonable assistance in connection with establishing and conducting such Clinical Trial, including assistance with all applications required by Applicable Law and (b) Licensee shall reimburse Licensor for (i) any out-of-pocket costs incurred in providing such assistance and (ii) for any internal costs incurred in providing such assistance beyond **[***]** per Clinical Trial or that extends beyond **[***]** after commencement of such Clinical Trial, in each case, within **[***]** after receipt of an invoice therefor. Licensee will be responsible for the implementation and the day-to-day management of all Clinical Trials to be performed in the Territory in accordance with this Agreement, including Territory-specific Trials and that part of Global Trials that is to be performed in the Territory. Without limiting the foregoing, Licensee shall be responsible for recruiting, enrolling, dosing, treating, and providing follow-up support to, all human subjects that are to participate in a Territory-specific Trial or in a Global Trial in the Territory in accordance with the Development Plan.

3.5. Ownership in Clinical Data; Data Sharing. Subject to the rights granted to Licensee under Section 7.1, Licensor shall own all Clinical Data resulting from Clinical Trials

performed in relation to Licensed Products in the Territory (including all Clinical Data resulting from Territory-specific Trials or Global Trials), and Licensee shall assign to Licensor, and hereby assigns to Licensor, all of its right, title and interest in, to and under such Clinical Data. Section 9.1.3 shall apply accordingly. Licensee shall provide to Licensor all Clinical Data and analyses resulting from Clinical Trials performed in the Territory. As reasonably requested by Licensee, Licensor shall cooperate to exchange all Clinical Data and analyses that are (a) necessary or useful to support Regulatory Approval for Licensed Product in the Territory, and (b) from (i) a New Global Trial for which Licensee is not prohibited from having a right to use such Clinical Data pursuant to Section 3.3.1, (ii) a Global Trial for which Licensee is performing activities in the Territory pursuant to the Development Plan or (iii) a Clinical Trial for Licensed Product commenced prior to the Effective Date; provided that, (A) for any such Clinical Data and analyses generated on behalf of Licensor or its Affiliate by a Third Party after the Effective Date in a Clinical Trial that is not part of the Global Trial Plan existing as of the Effective Date, Licensor shall only be required to exchange such Clinical Data and analyses to the extent Controlled by Licensor or any of its Affiliates; (B) Licensor shall use diligent efforts to obtain Control of such Clinical Data and analyses in its agreement with such Third Party to enable such exchange with Licensee; and (C) if Licensor cannot obtain such Control in its agreement with a particular Third Party such that Licensor cannot provide Licensee with the Clinical Data or analyses generated by such Third Party with respect to the Licensed Product, then Licensor shall not have the right to provide such Third Party with any Clinical Data or analyses generated by Licensee with respect to the Licensed Product under this Agreement (other than safety data, which Licensor shall have the right to provide). Notwithstanding the foregoing, nothing in this Agreement shall require Licensor to provide to Licensee any Clinical Data that Licensor is not allowed to share due to restrictions resulting from informed consent forms or Applicable Law.

3.6. Development Reports.

3.6.1. On a Licensed Product-by-Licensed Product basis, Licensee shall, on a quarterly basis during the Term (without limiting any more frequent reporting obligations otherwise agreed pursuant to this Agreement), provide the JDC with written reports in English language summarizing the following with respect to the Licensed Products: (a) the results and progress of all Development activities that Licensee has performed, or caused to be performed, since the preceding report (including details of safety and efficacy data from Clinical Trials of Licensed Products in the Field in the Territory), (b) Licensee's Development activities in process, (c) the future material activities such Party expects to initiate during the then-current Calendar Year, including timelines related thereto, (d) updates regarding material regulatory matters, including an update of all Drug Approval Applications filed, in each case on a jurisdiction-by-jurisdiction basis, (e) such other information as Licensor may reasonably request relating to the Development in order to enable Licensor to assess Licensee's compliance with its Development obligations under this Agreement with respect to the Licensed Products.

3.6.2. On a Licensed Product-by-Licensed Product basis, Licensor shall discuss at meetings of the JDC (no more than on a quarterly basis) the following with respect to the Licensed Products outside the Territory: (a) an overview of the results and progress of Development since the preceding report, (b) an overview of Development activities in process, (c)

an overview of the future material activities Licensor expects to initiate during the then-current Calendar Year, including timelines related thereto, and (d) jurisdictions in which Drug Approval Applications have been filed.

3.7. Development Funding.

3.7.1. Territory-specific Development Costs.

(a) Subject to Section 3.7.1(b), as between the Parties, Licensee shall be solely responsible for all costs and expenses in connection with Licensee's, its Affiliates and sublicensees' Development of Licensed Products in the Field in the Territory, including for pre-clinical studies, Territory-specific Trials and Territory-specific PoC Trials.

(b) Licensor will compensate Licensee for **[***]** of the human subjects enrolled in a Territory-specific PoC Trial in accordance with, and up to the number of subjects set forth in, the mutually agreed Development Plan at **[***].**

3.7.2. Global Trials.

(a) Subject to Section 3.3.1(c), 3.7.2(b) and Section 3.7.2(c), Licensor will be responsible for all costs and expenses incurred by Licensor in connection with a Global Trial.

(b) Licensee will be responsible for all costs and expenses incurred by Licensee in connection with a Global Trial in the Territory in accordance with the Development Plan, including all costs and expenses for recruiting, enrolling, dosing, treating, and providing follow-up support to, the human subjects to be enrolled by Licensee as part of such Global Trial in the Territory in accordance with the Development Plan; provided, however, that for each Global Trial, unless the Parties agree otherwise, a maximum of **[***]** of the total number of human subjects participating in such Global Trial worldwide will be allocated to the Territory.

(c) If Licensee fails to enrol the number of human subjects to be enrolled by Licensee in the Territory as part of a Global Trial as set forth in the Development Plan for such Global Trial or otherwise agreed upon by the Parties in good faith, before the 'last patient in' for such Global Trial (excluding patients to be enrolled by Licensee), and such failure or shortfall is not attributable to Licensor's breach of this Agreement, Licensor's breach of the applicable clinical supply agreement between the Parties or any material delay caused by any actions or inactions of Licensor, Licensee shall **[***].** In the event Licensee enrols more than the number of human subjects originally agreed upon by the Parties to be enrolled by Licensee in the Territory as part of a Global Trial, Licensee shall **[***].**

3.7.3. Payments Terms. To the extent any reimbursement costs are due from one Party to the other, then within **[***]** after the end of each calendar month, each Party shall provide the other a written accounting of the costs incurred by such Party that are reimbursable in whole or in part under this Agreement together with supporting documentation for any Third Party costs for such calendar month. Within **[***]** of receipt by the Parties of each such

written accountings for a calendar month, Licensor shall provide Licensee with a reconciliation report setting forth the net payment due from one Party to the other Party to effectuate the sharing of costs as set forth herein. The Party that is owed money pursuant to such reconciliation report shall issue an invoice to the paying Party for the applicable net payment set forth in such reconciliation report promptly after receipt (or delivery, as applicable) of such reconciliation report. The Party receiving such invoice shall pay to the other Party the undisputed amount of such invoice within **[***]** after receipt of such invoice.

ARTICLE 4

REGULATORY MATTERS

4.1. Regulatory Strategy. The Parties will discuss and determine in the JDC the regulatory strategy for the Licensed Products in the Field in the Territory.

4.2. Regulatory Lead. Licensor (or its designee) shall be the holder of all Regulatory Filings and Regulatory Approvals for Licensed Products in the Field in the Territory, and Licensee shall be the local legal representative of Licensor (or Licensor's designee) for all regulatory matters with respect to the Licensed Products in the Field in the Territory; provided that, if Applicable Laws in the Territory allow Licensee to hold such Regulatory Approvals and Regulatory Filings for the Licensed Product in the Territory and such transfer would be mutually beneficial, the Parties shall discuss in good faith (but shall have no obligation to enter into) an amendment to this Agreement providing for the transfer of such Regulatory Approvals and Regulatory Filings to Licensee. Licensee shall be the main point of contact for the regulatory relationship and communication with Regulatory Authorities within the Territory, and shall be responsible, at Licensee's sole expense (including payment of all filing fees and all other associated costs), for making Regulatory Filings, and obtaining and maintaining Regulatory Approvals for Licensed Products in the Field in Territory, in accordance with this Agreement and the applicable Development Plan.

4.3. Regulatory Filings and Approvals. Licensee will file all CTAs and Drug Approval Applications on behalf, and in the name of Licensor, and will hold all Regulatory Approvals in the name of Licensor or Licensor's designee. Licensor or its designee will support Licensee, as may be reasonably necessary or appropriate for Licensee to comply with its regulatory obligations hereunder, including by providing necessary documents, signatures or other materials required by Applicable Law or Regulatory Authorities.

4.4. Regulatory Communication and Meetings.

(a) Subject to Section 4.4(b), Licensee shall provide to Licensor copies of all material Regulatory Filings (and an English translation thereof) in the Territory prior to submission with a reasonable amount of time (and in any case, to the extent practicable, at least **[***]** prior to the envisaged date of submission) to allow Licensor to review and comment on such Regulatory Filings. Licensee will endeavour to inform Licensor in advance of an intention to present a draft Regulatory Filing for review to Licensor and at Licensor's request, to the extent practicable, an additional term of no more than **[***]** shall be given for review and comments to such submission by Licensor. Licensee will consider in good faith all of Licensor's comments and

proposed revisions and will address such comments and proposed revisions, in each case, prior to submission. In the event of a disagreement between the Parties with respect to the implementation of Licensor's comments and proposed revisions, such disagreement shall be escalated to the JSC. As used herein, "material" Regulatory Filings shall mean all CTAs and filings for Regulatory Approval, as well as supporting Regulatory Documentation therefor.

(b) In case an exigent action is required, Licensee shall notify Licensor prior to submitting any material Regulatory Filings in the Territory, and shall provide Licensor with copies of such submitted Regulatory Filings (and an English translation thereof) promptly and in no case later than **[***]** after its submission. At Licensor's request, Licensee shall provide Licensor copies of all other Regulatory Filings (and an English translation thereof) **[***]**.

(c) As between the Parties, Licensor retains the right (in its sole discretion) to conduct all regulatory activities with respect to the Licensed Products outside the Territory. Additionally, with respect to (i) any Global Trial that Licensee is participating in, (ii) any New Global Trials of Licensed Products in the Territory for which Licensee has a right to use Clinical Data pursuant to Section 3.3.1, and (iii) Clinical Trials for Licensed Product commenced prior to the Effective Date, Licensor shall provide Licensee with copies of material Regulatory Filings and material Regulatory Documentation relating to any such Clinical Trials in the United States, Japan, European Union, United Kingdom promptly after submission or receipt thereof, as applicable, provided that, (A) for any such Regulatory Filings and Regulatory Documentation generated on behalf of Licensor or its Affiliate by a Third Party after the Effective Date that is not related to a Clinical Trial as part of the Development Plan existing as of the Effective Date, Licensor shall only be required to provide copies of such Regulatory Filings and Regulatory Documentation to the extent Controlled by Licensor or any of its Affiliates; (B) Licensor shall use diligent efforts to obtain Control of such Regulatory Filing and Regulatory Documentation in its agreement with such Third Party to enable such provision to Licensee; and (C) if Licensor cannot obtain such Control in its agreement with a particular Third Party such that Licensor cannot provide Licensee with such Regulatory Filing or Regulatory Documentation generated or by such Third Party with respect to the Licensed Product, then Licensor shall not have the right to provide such Third Party with any Regulatory Filing or Regulatory Documentation generated by Licensee with respect to the Licensed Product under this Agreement. (other than safety data, which Licensor shall have the right to provide). Notwithstanding the foregoing, nothing in this Agreement shall require Licensor to provide to Licensee any Regulatory Filing or Regulatory Documentation that Licensor is not allowed to share due to restrictions resulting from informed consent forms or Applicable Law.

4.5. Regulatory Documentation and Regulatory Data. Licensee shall promptly provide Licensor access to, and an English translation of, all Regulatory Documentation in the Territory that is held by Licensee or its subcontractors, when and as such Regulatory Documentation becomes available. Subject to the rights granted to Licensee under Section 7.1, Licensor shall own all Regulatory Documentation and all Regulatory Data in the Territory, and Licensee shall assign to Licensor, and herewith assigns to Licensor, all of Licensee's rights, title and interest in, to and under such Regulatory Documentation and Regulatory Data.

4.6. Audits of Systems, Processes and Procedures. Upon reasonable advance notice and at reasonable times and no more frequently than once per Calendar Year (unless for cause), Licensor or its representatives shall be entitled to conduct an audit of any system, process or practice used by Licensee for the conduct and quality control of Licensee's activities under this Agreement, including the safety and regulatory systems, procedures or practices of Licensee and its subcontractors relating to the Licensed Products. Licensor shall treat all information subject to review under this Section 4.6 as Confidential Information of Licensee.

4.7. Regulatory Authority Inspections and Actions.

(a) Each Party shall promptly notify the other Party of any announced or unannounced inspection of such Party, its Affiliates, or subcontractors (including clinical trial sites and manufacturing sites) relating to Licensed Products by any Regulatory Authority in the Territory and shall provide the other Party with all information in such Party's Control related thereto. The other Party will have the right to be present at such inspection, and participate to the extent allowed under Applicable Law, as relevant and agreed between the Parties. If a prior notification is not reasonably feasible, despite good faith efforts of the inspected Party, the inspected Party shall notify the other Party promptly upon such inspection, but in no case later than 48 hours thereafter. The inspected Party will provide the other Party with a written summary in English of any findings of a Regulatory Authority relating to Licensed Products following a regulatory inspection (and any written correspondences in relation thereto) within **[***]** following any such inspection, and will provide the other Party with an unredacted copy of any report issued by such Regulatory Authority in the Territory (including a certified English translation thereof if such report is not in English) within **[***]** following such inspection, or a shorter timeframe if necessary to accommodate deadlines set for responses to Regulatory Authorities.

(b) If any Regulatory Authority in the Territory takes, or gives notice of its intent to take, any regulatory action with respect to any activity of Licensee relating to the Licensed Product and (i) such action is reasonably likely to have a material adverse effect on the label, safety, Development or Commercialization of the Licensed Product outside of the Territory, then Licensee shall notify Licensor of such notice within **[***]** of its receipt thereof and (ii) for other material regulatory actions, Licensee shall notify Licensor within than **[***]** thereafter. Licensee will address Licensor's comments to Licensor's reasonable satisfaction.

4.8. Pharmacovigilance. Both Parties shall make good faith efforts to within **[***]** after the Effective Date, enter into an agreement with regard to a process for the exchange of safety data (including post-marketing spontaneous reports received by each Party and its Affiliates) between the Parties in a mutually agreed format in order to monitor the safety of the Licensed Compounds and Licensed Products and to meet reporting requirements with any applicable Regulatory Authority ("**Pharmacovigilance Agreement**"). The Pharmacovigilance Agreement shall include procedures regarding the receipt, investigation, recording, communication, and exchange (as between the Parties), and regulatory submission of, adverse event reports, exposure during pregnancy reports, and any other information concerning the safety of the Licensed Products, including those matters set forth on **Schedule 4.8**.

4.9. Global Safety Database. Licensor will set up, hold, and maintain a global safety database for Licensed Products. Licensee shall provide Licensor with all information necessary or desirable for Licensor to comply with its pharmacovigilance responsibilities in the Territory, including, as applicable, any adverse drug experiences, from pre-clinical or clinical laboratory, animal toxicology and pharmacology studies, and Clinical Trials for Licensed Product, in each case in the form reasonably requested by Licensor. It is understood that each Party and its Affiliates, licensees and sublicensees shall have the right to access, use and disclose such information in the global safety database for Licensed Products if such disclosure is reasonably necessary to comply with Applicable Laws or requirements of any applicable Regulatory Authority.

ARTICLE 5

MANUFACTURING

5.1. Manufacturing Right. Subject to Section 5.4, Licensor shall have the sole right and, subject to the terms of this Agreement, any pre-clinical or clinical supply agreement, and the Commercial Supply Agreement, responsibility to Manufacture and supply Licensee's requirements of the Licensed Compound and Licensed Products.

5.2. Pre-Clinical and Clinical Supply. Licensor shall, either by itself or through its CMO, Manufacture and supply to Licensee all quantities of Licensed Compound and Licensed Products required by Licensee in accordance with this Agreement for the Development of Products (including for Clinical Trials), subject to and in accordance with the terms and conditions of one or more clinical supply agreement(s) and associated Quality Agreement(s) to be negotiated and agreed between Licensee and Licensor in good faith no later than **[***]** after the Effective Date, taking into account the terms and conditions of the In-licensing Agreements and other third party contracts relevant to the Licensor supply chain, including production of drug substance, drug product and fill and finish services and as of the date hereof, including contracts with **[***]**. All pre-clinical and clinical supply of Licensed Compound and Licensed Products will be at **[***]**. Licensor's best estimate of COGS to Manufacture and supply Development quantities of Licensed Compound and Licensed Products to Licensee as of the Effective Date is set forth on **Schedule 5.3**.

5.3. Commercial Supply. On a Licensed Product-by-Licensed Product basis, upon the request of Licensee, but in any case no later than six months prior to the first anticipated approval in the Territory, the Parties will negotiate and agree in good faith on a commercial supply agreement (each a "**Commercial Supply Agreement**") with respect to such Licensed Product (including a Quality Agreement) under which Licensor (or its CMO) will Manufacture and supply to Licensee the quantities of Licensed Product required by Licensee, whereby:

(a) terms and conditions applicable to Licensor (or its Affiliates) pursuant to the In-licensing Agreements and other third party contracts relevant to the Licensor supply chain, including production of drug substance, drug product and fill and finish services and the maximum capacities available thereunder, shall be taken into account;

(b) a binding forecast will be made by Licensee, mirroring the binding forecasting mechanisms and principles applicable to Licensor in its contracts with third party manufacturers ("**Binding Forecast**");

(c) distinctions will be made where relevant between the different formulations of Licensed Product; and

(d) commercial supply of Licensed Products will be at COGS plus a handling fee of **[***]** and will be delivered EXW manufacturing site (Incoterms 2020) (Licensor's best estimate of COGS to Manufacture and supply commercial supply of Licensed Product to Licensee as of the Effective Date is set forth on **Schedule 5.3**),

all as to be further agreed in the Commercial Supply Agreement.

5.4. Manufacture by Licensee.

5.4.1. From time to time, the Parties, through the JMC, will evaluate the option to perform a technology transfer for the Manufacture of Licensed Products designated for the Territory from Licensor to Licensee in the light of demand increase and supply requirements considering the forecasts provided by Licensee under the Commercial Supply Agreement. **[***]**.

5.4.2. Without limiting the foregoing, in the event of a supply shortage or supply failure that results in Licensor being unable to supply the quantities of Licensed Product set out in Licensee's Binding Forecast under either the clinical supply agreement negotiated pursuant to Section 5.2 or the Commercial Supply Agreement, then Licensor shall allocate its available supply of Licensed Product between Licensee, itself, its Affiliates and Third Party licensees: (a) first to supply patients who are already on study drug in registration Clinical Trials or early access programs before commercial supply; (b) then for commercial supply on a pro-rata basis determined based on **[***]**, and (c) then for new patients in registration Clinical Trials, all as to be further set out in the Commercial Supply Agreement.

5.4.3. If Licensor fails to supply at least **[***]** of Licensee's Binding Forecast (a) during **[***]** or (b) during **[***]**, then (i) the Parties shall discuss in good faith and at Licensee's request, Licensor shall use Commercially Reasonable Efforts to secure any approvals required under the Lonza Agreement to perform a manufacturing technology transfer to, at Licensee's election, either Licensee, its Affiliate or a qualified Third Party CMO acceptable to Licensor (such acceptance not to be unreasonably withheld, conditioned or delayed) and (ii) if such approval is granted, the Parties shall amend this Agreement, to include additional provisions related to such manufacturing technology transfer and the Manufacture of Licensed Compound and Licensed Product in the Territory by or for Licensee. Licensee acknowledges and agrees that any such manufacturing technology transfer and any associated amendment to this Agreement shall be subject to the terms of the Lonza Agreement and any approvals required by the Lonza Agreement.

ARTICLE 6

COMMERCIALIZATION

6.1. Commercialization Generally.

6.1.1. Subject to the terms and conditions of this Agreement, Licensee shall be solely responsible for Commercialization of the Licensed Products in the Field in the Territory at Licensee's own cost and expense.

6.1.2. Notwithstanding the foregoing, subject to Applicable Law, Licensee will discuss in good faith and coordinate with Licensor with respect to Licensee's Commercialization activities for Licensed Products in the Field in the Territory. Licensee will consider in good faith Licensor's input and comments with respect thereto. Without limiting the foregoing, if Licensor determines, in its reasonable discretion, that a given Commercialization activity for Licensed Products in the Field in the Territory is reasonably likely to pose a material safety issue or otherwise adversely impact the Licensed Products outside the Field or outside the Territory, then Licensor will have the right to notify Licensee thereof in writing and consult with Licensee in connection therewith and, thereafter, Licensee will not (and will cause its subcontractors not to) conduct the applicable Commercialization activity unless and until a mutually agreed resolution is approved by the JCC.

6.1.3. As between the Parties, Licensor retains the right (in its sole discretion) to Commercialize the Licensed Products outside the Field or outside the Territory.

6.2. Commercialization Plan and Diligence.

6.2.1. On an indication-by-indication basis, at least **[***]** prior to the first anticipated filing of a Drug Approval Application of a Licensed Product in such indication in the Territory, Licensee shall present a commercialization plan for Licensed Product(s) in such indication to the JCC for review and approval (each, a "**Commercialization Plan**"). The Commercialization Plan for the Initial Indications shall be designed to be consistent with Licensor's global brand, commercialization and pricing strategy and shall be substantially in the form attached hereto as **Schedule 6.2.1**, and shall include: **[***]**. Licensee may, from time-to-time, but at least annually, propose amendments to the Commercialization Plans for the JCC's review and approval. Each Commercialization Plan (including any amendments thereto) shall be consistent with Licensor's global brand and Global Marketing Guidelines, high-level Commercialization strategy and the diligence obligations set forth below.

6.2.2. Licensee shall use Commercially Reasonable Efforts to Commercialize the Licensed Products in each Initial Indication and, if the Parties agree to collaborate on one or more Additional Indication(s), such Additional Indication(s), in each case, in the PRC (not including Hong Kong, Taiwan or Macau) and shall do so consistent with the approved Commercialization Plans. Without limiting the generality of the foregoing, Licensee shall use Commercially Reasonable Efforts to make the First Commercial Sale of the Licensed Product in each indication as soon as reasonably practicable following the issuance of the respective Regulatory Approval, and in all cases shall do so **[***]** after the later of **[***]**.

6.2.3. Licensee shall, and shall cause its subcontractors to, comply with all Applicable Law with respect to the Commercialization of the Licensed Products.

6.2.4. If at any time Licensor has a reasonable basis to believe that Licensee is in material breach of its obligations under this Section 6.2, then Licensor may so notify Licensee in writing, specifying the basis for its belief, and, without limitation to any other right or remedy available to Licensor hereunder, at Licensor's request, the Parties shall meet within **[***]** days after such notice to discuss in good faith Licensor's concerns and Licensee's Commercialization plans with respect to the Licensed Products.

6.3. [***]

6.3.1. [***].

6.3.2. [***].

6.4. Statements and Compliance with Applicable Law. Licensee shall, and shall cause its subcontractors to, comply with all Applicable Law (as well as any other compliance or regulation agreed upon in writing by the Parties) with respect to the Commercialization of the Licensed Products. Licensee shall avoid, and shall cause its Affiliates, employees, representatives, agents, and subcontractors to avoid, taking, or failing to take, any actions that Licensee knows would jeopardize the goodwill or reputation of Licensor or the Licensed Products or any Trademark associated therewith. Without limitation to the foregoing, Licensee shall in all material respects conform its practices and procedures relating to the Commercialization of the Licensed Products and educating the medical community in the Territory with respect to the Licensed Products to any applicable industry association regulations and policies in the Territory, as the same may be amended from time to time, and Applicable Law.

6.5. Training and Promotion Materials. The JCC will review and discuss the application to the Territory of Licensor's global guidelines for branding, positioning, core messages and messaging for promotion materials, training programs and marketing materials (collectively, the "**Global Marketing Guidelines**"). Licensor shall provide Licensee with copies of Licensor's promotional materials, market research, health economics and outcomes research, medical affairs or other materials related to Licensor's Commercialization of the Licensed Product outside the Territory or globally that Licensor determines are reasonably necessary to promote consistency globally. Licensee shall have the right to use such materials solely to prepare promotion materials, training programs and marketing materials for the Licensed Product in the Field in the Territory ("**Territory Marketing Materials**"). All translations of any of Licensor's materials and the Territory Marketing Materials shall be owned by Licensor and Licensee hereby assigns to Licensor, all of its right, title and interest in, to and under such Territory Marketing Materials. Licensee shall ensure the Territory Marketing Materials are consistent with all Applicable Laws and, unless otherwise approved by the JCC, the Global Marketing Guidelines. Licensee shall not use any Territory Marketing Materials that Licensor reasonably determines would materially adversely affect the Commercialization or global brand of Licensed Compound or Licensed Product. The JCC will establish a process under which Licensee will provide Licensor with copies of the Territory Marketing Materials upon Licensor's reasonable request and the

Parties will review and comment on the application of the Global Marketing Guidelines to the Territory with respect to such Territory Marketing Materials. For clarity, Licensor shall have sole discretion with respect to the Global Marketing Guidelines and neither the JCC nor any other Committee shall have any approval rights over the Global Marketing Guidelines.

6.6. Booking of Sales; Distribution. Licensee or its Affiliates shall invoice and book sales, establish all terms of sale (including pricing and discounts) and warehousing, and distribute the Licensed Products in the Field in the Territory and perform or cause to be performed all related services. Licensee shall handle all returns, recalls, or withdrawals, order processing, invoicing, collection, distribution, and inventory management with respect to the Licensed Products in the Field in the Territory.

6.7. Commercialization Reports.

6.7.1. Commencing upon filing a Drug Approval Application for a Licensed Product in the Field in the Territory, Licensee shall provide to Licensor, through the JCC, at least on a Calendar Yearly basis, a report summarizing (a) the Commercialization activities it or its subcontractors have performed, or caused to be performed, during the applicable reporting period and on a Calendar Year-to-date basis for Licensed Products in the Field in the Territory; (b) its Commercialization activities in process and the future activities it expects to initiate during the then-current Calendar Year, including estimated timelines related thereto; (c) a non-binding twenty-four month sales forecast on a regional basis for Net Sales for Licensed Products in the Territory, including details on estimated expected new patients and estimated total number of patients on therapy; and (d) such other information as Licensor may reasonably request relating to the Commercialization of the Licensed Products in order to enable Licensor to assess Licensee's compliance with its Commercialization obligations under this Agreement with respect to the Licensed Products.

6.7.2. Licensee shall keep Licensor regularly and timely informed on the status of any application for pricing or reimbursement approval for Licensed Products in the Field in the Territory, including any discussion with the applicable Regulatory Authority with respect thereto, in accordance with ARTICLE 4.

6.7.3. Licensee shall report to Licensor the First Commercial Sale in each country in the Territory within **[***]** days of such occurrences.

6.8. Product Trademarks. The Parties will discuss, through the JCC, the Product Trademarks that Licensor has secured for the Licensed Product in the Territory and such other Product Trademarks as Licensor may choose, in consultation with Licensee, for Licensee's use in the Territory. Licensee shall conduct all Commercialization activities in the Territory in accordance with Licensor's global brand strategy.

6.9. Diversion. Each Party covenants and agrees that it shall not, and shall ensure that its Affiliates and subcontractors shall not, either directly or indirectly, promote, market, distribute, import, export, sell or have sold any Licensed Products, including via the Internet or mail order, to any Third Party or to any address or Internet Protocol address or the like or otherwise

Commercialize Licensed Products (a) in the case of Licensee, outside the Territory or for use outside the Field or (b) in the case of Licensor, for use in the Field in the Territory. Without limiting the foregoing, neither Party shall engage, nor permit its Affiliates or subcontractors to engage, in (x) any advertising or promotional activities relating to any Licensed Products for use directed primarily to customers or other buyers or users of Licensed Products located (i) in the case of Licensee, outside the Territory or for uses outside the Field or (ii) in the case of Licensor, for use in the Field in the Territory, or (y) solicitation of orders from any prospective purchaser located (i) in the case of Licensee, outside the Territory or (ii) in the case of Licensor, for use in the Field in the Territory. If either Party receives any request for Licensed Products for use from a prospective purchaser located outside of its respective territory or, in the case of Licensee, for use outside the Field, such Party shall promptly refer that order to the other Party. Licensee shall not, nor shall it permit its Affiliates or subcontractors to, deliver or tender (or cause to be delivered or tendered) any Licensed Products for use outside the Territory or outside the Field. For clarity, this Section 6.9 is not intended to preclude Licensor from providing supply of Licensed Products to the Territory as set forth in this Agreement or a supply agreement or from conducting Development activities in the Territory as permitted in this Agreement.

6.10. Compliance Self-Audit. Licensor shall at least once per Calendar Year perform (or have performed) an audit of its compliance with Applicable Laws (the "**Compliance Self-Audit**"). Licensee will, on **[***]** of each Calendar Year (commencing on **[***]** 2022) provide the JSC with a written report of the outcome of its annual Compliance Self-Audit, in any case specifying any material non-compliance with Applicable Laws in relation to the Development or Commercialization of Licensed Products, its expected impact and the remedial actions taken or to be taken and report on how the remediation has been implemented. The report of the Compliance Self-Audit shall be discussed at the JSC. The Parties will cooperate to maintain any privileged nature of such report and related communications.

ARTICLE 7

GRANT OF RIGHTS

7.1. Grants to Licensee. Subject to the terms and conditions of this Agreement, Licensor (on behalf of itself and its Affiliates) hereby grants to Licensee:

7.1.1. an exclusive (including with regard to Licensor and its Affiliates) license, with the right to grant sublicenses in accordance with Section 7.2, under the Licensed Technology to Develop the Licensed Compound and the Licensed Products in the Field in the Territory in accordance with the applicable Development Plans and Global Trials Plans (in each case as approved or subsequently amended by the JDC), and Commercialize the Licensed Compound and the Licensed Products in the Field in the Territory; and

7.1.2. subject to the next sentence, an exclusive right to Exploit (including a right of reference to) the Regulatory Approvals and other Regulatory Documentation relating to Licensed Products in the Territory Controlled by Licensor during the Term as necessary for purposes of Developing and Commercializing the Licensed Compound and Licensed Products in the Field in the Territory in accordance with the terms of this Agreement. Notwithstanding

anything to the contrary, if Licensee has not borne its share of the global Development costs relating to a New Global Trial for a particular Licensed Product in a particular indication in accordance with Section 3.7.2 or Section 3.3.1(c), as applicable, then Licensee shall not have the right to use **[***]**; provided that, if Licensee is required by the Regulatory Authority in the Territory to provide or reference such Regulatory Data or Regulatory Documentation in support of Licensee's other Development or Commercialization activities for an indication for which Licensee has borne such share of costs, then, at Licensee's request, Licensor will discuss in good faith granting Licensee the right to provide or reference such Regulatory Data or Regulatory Documentation for such indications to the extent so required.

7.2. Sublicenses. Licensee shall have the right to grant sublicenses under the licenses granted in Section 7.1 to: (a) Sublicensable Affiliates, provided that any such sublicense shall automatically terminate, and all rights shall revert back to Licensee in case such Sublicensable Affiliate ceases to be a Sublicensable Affiliate; and (b) to Affiliates that are not Sublicensable Affiliates and Third Parties with the prior written approval of Licensor. Licensee shall cause each sublicensee to comply with the applicable terms and conditions of this Agreement. Licensee hereby guarantees the performance of its sublicensees, and the grant of any such sublicense shall not relieve Licensee of its obligations under this Agreement, except to the extent they are satisfactorily performed by such sublicensee. All sublicenses shall be consistent with and expressly made subject to the terms and conditions of this Agreement. Sublicensee must agree in writing to be bound by the applicable terms and conditions of this Agreement, and each sublicense agreement shall indicate that Licensor is a third party beneficiary of such sublicense agreement. In case a Sublicensable Affiliate that has been granted a sublicense under this Agreement ceases to be a Sublicensable Affiliate, the respective sublicense agreement shall automatically terminate, and all rights shall revert back to Licensee. A copy of any sublicense agreement executed by Licensee (which must have received Licensor's prior written approval in case of a sublicense agreement with a Third Party as set forth above) shall be provided to Licensor within **[***]** days after its execution. As between the Parties, Licensee shall be fully responsible for all acts and omissions of its sublicensees.

7.3. Use of Affiliates and CROs. Licensee may subcontract its rights and obligations under this Agreement to: (a) Subcontractable Affiliates; and (b) to Affiliates that are not Subcontractable Affiliates and Third Parties with the prior written approval of Licensor (such approval not to be unreasonably withheld); provided that, in each case of (a) and (b), (i) no such permitted subcontracting shall relieve Licensee of any liability or obligation hereunder except to the extent satisfactorily performed by such subcontractor, and (ii) the agreement pursuant to which Licensee engages any subcontractor must (x) be consistent in all material respects with this Agreement, (y) contain an obligation to assign to Licensee ownership of all Information and Patents that are created, conceived or discovered by such subcontractor in the performance of such activities and that is related to the Licensed Compound or Licensed Products, and (z) contain terms obligating such subcontractor to comply with the confidentiality, intellectual property, and all other relevant provisions of this Agreement. As between the Parties, Licensee shall be fully responsible for all acts and omissions of its sublicensees.

For distribution activities, Licensee may use the Third Parties set forth on **Schedule 7.3** subject to **[***]**, whereby (1) **[***]** and (2) **[***]**.

7.4. Grants to Licensor. Subject to the terms and conditions of this Agreement, Licensee (on behalf of itself and its Affiliates) hereby grants to Licensor an exclusive, royalty free, perpetual, irrevocable license, with the right to grant sublicenses through multiple tiers, to Exploit the Sole Program IP and the Sole Program Patents Controlled by Licensee for the Development, Manufacture or Commercialization of Licensed Products outside the Territory.

7.5. Retention of Rights.

7.5.1. Except as expressly provided herein, neither Party grants any right or license, including any rights or licenses to any Patents, Information, regulatory documentation, any corporate names, Trademarks or logos owned or used by such Party or any of its Affiliates, or any other Patent or intellectual property rights not otherwise expressly granted herein, whether by estoppel, implication or otherwise.

7.5.2. Notwithstanding the grants in this ARTICLE 7, Licensor reserves the right to conduct Clinical Trials in the Territory to the extent this Agreement provides Licensor the right to do so, including pursuant to Section 3.3.

7.6. Confirmatory Patent License. Licensor shall execute all documents, give all declarations and reasonably cooperate with Licensee to the extent such documents, declarations or cooperation is/are required for the recording or registration of the licenses granted hereunder at the various patent offices in the Territory for the benefit of Licensee. Licensee shall reimburse Licensor for its reasonable out-of-pocket costs associated therewith.

7.7. In-licensing Agreements.

7.7.1. Licensee acknowledges that the In-licensing Agreements were executed prior to the Effective Date. Accordingly, any rights under the In-licensing Agreement that are sublicensed to Licensee under this Agreement are subject to the terms of the In-licensing Agreements and in no event shall this Agreement operate in any manner that would violate the terms of the In-licensing Agreements. Licensor will not amend, modify or terminate any In-licensing Agreement in any manner that would materially adversely affect Licensee's rights under this Agreement or materially increase Licensee's obligations under this Agreement, in each case, without Licensee's prior written consent. Licensor shall promptly provide Licensee with a copy of any amendment to an In-licensing Agreement if such amendment impacts Licensee's rights or obligations under this Agreement. Without limiting the foregoing, (a) the terms of the In-licensing Agreements set forth in **Schedule 7.7.1** shall be binding upon Licensee as if it were a party to the In-licensing Agreements to the extent applicable to the Territory and (b) Licensor shall have the right to forward reports and other Information provided by Licensee hereunder in accordance with the In-licensing Agreements.

7.7.2. Where the Patents in-licensed under the In-licensing Agreements are licensed to Licensor on a non-exclusive basis, the rights granted to Licensee under Section 7.1 shall be exclusive with respect to Licensor's non-exclusive rights.

7.7.3. Other In-Licenses. If, after the Effective Date, Licensor or its Affiliates enters into an agreement for rights to Patents or Information of a Third Party that claim or cover improvements or modifications to the Licensed Products (such as a new delivery system or another active ingredient intended for use in combination with the Licensed Compound), Licensor shall provide Licensee with written notice thereof. If Licensee desires to use such Patents or Information in connection with the Development or Commercialization of Licensed Product in the Field in the Territory, it shall provide written notice to Licensor and the Parties shall discuss and negotiate in good faith the economic and other terms upon which Licensor would grant Licensee rights to such Patents and Information. Unless and until the Parties have entered into an agreement or amendment to this Agreement providing for a grant of rights to Licensee under such Patents and Information, such Patents and Information shall be excluded from the Licensed Patents and Licensed Know-How.

7.8. Exclusivity with Respect to the Territory.

7.8.1. During the Term and for a period of **[***]**, except in case of termination of the Agreement by Licensee due to a material breach of Licensor, Licensee shall not, and shall cause its Affiliates not to (a) directly or indirectly, research, develop, commercialize or manufacture any Competing Product in any jurisdiction in the Territory, or (b) license, authorize, appoint, or otherwise enable any Third Party to directly or indirectly, develop, commercialize or manufacture any Competing Product in any jurisdiction in the Territory.

7.8.2. During the Term, Licensor shall not, and shall cause its Affiliates not to (a) directly or indirectly, research, develop, commercialize or manufacture any Competing Product in any jurisdiction in the Territory, (b) license, authorize, appoint, or otherwise enable any Third Party to directly or indirectly, develop, commercialize or manufacture any Competing Product in any jurisdiction in the Territory or (c) except as permitted in Section 3.3.1(b), grant a license to a Third Party to Develop the Licensed Compound or the Licensed Products in the Field in the Territory.

7.8.3. Notwithstanding Section 7.8.1 or Section 7.8.2, if a Party is subject to a Change of Control and, on the date of the closing of such Change of Control, the acquirer or any of its Affiliates prior to such Change of Control (collectively, the "**Acquiring Person**") is Developing, Manufacturing, or Commercializing a Competing Product for use in the Field (based on the applicable Regulatory Approval), then the Acquiring Person shall not be in breach of Section 7.8.1 or Section 7.8.2, as applicable, as a result of such Change of Control; provided, that, such Acquiring Person at all times Segregates the Competing Product and the Acquiring Person does not utilize or access the Licensed Technology for the Competing Product.

7.8.4. In case of a failure of either Party to comply with its covenants under this Section 7.8, the other Party shall have the right to terminate this Agreement for material breach **[***]**; provided that: (i) in the event the activity constituting non-compliance is carried out by such

Third Party, then such other Party shall not have the right to terminate this Agreement if the non-compliant Party takes **[***]** action (in any event within **[***]** days after such non-compliant Party learns of such non-compliance) to terminate its agreement with such Third Party or to cause the cessation of such non-compliance activities and such termination or cessation occurs in such **[***]** day period; and (ii) in the event the activity constituting non-compliance is the conduct of research on compounds that the non-compliant Party was not aware are Competing Products, then such other Party shall not have the right to terminate this Agreement if the non-compliant Party takes **[***]** action to cease such research (in any event ceases such research within **[***]** days after such non-compliant Party learns that such compounds are Competing Products).

ARTICLE 8

PAYMENTS AND RECORDS

In consideration of the rights granted by Licensor to Licensee on the Licensed Technology in accordance with Section 7.1 and the strong wish of the Licensor to have the commercialisation of the Licensed Product start as soon as possible in the Territory, the Licensee will make the below mentioned payments to the Licensor.

8.1. Upfront Payment. In partial consideration of the rights granted by Licensor to Licensee hereunder on the Licensed Technology as set out in Section 7.1, Licensee shall make a non-refundable, non-creditable payment of seventy five million Dollars ($75 million), which Licensor shall use to perform its investment obligations set out in the Share Issuance Agreement as attached hereto as **Schedule 8.1**. Upon the issuance and Delivery to the Subscriber of the Subscription Shares (each, as defined in the Share Issuance Agreement), Licensee's obligations under this Section 8.1 shall be satisfied in full.

8.2. Development Cost-Sharing Payment. In partial consideration of the rights granted by Licensor to Licensee hereunder on the Licensed Technology as set out in Section 7.1, Licensee shall make to Licensor a one-time, non-refundable and non-creditable payment of seventy five million Dollars ($75 million) in cash within **[***]** days after the Effective Date.

8.3. Development Milestone Payment. In partial consideration of the rights granted by Licensor to Licensee hereunder on the Licensed Technology as set out in Section 7.1, Licensee shall pay to Licensor a one-time milestone payment of twenty-five million Dollars ($25 million) in cash upon the first Regulatory Approval of a Licensed Product by the FDA for Myasthenia Gravis. Licensor will notify Licensee in writing upon the achievement of such milestone event. Licensee shall pay to Licensor the milestone payment within **[***]** days upon receipt of an invoice from Licensor.

8.4. Royalties.

8.4.1. Royalty Rates. As further consideration for the rights granted by Licensor to Licensee on the Licensed Technology in accordance with Section 7.1 hereunder, during the applicable Royalty Term, Licensee shall pay to Licensor royalties on Net Sales of all Licensed Products in the Territory, calculated as follows:

Net Sales of all Licensed Products in a Calendar Year	Royalty Rate
For that portion of aggregate Net Sales of all Licensed Products in the Territory during a Calendar Year less than **[***]**	**[***]**%
For that portion of aggregate Net Sales of all Licensed Products in the Territory during a Calendar Year equal to or greater than **[***]**	**[***]**%
For that portion of aggregate Net Sales of all Licensed Products in the Territory during a Calendar Year equal to or greater than **[***]**	**[***]**%
For that portion of aggregate Net Sales of all Licensed Products in the Territory during a Calendar Year equal to or greater than **[***]**	**[***]**%
For that portion of aggregate Net Sales of all Licensed Products in the Territory during a Calendar Year equal to or greater than **[***]**	**[***]**%

8.4.2. Royalty Term. On a Licensed Product-by-Licensed Product and jurisdiction-by-jurisdiction basis, Licensee's royalty obligations as set forth in this Section 8.4 shall begin with the First Commercial Sale of such Licensed Product in such jurisdiction in the Territory by Licensee, its Affiliates or sublicensees, and shall expire upon the last to occur of: (a) the expiry of the last to expire Valid Claim of any Licensed Patents (whether Controlled by Licensor alone or jointly with Licensee or a Third Party) that covers such Licensed Product, its Manufacture or its use in such jurisdiction in the Territory; (b) expiration of Regulatory Exclusivity in such jurisdiction in the Territory for such Licensed Product; or (c) twelve (12) years after the date of such First Commercial Sale of such Licensed Product in such jurisdiction in the Territory (the "**Royalty Term**").

8.4.3. Know-How Reduction. If, and for so long as, during the Royalty Term for a given Licensed Product in a jurisdiction in the Territory, there is both (i) no Valid Claim that claims or covers such Licensed Product or its method of use, and (ii) no Regulatory Exclusivity covering such Licensed Product, the royalty rate set forth in Section 8.4.1 with respect to such jurisdiction, shall be reduced to **[***]** of the royalty rate set forth in Section 8.4.1 solely with respect to Net Sales of such Licensed Product in such jurisdiction.

8.4.4. Third Party Agreements.

(a) Existing Licensor Agreements. If and for so long as Licensor is obligated to pay royalties under the **[***]** Agreement with respect to sales of Licensed Product

in the Territory, Licensee shall reimburse Licensor on a quarterly basis for an amount equal to **[***]** (as defined in the **[***]** Agreement) by Licensee, its Affiliates and sublicensees of Licensed Product (solely to the extent such Licensed Product constitutes a Product (as defined in the **[***]** Agreement)) in the Territory within **[***]** days after receipt of an invoice from Licensor. Except with respect to the **[***]** Agreement as set forth above, Licensor shall remain solely responsible for the payment of royalty, milestone, and other payment obligations, if any, due to Third Parties under the In-licensing Agreements and any other agreement entered into by Licensor prior to the Effective Date. In relation to the aforementioned, Licensee shall provide Licensor with such reasonably detailed information as is required to determine the total of Net Sales as defined in the **[***]** Agreement insofar as relating to the Territory.

(b) Licensee Agreements. Licensee shall be solely responsible for the payment of royalty, milestone, and other payment obligations, if any, due to Third Parties under any Third Party license agreement that Licensee or its Affiliates enters into after the Effective Date in connection with this Agreement; provided, however, that on a jurisdiction-by-jurisdiction and Licensed Product-by-Licensed Product basis, if, during the Royalty Term, Licensee **[***]** a license under certain Third Party Patents **[***]** for the use or exploitation of the Licensed Technology as contemplated under this Agreement, then, for the calculation of royalty payments due under Section 8.4.1 for such Licensed Product in such jurisdiction, Licensee may deduct **[***]** of the amounts payable by Licensee to such Third Party under such license agreement in relation to the respective Licensed Product in such jurisdiction.

(c) New Licensor Agreements. Licensee shall be responsible for any payments agreed to pursuant to Section 7.7.3.

8.4.5. Biosimilar Competition. If with respect to a given Licensed Product, one or more Biosimilar Products is/are sold in a particular jurisdiction in the Territory during a particular Calendar Quarter, and during such Calendar Quarter (a) the **[***]** and (b) the **[***]**, then the royalty rate for such Licensed Product in such jurisdiction will be reduced by **[***]** for **[***]**, provided that this Section 8.4.5 **[***]**.

8.4.6. Cumulative Deductions. Notwithstanding the above, any royalty reduction made pursuant to Section 8.4.3, Section 8.4.4 or Section 8.4.5 shall in no event reduce the applicable royalty rate for the respective Licensed Product in the respective jurisdiction to less than **[***]** of the amounts determined pursuant to Section 8.4.1.

8.4.7. Bundling Sale. If a Licensed Product is sold as part of a bundle including both (i) a Licensed Product, and (ii) other pharmaceutical products (a "**Bundling Sale**"), the Net Sales amount for the Licensed Product sold in such a Bundling Sale shall be adjusted to correspond to the price of the Licensed Product when sold separately in the Territory (if the Licensed Product is sold separately in the Territory) or (if the Licensed Product is not sold separately in the Territory) to the price reflecting the commercial value of the Licensed Product as compared to the other product included in the Bundling Sale. The factors to determine such price shall include the prices charged for the Licensed Product and the other product if sold separately in the Territory and the prices charged for products or corresponding market value and position in

the Territory. Notwithstanding the foregoing, in the case of discounts on the Bundling Sale, such discount with respect to the bona fide list price of a Licensed Product shall not, for purposes of calculating Net Sales, exceed a percentage that is greater than the average percentage discount of all products of Licensee, its Affiliates, or sublicensees in a particular "bundle", calculated as follows: Average percentage discount on a particular "bundle" = [1 - (X/Y)] x 100 where X equals the total discounted price of a particular "bundle" of products, and Y equals the sum of the undiscounted bona fide list prices of each unit of every product in such "bundle".

8.4.8. Royalty Payments and Reports.

(a) Commencing with the Calendar Quarter in which there is the First Commercial Sale of a Licensed Product, Licensee shall furnish to Licensor a written report showing in reasonably specific detail and to the extent reasonably possible, on a jurisdiction-by-jurisdiction basis,: (a) the quantity, average sales price and aggregate gross sales of all Licensed Products sold by Licensee, its Affiliates and its sublicensee(s) during such Calendar Quarter in the Territory, and the calculation of Net Sales from such gross sales, specifically listing the deductions from such gross sales, disaggregated by type, as permitted by this Agreement; (b) the calculation of the royalties which shall have accrued based upon such Net Sales; (c) the withholding taxes, if any, required by law to be deducted with respect to such sales; and (d) the exchange rate used in determining the amount of Dollars. Licensee shall provide to Licensor the final report containing such information within **[***]** after the end of each Calendar Quarter. In addition, Licensee shall provide to Licensor a non-binding preliminary report containing estimates on Net Sales and estimated calculation of royalties for the Territory within **[***]** after the end of each Calendar Quarter.

(b) All sales of Licensed Products shall be expressed both in the currency in which the sale is invoiced and in the Dollar equivalent converted in accordance with Section 8.5.

(c) All royalties shown to have accrued by each royalty report provided under this Section 8.4.8 shall be payable **[***]** days after the delivery of such royalty report. Payment of royalties in whole or in part may be made in advance of such due date.

8.5. Mode of Payment; Offsets. All payments to either Party under this Agreement shall be made by deposit of Dollars in the requisite amount to such bank account as the receiving Party may from time to time designate by notice in writing to the paying Party. For the purpose of calculating any sums due under, or otherwise reimbursable pursuant to, this Agreement (including the calculation of Net Sales expressed in currencies other than Dollars), a Party shall convert any amount expressed in a foreign currency into Dollar equivalents using the New York foreign exchange rate quoted in *The Wall Street Journal* (or, if *The Wall Street Journal* is no longer providing such exchange rate, a mutually agreed source) on the last Business Day of the Calendar Quarter to which such payment pertains. Except as provided in Section 8.7 or Section 3.7.3, Licensee shall have no right to offset, set off or deduct any amounts from or against the amounts due to Licensor. Except as provided in Section 8.10 and Section 8.7.4, all payments to Licensor under this Agreement will be irrevocable, non-refundable and non-creditable.

8.6. Forecasting. Throughout the Term, Licensee shall, no later than **[***]** of each Calendar Year, provide Licensor with a guidance forecast setting out an estimate of royalty payments for such four (4) Calendar Quarters (broken out by each Calendar Quarter). It is understood by the Parties that the guidance forecast provided shall be non-binding but in good faith and the royalty information provided is not a performance commitment or guarantee.

8.7. Taxes.

8.7.1. All payments by Licensee to Licensor pursuant to this Agreement shall be paid free and clear of any and all taxes, assessments, fees, duties or other charges of any kind to governmental, regulatory, or other Third Party, except for any withholding taxes required by Applicable Law in the Territory as covered by Section 8.7.2.

8.7.2. If Licensee is required by Applicable Law in the Territory to withhold any withholding taxes in respect of the payments by Licensee to Licensor pursuant to this Agreement, other than VAT and Indirect Taxes ("**Withholding Income Taxes**" and together with VAT and Indirect Taxes, "**Withholding Taxes**"), Licensee shall be entitled to make such deduction or withholding and shall timely pay the full amount deducted or withheld to the relevant tax authorities in accordance with Applicable Law and, each such amount payable under this Agreement will be increased by an amount equal to **[***]** of the **[***]** Tax required by Applicable Law in the Territory to be withheld. If, however, the Withholding Taxes are imposed as a result of an assignment or transfer of this Agreement or any rights and/or obligations resulting from this Agreement by the Licensee, the Licensee will be obliged to increase the payments due as per ARTICLE 8 in such a manner that taking into account the Withholding Taxes, Licensor will receive, after the withholding of such taxes, the amount that would have been payable by Licensee had no such assignment or transfer occurred. Additionally, if, however, the Withholding Taxes are imposed as a result of an assignment or transfer of this Agreement or any rights and/or obligations resulting from this Agreement by the Licensor, Licensee will not be obliged to increase the payments due under ARTICLE 8 to account for such increased Withholding Taxes, and Licensee will only be obliged to increase the payments due as per ARTICLE 8 in such a manner that taking into account the Withholding Taxes, Licensor will receive, after the withholding of such taxes, the amount that would have been payable by Licensee had no such assignment or transfer occurred.

8.7.3. Notwithstanding anything to the contrary herein, Licensee shall not assign its rights or obligations hereunder to any Person located, established or residing in a Non-Cooperative Jurisdiction.

8.7.4. To the extent that Applicable Law in the Territory requires Licensee to withhold any Withholding Tax in respect of the payments by Licensee to Licensor pursuant to this Agreement and that obligation on Licensee can be relieved (or the amount to be withheld can be reduced to a lesser amount) on the basis of an application for relief by Licensor, Licensor shall, at Licensee's request, as soon as is reasonably practicable, make such application (including but not limited to seeking relief under any applicable double taxation treaty or convention), to enable Licensor to receive amounts payable under this Agreement without any Withholding Taxes being withheld (or to receive amounts at a reduced rate of withholding tax). If Licensor obtains a refund

or credit of any such Withholding Taxes, Licensor shall remit or assign **[***]**%) of any such refund or credit to Licensee by applying the refund or credit as credit against future amounts due under this Agreement.

8.7.5. All payments due to the terms of this Agreement are expressed to be exclusive of VAT and Indirect Taxes. The Parties will cooperate to minimize and to obtain all available exemptions from any VAT and Indirect Taxes. If Licensee is required to deduct or withhold any VAT and Indirect Taxes on any payments payable by Licensee under this Agreement, Licensee shall be entitled to make such deduction or withholding and shall timely pay the full amount deducted or withheld to the relevant tax authorities in accordance with Applicable Law and such amount payable under this Agreement will be increased by an amount equal to such VAT and Indirect Taxes required by Applicable Law in the Territory to be withheld.

8.8. Interest on Late Payments. If any payment due to either Party under this Agreement is not paid when due, then, without limiting any rights or remedies of the receiving Party, such paying Party shall pay interest thereon (before and after any judgment) at a rate of **[***]** above the **[***]** rate of the respective currency for the time period in which such amount is outstanding, such interest to run from the date on which payment of such sum became due until payment thereof in full together with such interest.

8.9. Records.

8.9.1. Development and Commercialization Records. Licensee shall maintain records in sufficient detail and in good scientific manner appropriate for Patent and regulatory purposes, and in compliance with Applicable Law, which shall be complete and accurate and shall properly reflect all work done and results achieved in the performance of its Development and Commercialization activities by or on behalf of Licensee with respect to the any Licensed Product. Such records shall be retained by Licensee for at least **[***]** years after the termination of this Agreement, or for such longer period as may be required by Applicable Law. Upon request, Licensee shall provide copies of (and no more frequently than once per Calendar Year, except for cause, allow Licensor, or its designee, to inspect) the records it has maintained pursuant to this Section 8.9.1 to Licensor.

8.9.2. Financial Records. Licensee shall, and shall cause its subcontractors to, keep complete and accurate books and records pertaining to Net Sales of Licensed Products, in sufficient detail to calculate all amounts payable hereunder and to verify compliance with its payment obligations under this Agreement. Such books and records shall be retained by Licensee and its subcontractors until the later of (a) **[***]** years after the end of the Calendar Quarter to which such books and records pertain, and (b) the expiration of the applicable tax statute of limitations (or any extensions thereof), or for such longer period as may be required by Applicable Law.

8.10. Audit. Subject to the other terms of this Section 8.10, at the request of Licensor, Licensee shall, and shall cause its Affiliates and subcontractors to, permit an independent, certified public account designated by Licensor and reasonably acceptable to Licensee, its Affiliates and subcontractors at reasonable times and upon reasonable notice, to audit

the books and records maintained pursuant to Section 8.9 to ensure the accuracy of all reports and payments made hereunder for any Calendar Year ending not more than **[***]** months prior to the date of such request. These rights with respect to any Calendar Year shall be limited to once each Calendar Year (except for cause). The cost of this audit shall be borne by Licensor, unless the audit reveals a variance of more than **[***]**%) from the reported amounts, in which case Licensee shall bear the cost of the audit. If such audit concludes that (a) additional amounts were owed by Licensee, Licensee shall pay the additional amounts, with interest from the date originally due as provided in Section 8.8, or (b) excess payments were made by Licensee, Licensor shall reimburse such excess payments, in either case ((a) or (b)), within **[***]** days after the date on which such audit is completed. Licensor shall treat all financial information subject to review under this Section 8.10 as Confidential Information of Licensee and, prior to commencing such audit, shall cause its accounting firm to enter into a confidentiality agreement reasonably acceptable to Licensee. During the Term, each Party shall consider in good faith other reasonable procedures proposed by the other Party for sharing financial information in order to permit the other Party to close its books periodically in a timely manner.

8.11. No Other Compensation. Each Party hereby agrees that the terms of this Agreement and the Share Issuance Agreement fully define all consideration, compensation and benefits, monetary or otherwise, to be paid, granted or delivered by one Party to the other Party in connection with the transactions contemplated herein. Neither Party previously has paid or entered into any other commitment to pay, whether orally or in writing, any of the other Party's employees, directly or indirectly, any consideration, compensation or benefits, monetary or otherwise, in connection with the transaction contemplated herein.

ARTICLE 9

INTELLECTUAL PROPERTY

9.1. Ownership of Intellectual Property.

9.1.1. Background IP. Subject to the rights and licenses expressly granted under this Agreement, each Party shall retain all rights, title, and interests in, to and under any and all Patents and Information that are Controlled by such Party prior to the Effective Date or independent of this Agreement.

9.1.2. Program IP.

(a) As between the Parties, Licensor shall own all right, title, and interest in and to any and all Program IP that is an improvement, enhancement or modification to the Licensed Compound or Licensed Products or their method of use or manufacture ("**Product Improvement**"). Licensee will promptly disclose in writing to Licensor the conception, discovery, development or making of any Product Improvements. Licensee shall have no right to apply for Patents on any Product Improvements. Licensee shall, and hereby does (and shall cause its employees, agents, and subcontractors to, and shall cause its Affiliates and their respective employees, agents and subcontractors to), assign to Licensor all of its and their right, title and interest in and to Product Improvements. Upon Licensor's written request, Licensee shall, and shall cause its employees, agents, and subcontractors to, and shall cause its Affiliates and their

respective employees, agents and subcontractors to, execute and deliver such instruments and do such acts and things as may be necessary under Applicable Law, or as Licensor may reasonably request to effectuate and confirm the vesting of all right, title and interest in and to Product Improvements in Licensor. Product Improvements shall be part of Licensor's Sole Program IP and will be included within the Licensed Technology.

(b) Subject to Section 3.5, Section 4.5 and Section 9.1.2(a), as between the Parties, each Party shall own all right, title, and interest in and to any and all Program IP that is conceived, discovered, developed, or otherwise made solely by or on behalf of such Party or its Affiliates or subcontractors ("**Sole Program IP**").

(c) Subject to Section 3.5, Section 4.5 and Section 9.1.2(a), as between the Parties, Licensor and Licensee shall jointly own any Program IP (other than Product Improvements) that is conceived, discovered, developed, or otherwise made jointly pursuant to a Development Plan by or on behalf of Licensor, its Affiliates or subcontractors, on the one hand, and Licensee, or its Affiliates on the other hand ("**Joint Program IP**"). Each Party will promptly disclose in writing to the other Party the conception, discovery, development or making of any Joint Program IP. Each Party will have an undivided one-half interest in and to the Joint Program IP and shall, and hereby does (and shall cause its employees, agents and subcontractors to, and shall cause its Affiliates and their respective employees, agents and subcontractors to), make such assignment to the other Party as is needed to effectuate such joint ownership. Each Party may exercise its ownership rights in and to such Joint Program IP, including the right to license and sublicense or otherwise to Exploit, transfer, or encumber its ownership interest, without an accounting or obligation to, or consent required from, the other Party, but subject to the rights and licenses granted hereunder and the other terms and conditions of this Agreement. At the reasonable written request of a Party, the other Party will in writing grant such consents and confirm that no such accounting is required to effect the foregoing regarding Joint Program IP (but subject to the licenses granted under ARTICLE 7).

9.1.3. Employees and Agents. Prior to commencing any activities under this Agreement, each Party shall require all of its and its Affiliates' and subcontractors' employees and agents to assign all Program IP to such Party such that the Program IP can be assigned as set forth in Section 9.1.2 free and clear of all liens, encumbrances, charges, security interests, mortgages or other similar restrictions.

9.1.4. Ownership of Corporate Names. Each Party shall retain all right, title and interest in and to any corporate names, Trademarks and logos owned or otherwise used by such Party or any of its Affiliates.

9.2. Maintenance and Prosecution of Patents.

9.2.1. Patent Prosecution and Maintenance of Licensed Patents and Joint Patents.

(a) Subject to the remainder of this Section 9.2.1, Licensor shall, at its sole cost and expense, have the first right (but not the obligation) to prepare, file, prosecute,

and maintain all of the Licensed Patents (other than Joint Patents) in Licensor's name and all Joint Patents in the name of both Parties in the Territory through the use of internal or external counsel. Licensor shall keep Licensee reasonably informed with regard to the preparation, filing, prosecution, and maintenance of all Licensed Patents and Joint Patents in the Territory and shall provide Licensee with copies of a draft of any proposed filings of Licensed Patents and Joint Patents in the Territory at least **[***]** days prior to any proposed filing. Licensee shall have an opportunity to review and comment upon prosecution and filing decisions of Licensed Patents and Joint Patents prior to the filing and submission of correspondences to the Patent authorities in connection with any Licensed Patents and Joint Patents in the Territory. Licensee shall provide to Licensor any comments at least **[***]** days prior to the proposed filing, and Licensor shall consider any comments timely received from Licensee in good faith, and implement as appropriate.

(b) If Licensor decides not to prepare, file, prosecute, or maintain a Licensed Patent or Joint Patent in a jurisdiction in the Territory, Licensor shall provide **[***]** days prior written notice to Licensee of such intention, and, Licensee shall thereupon have the option, in its sole discretion, to assume the control and direction of the preparation, filing, prosecution, and maintenance of such Licensed Patent (other than a Joint Patent, in Licensor's name) or Joint Patent (in the name of both Parties) at its expense in such jurisdiction. In such event, Licensor shall promptly provide Licensee with the appropriate documents for transfer of responsibility for filing, prosecution and maintenance of such Licensed Patent or Joint Patent to Licensee or its designee and shall reasonably cooperate with Licensee or its designee as provided under Section 9.2.2. Thereafter, Licensee shall keep Licensor reasonably informed with regard to the preparation, filing, prosecution, and maintenance of such Patents and shall provide Licensor with copies of any proposed Patent filings at least **[***]** days prior to any proposed filing. Licensor shall have an opportunity to review and comment upon Patent prosecution and filing decisions prior to the submission of filing and correspondences to the Patent authorities in connection with any Licensed Patents and Joint Patents in the Territory. Licensor shall provide to Licensee any comments at least **[***]** days prior to the proposed filing, and Licensee shall consider any comments timely received from Licensor in good faith, and implement as appropriate.

9.2.2. Cooperation. The Parties agree to cooperate fully in the preparation, filing, prosecution, and maintenance of the Licensed Patents and Joint Patents in the Territory under this Agreement. Each Party's cooperation shall include executing all papers and instruments, or requiring its employees, consultants or contractors to execute such papers and instruments, so as to (a) effectuate the ownership of intellectual property set forth in Section 9.1.2; (b) enable the other Party to apply for and to prosecute Patent applications in the Territory; and (c) obtain and maintain any Patent extensions, supplementary protection certificates, and the like with respect to the Licensed Patents and Joint Patents in the Territory, in each case ((a), (b), and (c)) to the extent provided for in this Agreement.

9.2.3. Patent Prosecution and Maintenance of Sole Program Patents. Except as set forth in Section 9.2.1 with respect to any Sole Program Patents that are Licensed Patents, each Party, at its sole cost and expense and in its sole discretion, shall have the right (but not the obligation) to prepare, file, prosecute, and maintain all of the Sole Program Patents that it Controls.

9.2.4. Patent Term Extension and Supplementary Protection Certificate. Licensor shall have the right to make decisions regarding Patent term extensions, including supplementary protection certificates and any other extensions that are now or become available in the future, wherever applicable, for Licensed Patents and Joint Patents that cover the Licensed Compound or Licensed Products in the Territory. Licensor shall consult with Licensee prior to such decisions and shall consider Licensee's comments in good faith and implement as appropriate. Licensor shall have the primary responsibility of applying for any extension or supplementary protection certificate with respect to such Patents in the Territory at its cost and expense. Licensee shall provide reasonable assistance, as requested by and at the sole cost of Licensor, including by taking such action as a joint owner of the Joint Patents as is required under any Applicable Law to obtain such extension or supplementary protection certificate.

9.3. Enforcement of Patents.

9.3.1. Enforcement and Defense of Licensed Patents and Joint Patents.

(a) Each Party shall, promptly after becoming aware, notify the other Party in writing of any suspected or threatened infringement of the Licensed Patents or Joint Patents by a Third Party product in the Territory that is competitive with any Licensed Product, including suspected or threatened infringement based on the development, commercialization, or an application to market a generic or biosimilar product in the Territory (a "**Product Infringement**"). As between the Parties and subject to the In-licensing Agreements with respect to Patents in-licensed by Licensor under the In-licensing Agreements, Licensee shall have the first right, but not the obligation, to institute, prosecute and control any claim, suit or proceeding with respect to any Product Infringement of any Licensed Patent or Joint Patent in the Territory at its sole expense and Licensee shall retain control of the prosecution of such claim, suit or proceeding. If Licensee prosecutes any Product Infringement, Licensor shall have the right to join as a party to such claim, suit, or proceeding in the Territory and participate with its own counsel at its own expense; provided that Licensee shall retain control of the prosecution of such claim, suit, or proceeding.

(b) If Licensee does not undertake Commercially Reasonable Efforts to enforce or prosecute a Product Infringement (i) within **[***]** days following the first notice provided above with respect to the Product Infringement, or (ii) **[***]** Business Days before the time limit, if any, set forth in appropriate laws and regulations for filing of such actions, whichever comes first, then Licensor may (but shall have no obligation to) prosecute the Product Infringement of a Licensed Patent or Joint Patent in the Territory at its own expense and Licensor shall retain control of such prosecution. Licensor shall keep Licensee updated as to the steps it intends to take to prosecute a Product Infringement and shall otherwise provide Licensee with any information reasonably requested by Licensee.

(c) Licensor shall have the exclusive right (but not the obligation), in its sole discretion, to enforce Licensed Patents and Joint Patents for any infringement that is not a Product Infringement.

9.3.2. Cooperation. The Parties agree to cooperate fully in any Product Infringement action brought pursuant to Section 9.3.1. If a Party brings such an action, then the other Party shall, if necessary, either furnish a power of attorney solely for such purpose, join in, or be named as a necessary party to, such action. Unless otherwise set forth herein, the Party entitled to bring any Product Infringement litigation in accordance with Section 9.3.1 shall have the right to settle such claim; *provided* that Licensee shall have no right to settle any Product Infringement litigation in a manner that would in effect be equivalent to granting a license of any Licensed Patent or Joint Patent to any Third Party, and neither Party shall have the right to settle any Product Infringement litigation in a manner that has a material adverse effect or meaningfully diminishes the rights or interests of the other Party (including in the case of settlement by Licensee, a material adverse effect on the Licensed Product outside the Territory or outside the Field), or in a manner that imposes any costs or liability on, or involves any admission of fault by, the other Party, without the express written consent of such other Party. The Party commencing the litigation shall provide the other Party with copies of all pleadings and other documents filed with the court and shall consider reasonable input from the other Party during the course of the proceedings.

9.3.3. Recovery. Except as otherwise agreed by the Parties in connection with a cost sharing arrangement, any recovery realized as a result of such litigation described in Section 9.3.1 (whether by way of settlement or otherwise) shall be first allocated to reimburse the Parties for their costs and expenses in making such recovery (which amounts shall be allocated pro rata if the recovery is insufficient to cover the totality of such expenses). Any remainder for enforcement of Product Infringement after such reimbursement is made shall be (a) **[***]** in the event **[***]**; provided, however, that any **[***]** and (b) **[***]** in the event **[***]**. Any remainder for infringement actions brought by Licensor pursuant to Section 9.3.1(c) that are not Product Infringements shall be retained by Licensor.

9.3.4. Enforcement of Sole Program Patents. Except as set forth in Section 9.3.1 with respect to any Sole Program Patents that are Licensed Patents, each Party, at its sole cost and expense and in its sole discretion, shall have the right (but not the obligation) to institute, prosecute, control and retain all recoveries from any claim, suit or proceeding with respect to suspected or threatened infringement of Sole Program Patents that it Controls.

9.4. Infringement Claims by Third Parties. If the Development or Commercialization of the Licensed Compound or a Licensed Product in the Field in the Territory pursuant to this Agreement results in, or may result in, any claim, suit, or proceeding by a Third Party alleging Patent infringement by Licensee (or its Affiliates), Licensee shall promptly notify Licensor thereof in writing. Subject to the remainder of this Section 9.4 and Section 12.2, Licensee (or its Affiliates) shall have the right to defend any action which names Licensee (or its Affiliates) or claims the infringement, after the Effective Date, of any Third Party's Patent through the Development or Commercialization of the Licensed Product in the Field in the Territory. If necessary and at Licensee's expense, Licensor will reasonably assist and cooperate with Licensee in any such defense. Licensee shall keep Licensor reasonably informed of all material developments in connection with any such claim, suit, or proceeding, including by providing Licensor with copies of all pleadings filed in such action. Licensor shall have the right to (a) assume the defense of any claims that name Licensor or its Affiliates (and Licensee shall assist

and cooperate in any such defense) or (b) participate in the defense of the claims in actions defended by Licensee. Neither Party may enter into any settlement that affects the other Party's rights or interests without such Party's written consent, which consent will not be unreasonably withheld, conditioned, or delayed. Licensee will bear all costs and expenses (including attorneys' fees) and pay all damages and settlement amounts arising out of or in connection with any action described in this Section 9.4.

9.5. Invalidity or Unenforceability Defenses or Actions.

9.5.1. Notice. Each Party shall promptly notify the other Party in writing of any alleged or threatened assertion of invalidity or unenforceability of any of the Licensed Patents or Joint Patents by a Third Party, in each case in the Territory and of which such Party becomes aware.

9.5.2. Licensed Patents and Joint Patents. Licensor shall have the first right, but not the obligation, to defend and control the defense of the validity and enforceability of the Licensed Patents and Joint Patents at its own expense in the Territory. Licensee may participate in any such claim, suit, or proceeding in the Territory applicable to the Field with counsel of its choice at its own expense; provided that Licensor shall retain control of the defense in such claim, suit, or proceeding. If Licensor elects not to defend or control the defense of any such Licensed Patents or Joint Patent in a suit brought in the Territory that is applicable to the Field, or otherwise fails to initiate and maintain the defense of any such claim, suit, or proceeding, then Licensee may conduct and control the defense of any such claim, suit, or proceeding of such Licensed Patents or Joint Patent at its own expense and Licensor may participate with counsel of its choice at its own expense.

9.5.3. Cooperation. Each Party shall assist and cooperate with the other Party as such other Party may reasonably request from time to time in connection with the defense of Licensed Patents and Joint Patents as set forth in Section 9.5.2, including by being joined as a party plaintiff in such action or proceeding, providing access to relevant documents and other evidence, and making its and its Affiliates' employees, subcontractors, agents and consultants available at reasonable business hours and for reasonable periods of time. In connection with any such defense or claim or counterclaim, the controlling Party shall consider in good faith any comments from the other Party and shall keep the other Party reasonably informed of any steps taken, and shall provide copies of all documents filed, in connection with such defense, claim, or counterclaim. In connection with the activities set forth in this Section 9.5, each Party shall consult with the other as to the strategy for the defense of the Licensed Patents or Joint Patents in the Territory.

9.5.4. Sole Program Patents. Except as set forth in Section 9.5.2 with respect to any Sole Program Patents that are Licensed Patents, each Party, at its sole cost and expense and in its sole discretion, shall have the right (but not the obligation) to control the defense of the validity and enforceability of the Sole Program Patents that it Controls.

9.6. Product Trademarks. Licensor shall own all right, title, and interest to the Product Trademarks in the Territory, and shall have the sole right and responsibility for the

registration, prosecution, maintenance and enforcement thereof. All costs and expenses of registering, prosecuting, maintaining and enforcing the Product Trademarks in the Territory shall be borne solely by Licensee. Licensee shall provide all assistance and documents reasonably requested by Licensor in support of its prosecution, registration, maintenance and enforcement of the Product Trademarks in the Territory. Subject to the terms and conditions of this Agreement, Licensor hereby grants Licensee a non-exclusive, sublicensable (subject to Section 7.2) license under the Product Trademarks for Licensee to Commercialize the Licensed Products in the Field in the Territory in compliance with Applicable Laws and this Agreement. Licensee shall comply with Licensor's guidelines on the use and display of the Product Trademarks and quality control instructions. The Parties acknowledge and agree that the consideration for the provision of any rights or services by Licensor under this Section 9.6 is included in the payments payable by Licensee to Licensor pursuant to this Agreement.

9.7. Inventor's Remuneration. Each Party shall be solely responsible for any remuneration that may be due such Party's inventors under any applicable inventor remuneration laws or by contract.

9.8. Licensor Technology. Notwithstanding any provision in this Agreement to the contrary, Licensor shall have the right to transfer or assign ownership of any Licensed Know-How and Licensed Patents (including Licensor's interest in Joint Program IP and Joint Patents) as long as any such transfer or assignment is made in connection with a permitted assignment or transfer of this Agreement in accordance with Section 15.2.

ARTICLE 10

CONFIDENTIALITY AND NON-DISCLOSURE

10.1. Confidentiality Obligations. At all times during the Term and for a period of **[***]** years following termination or expiration of this Agreement, each Party shall, and shall cause its Affiliates, and such Party's and its Affiliates' officers, directors, employees and agents to, keep confidential and not publish or otherwise disclose to a Third Party and not use, directly or indirectly, for any purpose, any Confidential Information furnished or otherwise made known to it, directly or indirectly, by the other Party in connection with this Agreement, except to the extent such disclosure or use is expressly permitted by the terms of this Agreement or is in connection with the performance of, or the exercise of such Party's rights or obligations under, this Agreement. Notwithstanding the foregoing, but to the extent the receiving Party can demonstrate by documentation or other competent proof, the confidentiality and non-use obligations under this Section 10.1 with respect to any Confidential Information shall not include any information that:

10.1.1. has been published by a Third Party or is or hereafter becomes part of the public domain by public use, publication, general knowledge or the like through no wrongful act, fault or negligence on the part of the receiving Party;

10.1.2. has been in the receiving Party's possession prior to disclosure by the disclosing Party (as can be shown by competent written evidence) without any obligation of confidentiality with respect to such information;

10.1.3. is subsequently received by the receiving Party from a Third Party without restriction and without breach of any agreement between such Third Party and the disclosing Party; or

10.1.4. has been independently developed by or for the receiving Party without reference to, or use or disclosure of the disclosing Party's Confidential Information, as evidenced by such Party's internal records documenting such independent development.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the receiving Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the receiving Party unless the combination and its principles are in the public domain or in the possession of the receiving Party.

10.2. Permitted Disclosures.

10.2.1. Each Party may disclose Confidential Information to the extent that such disclosure is:

(a) in the reasonable opinion of the receiving Party's legal counsel, required to be disclosed pursuant to law, regulation or made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial and local governmental or regulatory body of competent jurisdiction, including by reason of filing with securities regulators; *provided*, *however*, that the receiving Party shall first have given **[***]** written notice (and to the extent possible, at least **[***]** days' notice) to the disclosing Party and cooperates with the disclosing Party in taking whatever action the disclosing Party deems necessary to protect its Confidential Information (for example, to quash such order or to obtain a protective order or confidential treatment requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or regulatory body or, if disclosed, be used only for the purposes for which the order was issued). If no protective order or other remedy is obtained, or the disclosing Party waives compliance with the terms of this Agreement, receiving Party shall furnish only that portion of Confidential Information which receiving Party is advised by counsel is legally required to be disclosed;

(b) made by or on behalf of the receiving Party to the Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval in accordance with the terms of this Agreement; *provided*, *however*, that reasonable measures shall be taken to assure confidential treatment of such information to the extent practicable and consistent with Applicable Law; or

(c) made by Licensor to third parties to the extent required pursuant to the terms of agreements entered into prior to the date hereof, in any case with respect to the **[***]** as part of applicable royalty reports and as otherwise required.

10.2.2. In addition, the receiving Party may disclose Confidential Information of the disclosing Party to the extent that such disclosure is:

(a) made to a Patent authority as may be reasonably necessary or useful for purposes of obtaining, defending or enforcing a Patent in accordance with the terms of this Agreement; *provided, however*, that reasonable measures shall be taken to assure confidential treatment of such information, to the extent such protection is available; or

(b) made to its or its Affiliates' financial and legal advisors who have a need to know such Confidential Information and are either under professional codes of conduct giving rise to expectations of confidentiality and non-use or under written agreements of confidentiality and non-use, or to potential investors, licensees or collaboration partners, in each case, at least as restrictive as those set forth in this Agreement; *provided, however*, that the receiving Party shall remain responsible for any failure by such financial and legal advisors or such investors, licensees or collaboration partners, to treat such Confidential Information as required under this ARTICLE 10.

10.3. Use of Name. Except as expressly provided herein, neither Party nor its Affiliates shall mention or otherwise use the name, logo, or Trademark of the other Party or any of its Affiliates (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material, or other form of publicity without the prior written approval of such other Party in each instance. The restrictions imposed by this Section 10.3 shall not prohibit either Party from making any disclosure identifying the other Party that, in the opinion of the disclosing Party's counsel, is required by Applicable Law; provided such Party shall submit the proposed disclosure identifying the other Party in writing to the other Party as far in advance as reasonably practicable so as to provide a reasonable opportunity to comment thereon.

10.4. Public Announcements. The Parties have agreed upon the content of a press release, which shall be issued promptly after the Effective Date substantially in the form attached as **Schedule 10.4**. Neither Party shall issue any other public announcement, press release, or other public disclosure regarding this Agreement or its subject matter without the other Party's prior written consent, except for any such disclosure that is, in the opinion of the disclosing Party's counsel, required by Applicable Law or the rules of a stock exchange on which the securities of the disclosing Party are listed. If a Party is, in the opinion of its counsel, required by Applicable Law or the rules of a stock exchange on which its securities are listed to make such a public disclosure, such Party shall submit the proposed disclosure in writing to the other Party as far in advance as reasonably practicable so as to provide a reasonable opportunity to comment thereon.

10.5. Publications.

10.5.1. The JDC will develop, and submit to the JSC for approval, a strategy for Publications, including at major medical conferences.

10.5.2. Licensee will submit to the JDC for review and comment written copies of each proposed Publication no later than **[***]** days before submission for publication or presentation. The JDC will provide its comments with respect to such Publication within **[***]**

after receipt of such written copy. Licensee shall incorporate any comments reasonably requested by the JDC in line with the Publication strategy. If the JDC cannot agree on a version of Licensee's Publication that is acceptable for both Parties, the matter shall be escalated to the JSC.

10.5.3. The JDC shall establish a process for efficient and rapid review and approval of Publications by Licensor that include Clinical Data generated by Licensee in the Territory.

10.5.4. Each Party shall remove any of the other Party's Confidential Information identified to the JDC from any such proposed Publication unless the other Party provides written consent. For clarity, Licensor shall be permitted to make Publications containing Licensor's Confidential Information, without any requirement of Licensee consent.

10.5.5. Any Publication under this Section 10.5 shall include recognition of the contributions of the other Party according to standard practice for assigning scientific credit, either through authorship or acknowledgement, as may be appropriate.

10.6. Trade Secrets. Each acknowledges that the other Party may transfer trade secrets to such Party in connection with this Agreement. With respect to any such information so disclosed that is identified as a trade secret by the disclosing Party, the receiving Party shall take all steps necessary to maintain such information as a trade secret for as long as such information remains a trade secret under Applicable Law, notwithstanding Section 10.1. No trade secret information of either Party may be transferred by the receiving Party to a Third Party until the receiving Party has (a) received the disclosing Party's written approval and (b) entered into a confidentiality agreement at least as restrictive as the confidentiality terms of this Agreement, and which shall contain provisions protecting the confidentiality of trade secrets as set forth herein. In addition, the receiving Party shall take steps reasonably necessary to ensure that such Third Party maintains such information as a trade secret. Such trade secrets may only be used by the receiving Party or such Third Party as expressly set forth in this Agreement.

10.7. Notification of Breach. The receiving Party shall notify the disclosing Party within **[***]** after the receiving Party or its Affiliates becoming aware of any disclosure of the disclosing Party's Confidential Information in violation of this ARTICLE 10, or any other breach of this ARTICLE 10, by the receiving Party, its Affiliates or its subcontractors or their respective officers, directors, employees or agents.

10.8. Return of Confidential Information. Upon the effective date of the termination of this Agreement for any reason, either Party may request in writing, and the other Party shall either, with respect to Confidential Information to which the other Party does not retain rights under the surviving provisions of this Agreement: (a) promptly destroy all copies of such Confidential Information in the possession of the other Party and confirm such destruction in writing to the requesting Party; or (b) promptly deliver to the requesting Party, at the other Party's expense, all copies of such Confidential Information in the possession of the other Party; *provided, however*, (i) the other Party shall be permitted to retain one copy of such Confidential Information for the sole purpose of performing any continuing obligations hereunder or for archival purposes and (ii) Licensor shall be permitted to retain Licensee's Confidential Information to the extent

necessary or reasonably useful for Licensor to Exploit Licensed Product after termination as contemplated by Section 14.1.3. Notwithstanding the foregoing, such other Party also shall be permitted to retain such additional copies of or any computer records or files containing such Confidential Information that have been created solely by such Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with such other Party's standard archiving and back-up procedures, but not for any other use or purpose.

10.9. Survival. All Confidential Information shall continue to be subject to the terms of this Agreement for the applicable periods set forth in this ARTICLE 10 regardless of the termination or expiration of this Agreement.

ARTICLE 11

REPRESENTATIONS AND WARRANTIES

11.1. Mutual Representations and Warranties. Licensor and Licensee each represents and warrants to the other, as of the Effective Date, and covenants, as follows:

11.1.1. Organization. It is duly organized, validly existing, and in good standing under the laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform this Agreement.

11.1.2. Authorization. The execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action, and do not violate (a) such Party's charter documents, bylaws, or other organizational documents, (b) in any material respect, any agreement, instrument, or contractual obligation to which such Party is bound, (c) any requirement of any Applicable Law, or (d) any order, writ, judgment, injunction, decree, determination, or award of any court or governmental agency presently in effect applicable to such Party.

11.1.3. Binding Agreement. This Agreement is a legal, valid, and binding obligation of such Party enforceable against it in accordance with its terms and conditions, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance, and general principles of equity (whether enforceability is considered a proceeding at law or equity).

11.1.4. No Inconsistent Obligation. It is not under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any material respect with the terms of this Agreement.

11.2. Additional Representations and Warranties of Licensor. Licensor further represents and warrants to Licensee, as of the Effective Date as follows:

11.2.1. Licensor or one of its Affiliates Controls the Licensed Patents listed in **Schedule 1.69** and the Licensed Know-How described in **Schedule 1.68**. Other than Patents or Information in-licensed under the In-licensing Agreements, there exists no Patent or Information

that is owned or in-licensed by Licensor or any of its Affiliates that is necessary or reasonably useful for the Development, Manufacture or Commercialization of the Licensed Compound or Licensed Product in the Field in the Territory that is not Controlled by Licensor or such Affiliate;

11.2.2. Schedule 1.69 sets forth a complete and accurate list of all Licensed Patents in the Territory;

11.2.3. Licensor has the right to grant to Licensee the licenses under the Licensed Technology in Section 7.1 and has not granted to any Third Party any license or other right with respect to Licensed Compounds, Licensed Products or Licensed Technology that conflicts with the licenses granted to Licensee hereunder;

11.2.4. to Licensor's knowledge, the Development of the Licensed Products in the Territory prior to the Effective Date did not infringe any valid claims of Patents owned or possessed by any Third Party and did not breach any obligation of confidentiality or non-use owed by Licensor or its Affiliates to a Third Party with respect to Information related to the Licensed Products;

11.2.5. to Licensor's knowledge, Licensor has provided to Licensee all material pre-clinical data and clinical data relating to Licensed Products that has been requested by Licensee; and

11.2.6. Licensor has received no written notice that a claim or action has been brought against Licensor, and Licensor has not received any written claim or demand as of the Effective Date alleging (a) that the Licensed Patents are invalid or unenforceable or (b) that the use of the Licensed Patents by Licensor in the Territory infringes or misappropriates the intellectual property rights of any Third Party. Licensor has received no written notice that an interference, opposition, cancellation or other protest proceeding has been filed against a Licensed Patent owned by Licensor.

11.3. Additional Representations and Warranties. Each Party further represents and warrants to the other Party, as of the Effective Date, and covenants during the Term, as follows:

11.3.1. it and its Affiliates have not ever been, are not currently, nor are they the subject of a proceeding that could lead to it or its Affiliates becoming a Debarred Entity, Excluded Entity or Convicted Entity and it and its Affiliates will not use in any capacity, in connection with the obligations to be performed under this Agreement, any person who is a Debarred Individual, Excluded Individual or a Convicted Individual. Such Party further covenants that if, during the Term, it or its Affiliates become a Debarred Entity, Excluded Entity or Convicted Entity, or listed on the FDA's Disqualified/Restricted List or if any employee or agent performing any of its obligations hereunder becomes a Debarred Individual, Excluded Individual or a Convicted Individual, or added to the FDA's Disqualified/Restricted List, such Party shall immediately notify the other Party. If Licensee is the notifying Party (or Licensor otherwise becomes aware that Licensee is in breach of this Section 11.3.1 and provides written notice thereof to Licensee), and if Licensee has not prevented such person from performing work under this

Agreement within **[***]** of becoming aware of such breach, then Licensor may terminate this Agreement immediately upon written notice to Licensee. This provision shall survive expiration of this Agreement. For purposes of this provision, the following definitions shall apply:

(a) a "**Debarred Individual**" is an individual who has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from providing services in any capacity to a Person that has an approved or pending drug or biological product application;

(b) a "**Debarred Entity**" is a corporation, partnership or association that has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from submitting or assisting in the submission of any abbreviated drug application, or a subsidiary or affiliate of a Debarred Entity;

(c) an "**Excluded Individual**" or "**Excluded Entity**" is (i) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General (OIG/HHS) of the U.S. Department of Health and Human Services, or (ii) is an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration (GSA).

(d) a "**Convicted Individual**" or "**Convicted Entity**" is an individual or entity, as applicable, who has been convicted of a criminal offense that falls within the ambit of 21 U.S.C. §335a (a) or 42 U.S.C. §1320a - 7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible; and

(e) "**FDA's Disqualified/Restricted List**" is the list of clinical investigators restricted from receiving investigational drugs, biologics, or devices if the FDA has determined that the investigators have repeatedly or deliberately failed to comply with regulatory requirements for studies or have submitted false Information to the study sponsor or the FDA.

11.3.2. Sanctioned Party Prohibition. The Parties acknowledge and agree that governmental authorities, including the U.S. federal government prohibits trade with certain sanctioned or blocked parties and publishes and maintains lists of Persons with whom trade is prohibited (each such governmental authority's list, a "**Sanctioned Party List**"). Each Party represents and warrants that it (a) is not on any Sanctioned Party List maintained by any governmental authority, (b) has no reason to believe it will be placed on any Sanctioned Party List, and (c) will not deal with, conduct any business with or otherwise transact in any manner related to the rights and obligations contained in this Agreement with any Person on any global Sanctioned Party List.

11.3.3. Anti-Corruption. Each Party and its Affiliates and their respective directors, officers, employees, agents or other persons or entities acting on its behalf have conducted and will conduct their activities under this Agreement in compliance with the US Foreign Corrupt Practices Act of 1977, as amended, the UK Bribery Act 2010 and any other applicable anti-corruption laws, rules or regulations (collectively, "**Anti-Corruption Laws**").

Without limiting the foregoing, each Party shall ensure that neither it, nor any of the foregoing Persons, shall offer, pay, promise, solicit or receive, directly or indirectly, any remuneration, benefit or advantage to or from any physician or other health care practitioner, governmental or political official, political party, candidate for public office, hospital, medical insurance company or similar provider organization, customer or other person in order to induce or encourage approval, referrals, purchase, or reimbursement or to obtain any other improper business advantage in violation of any Anti-Corruption Laws.

11.3.4. The Parties shall comply with all applicable data protection laws, including the General Data Protection Regulation (EU) 2016/679 of May 25, 2018, and those concerning medical confidentiality and privacy in relation to human subjects. The Parties acknowledge that they do not intend that one Party processes personal information for and on behalf of the other Party. If personal information is transferred between the Parties (as between controllers) pursuant to the performance of this Agreement, the Parties shall enter into a data processing agreement as is required by Applicable Laws. The Parties will enter into further data protection agreements if required by Applicable Laws. No personal data shall be shared by either Party if this would be in breach of Applicable Laws.

11.4. Diligence of Licensee. In accordance with the terms of this Agreement, Licensee acknowledges and agrees that to its best knowledge, it has received access to all Information relating to **[***]** that Licensee deemed necessary to conduct and complete its due diligence to its satisfaction, including **[***]**. Licensee acknowledges and agrees it had the opportunity to ask questions and request additional information, data and documents, and that **[***]**, and to Licensee's best knowledge, Licensor has provided all information, data and documents requested by Licensee.

11.5. DISCLAIMER OF WARRANTIES. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH IN THIS AGREEMENT, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, THE LICENSES GRANTED HEREIN ARE MADE “AS IS, WHERE IS” WITH ALL FAULTS. ANY INFORMATION PROVIDED BY LICENSOR OR ITS AFFILIATES TO LICENSEE IS OR HAS BEEN MADE AVAILABLE ON AN “AS IS” BASIS WITHOUT WARRANTY WITH RESPECT TO COMPLETENESS, COMPLIANCE WITH REGULATORY STANDARDS OR REGULATIONS OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER KIND OF WARRANTY WHETHER EXPRESS OR IMPLIED.

ARTICLE 12

INDEMNITY

12.1. Indemnification of Licensor. Licensee shall indemnify Licensor and its directors, officers, employees, and agents (the "**Licensor Indemnitees**") and defend and save each of them harmless, from and against any and all losses, damages, liabilities, penalties, costs, and expenses (including reasonable attorneys' fees and expenses) (collectively, "**Losses**") in connection with any and all suits, investigations, claims, or demands of Third Parties (collectively, "**Third Party Claims**") incurred by or rendered against the Licensor Indemnitees arising from or occurring as a result of: (a) the breach by Licensee or its Affiliates of this Agreement or any of its representations, warranties or obligations herein, (b) the negligence, reckless conduct or willful misconduct on the part of Licensee or its Affiliates, sublicensees or subcontractors or its or their respective directors, officers, employees, and agents in performing its or their obligations under this Agreement, or (c) the Exploitation by Licensee, or its Affiliates, sublicensees or subcontractors of the Licensed Technology, the Licensed Compound or any Licensed Products in the Territory, provided that the foregoing obligations of indemnification and saving harmless, in each case (a)-(c), shall not apply to the extent Licensor has an obligation to indemnify Licensee pursuant to Section 12.2.

12.2. Indemnification of Licensee. Licensor shall indemnify Licensee and its directors, officers, employees, and agents (the "**Licensee Indemnitees**"), and defend and save each of them harmless, from and against any and all Losses in connection with any and all Third Party Claims incurred by or rendered against the Licensee Indemnitees arising from or occurring as a result of: (a) the breach by Licensor or its Affiliates of this Agreement or any of its representations, warranties or obligations herein, (b) the negligence, reckless conduct or willful misconduct on the part of Licensor or its Affiliates or its or their respective directors, officers, employees, and agents in performing its obligations under this Agreement or (c) the Exploitation by Licensor, or its Affiliates, licensees or subcontractors (other than Licensee, its Affiliates, sublicensees or subcontractors) of the Licensed Technology, the Licensed Compound or any Licensed Products inside or outside the Territory, provided that the foregoing obligations of indemnification and saving harmless, in each case (a)-(c), shall not apply to the extent Licensee has an obligation to indemnify Licensor pursuant to Section 12.1.

12.3. Notice of Claim. All indemnification claims in respect of a Party, its Affiliates, or their respective directors, officers, employees and agents shall be made solely by such Party to this Agreement (the "**Indemnified Party**"). The Indemnified Party shall give the indemnifying Party prompt written notice (an "**Indemnification Claim Notice**") of any Losses or discovery of fact upon which such Indemnified Party intends to base a request for indemnification under this ARTICLE 12, but in no event shall the indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Losses (to the extent that the nature and amount of such Losses are known at such time). The Indemnified Party shall furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any Losses and Third Party Claims.

12.4. Control of Defense.

12.4.1. In General. At its option and sole expense, the indemnifying Party may assume the control of the defense of any Third Party Claim by giving written notice to the Indemnified Party within **[***]** days after the indemnifying Party's receipt of an Indemnification Claim Notice provided that the indemnifying Party has agreed to be fully responsible for all Losses relating to such claims to the extent provided in Section 12.1 or Section 12.2, as applicable. Upon assuming the defense of a Third Party Claim, the indemnifying Party shall have sole power to control the defense and, subject to Section 12.4.3, settlement of such Third Party Claim and sole power to appoint and control the retention of lead counsel for the defense of such Third Party Claim. If the indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party shall immediately deliver to the indemnifying Party all original notices and documents (including court papers) received by the Indemnified Party in connection with the Third Party Claim. Should the indemnifying Party assume the defense of a Third Party Claim, except as provided in Section 12.4.2, the indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party in connection with the analysis, defense or settlement of the Third Party Claim unless the incurring of those expenses were specifically requested in writing by the indemnifying Party.

12.4.2. Right to Participate in Defense. Without limiting Section 12.4.1, any Indemnified Party shall be entitled to participate in, but, subject to Section 12.4.1, not control, the defense of such Third Party Claim and to employ counsel of its choice for such purpose; *provided, however*, that such participation shall be at the Indemnified Party's own expense unless (a) the employment and control thereof has been specifically authorized by the indemnifying Party in writing, (b) the indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 12.4.1 (in which case the Indemnified Party shall control the defense), or (c) the interests of the Indemnified Party and the indemnifying Party with respect to such Third Party Claim are sufficiently adverse to prohibit the representation by the same counsel of both Parties under Applicable Law, ethical rules or equitable principles.

12.4.3. Settlement. With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim and that do not result in the Indemnified Party's becoming subject to injunctive or other relief or otherwise adversely affecting the business of the Indemnified Party in any manner, and as to which the indemnifying Party shall have acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, the indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Losses in connection with Third Party Claims, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 12.4.1, the indemnifying Party shall have authority to consent to the entry of any judgment, make any admissions that would adversely affect the Indemnified Party, enter into any settlement or otherwise dispose of such Loss; *provided* it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed), unless such compromise or settlement involves (a) any admission of legal wrongdoing by the Indemnified Party, (b) any payment by the Indemnified Party that is not indemnified under

this Agreement, or (c) the imposition of any equitable relief against the Indemnified Party (in which case, (a) through (c), the Indemnified Party may withhold its consent to such settlement in its sole discretion). If the indemnifying Party does not assume and conduct the defense of a Third Party Claim as provided in Section 12.4.1, the Indemnified Party may defend against such Third Party Claim in accordance with Section 13.2.4 *provided* that the Indemnified Party shall not settle any Third Party Claim without the prior written consent of the indemnifying Party, not to be unreasonably withheld, conditioned or delayed.

12.4.4. Cooperation. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party shall, and shall cause each indemnitee to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to the indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making Indemnified Parties and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the indemnifying Party shall reimburse the Indemnified Party for all its reasonable out-of-pocket expenses in connection therewith.

12.4.5. Expenses. Except as provided above, the costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party in connection with any Third Party Claim shall be reimbursed on a Calendar Quarter basis by the indemnifying Party, without prejudice to the indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund if the indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.

12.4.6. Subrogation. All rights an Indemnified Party may have against any Third Party who asserts a Third Party Claim that is paid by the indemnifying Party under this ARTICLE 12 shall be subrogated to the indemnifying Party.

12.5. Special, Indirect, and Other Losses. EXCEPT (A) FOR NEGLIGENCE OR WILLFUL MISCONDUCT, (B) FOR A PARTY'S BREACH OF ITS OBLIGATIONS UNDER ARTICLE 9 OR ARTICLE 10, OR (C) TO THE EXTENT ANY SUCH DAMAGES ARE REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A THIRD PARTY CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER THIS ARTICLE 12 OR AT LAW OR IN EQUITY, NEITHER PARTY NOR ANY OF ITS AFFILIATES SHALL BE LIABLE FOR INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR CONSEQUENTIAL DAMAGES, INCLUDING LOSS OF PROFITS OR BUSINESS INTERRUPTION, HOWEVER CAUSED, IN CONNECTION WITH OR ARISING IN ANY WAY OUT OF THE BREACH OF THE TERMS OF THIS AGREEMENT, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

ARTICLE 13

TERM AND TERMINATION

13.1. Term. This Agreement shall commence on the Effective Date and, unless earlier terminated in accordance herewith, shall expire on a jurisdiction-by-jurisdiction and Licensed Product-by-Licensed Product basis upon the date of expiration of the Royalty Term for such Licensed Product and jurisdiction (such period, the "**Term**"). Following the expiration of the Term (but not the termination of this Agreement), the grants in Section 7.1 shall survive and become fully-paid, **[***]** royalty-free and perpetual. Licensor shall upon expiration of the Term (but not the termination of this Agreement) endeavor to continue any supply of Licensed Products to Licensee in accordance with its ongoing supply obligations under the Commercial Supply Agreement, all as to be further specified in the Commercial Supply Agreement.

13.2. Termination for Cause.

13.2.1. Material Breach.

(a) Subject to Section 13.2.1(b), either Party (the "**Non-Breaching Party**") shall have the right to terminate this Agreement in its entirety immediately upon written notice if the other Party (the "**Breaching Party**") has materially breached this Agreement and the Breaching Party has not cured such breach within **[***]** days (or **[***]** days for breach of payment obligations) after receiving written notice from the Non-Breaching Party identifying such material breach with particularity (a "**Default Notice**").

(b) If the alleged Breaching Party disputes in good faith the existence or materiality of a breach specified in a Default Notice provided in accordance with Section 13.2.1(a), and such alleged Breaching Party provides the other Party notice of such dispute and submits such dispute for resolution in accordance with Section 15.5.2 within **[***]** after receipt of the Default Notice, the Non-Breaching Party shall not have the right to terminate this Agreement under Section 13.2.1(a) unless and until (i) the arbitrator(s), in accordance with Section 15.5.2, has determined that the alleged Breaching Party has materially breached this Agreement and the Breaching Party fails to cure such breach within **[***]** days following such arbitrators' decision, or (ii) if the alleged breach is in regards to a Party's diligence obligations under this Agreement, the Breaching Party fails to implement the measures contemplated in the last sentence of this Section 13.2.1(b). It is understood and agreed that during the pendency of such dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder. In the event the alleged breach is in regards to a Party's diligence obligations under this Agreement, then, concurrent with such dispute resolution process, the Parties shall discuss in good faith and implement appropriate measures that would improve the diligence level of such Party to address the other Party's concerns.

13.2.2. Termination for Bankruptcy, Insolvency or Similar Event. If either Party (a) becomes the subject, whether voluntarily or involuntarily, of any bankruptcy, insolvency, receivership or similar proceeding, and, in the event of an involuntary case under the bankruptcy code, such case is not dismissed within **[***]** days upon filing for such proceeding; (b) makes an assignment for the benefit of creditors; (c) appoints or suffers appointment of a receiver

or trustee over substantially all of its property; (d) files for or is subject to the institution of bankruptcy, liquidation or receivership proceedings; (e) admits in writing its inability to meet its obligations as they fall due in the general course; or (f) becomes subject to a warrant of attachment, execution, or distraint or similar process against substantially all of its property, then the other Party may terminate this Agreement in its entirety, effective immediately upon written notice to the other Party. The licenses and other rights granted pursuant to this Agreement shall be deemed to be grants of licenses to intellectual property for purposes of Section 365(n) of the United States Bankruptcy Code.

13.2.3. Additional Termination Right by Licensee. Licensee may terminate this Agreement in its entirety for any or no reason, upon **[***]** days' prior written notice to Licensor.

13.2.4. Termination for Patent Challenge. If Licensee or any of its Affiliates or sublicensees, anywhere in the Territory, challenges, or otherwise aides any Third Party to challenge, any claim in an Licensed Patent (or any corresponding worldwide family member) as invalid, unenforceable or otherwise not patentable or as not being infringed by Licensee's, its Affiliates' or sublicensees' activities absent the rights and licenses granted hereunder, then Licensor shall have the right to immediately terminate this Agreement upon written notice to Licensee; provided that (a) if such action is brought by Licensee's or its Affiliate's sublicensee and Licensee terminates the sublicense agreement with such sublicensee within **[***]** after such written notice, then Licensor shall not have the right to terminate this Agreement pursuant to this Section 13.2.4 and (b) this Section 13.2.4 will not apply to, and Licensor may not terminate this Agreement with respect to, any affirmative defense or other validity, enforceability, or non-infringement challenge, advanced by Licensee, any of its Affiliates or sublicensees in direct response to any claim or action brought in the first instance by, or on behalf of, Licensor against Licensee, its Affiliates or sublicensees.

ARTICLE 14

EFFECTS OF TERMINATION.

14.1. In the event of a termination of this Agreement, the following shall apply:

14.1.1. All rights and licenses granted by Licensor hereunder shall immediately terminate.

14.1.2. All payments accrued or paid to Licensor under this Agreement shall be irrevocable, non-refundable and non-creditable regardless of the cause for termination.

14.1.3. Licensee shall, at Licensor's written request, perform any or all of the following and agree upon a transition plan with Licensor that shall address the timing and logistics of the transition of the Licensed Products in the Field in the Territory to Licensor:

(a) effective upon Licensor's written request, Licensee shall, and hereby does grant (without any further action required on the part of Licensor) to Licensor and its Affiliates, an exclusive, royalty-free, fully paid, worldwide, irrevocable, perpetual license, with

the right to grant sublicenses through multiple tiers, under any Patents or Information Controlled by Licensee that is necessary or reasonably useful to Exploit Licensed Products in the Territory;

(b) Licensee shall, unless expressly prohibited by any Regulatory Authority, transfer control to Licensor of all clinical studies being conducted by Licensee as of the effective date of termination and, at Licensor's request, continue to conduct such clinical studies, **[***]**, for up to **[***]** to enable such transfer to be completed without interruption of any such Clinical Trial; *provided* that (i) Licensor shall not have any obligation to continue any Clinical Trial unless required by Applicable Law or (ii) with respect to each Clinical Trial for which such transfer is expressly prohibited by the applicable Regulatory Authority, if any, Licensee shall continue to conduct such Clinical Trial to completion at Licensee's cost if **[***]** or, if **[***]** and Licensor requests that Licensee continue such Clinical Trial, at Licensor's cost (including costs associated with any liabilities incurred after the effective date of such termination);

(c) Licensee shall assign (or cause its Affiliates to assign) to Licensor or its Affiliates any and all agreements with any Third Party with respect to the conduct of pre-clinical development activities or clinical studies for the Licensed Products, including agreements with contract research organizations, clinical sites, and investigators, unless, with respect to any such agreement, such agreement expressly prohibits such assignment or such agreement relates to products other than Licensed Products, in which case Licensee shall cooperate with Licensor in reasonable respects to secure the consent of the applicable Third Party to such assignment or to facilitate assignment in part of such agreement;

(d) Licensee shall assign (or cause its Affiliates to assign) to Licensor or its Affiliates any and all agreements with any Third Party that subcontracts or sublicenses any rights, obligations or activities related to the Licensed Products, including agreements with distributors, unless, with respect to any such agreement, such agreement expressly prohibits such assignment or such agreement relates to products other than Licensed Products, in which case Licensee shall cooperate with Licensor in reasonable respects to secure the consent of the applicable Third Party to such assignment or to facilitate assignment in part of such agreement;

(e) Licensee shall notify the applicable Regulatory Authorities and take any other action reasonably necessary to effect the transfers set forth in this Section 14.1.3;

(f) effective upon Licensor's written request, Licensee shall, and hereby does, assign to Licensor all right, title, and interest of Licensee and its Affiliates, if any, in each Product Trademark;

(g) Licensee shall duly execute and deliver, or cause to be duly executed and delivered, such instruments and shall do and cause to be done such acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary under, or as Licensor may reasonably request in connection with, or to carry out more effectively the purpose of, or to better assure and confirm unto Licensor its rights under, and to

effectuate and facilitate the transfer to Licensor of the Licensed Products in the Field in the Territory contemplated by, this Section 14.1.3; and

(h) Licensor shall have the right to obtain Licensee's inventory of Licensed Products at a price equal to the price paid by Licensee to Licensor under Section 5.2 or the Commercial Supply Agreement, respectively, provided that Licensee shall destroy the remaining inventory of Licensed Products at its sole cost and expense if Licensee does not exercise its right under this Section 14.1.3(h) within **[***]** months following the effective date of termination.

14.2. Remedies. Except as otherwise expressly provided herein, termination of this Agreement in accordance with the provisions hereof shall not limit remedies that may otherwise be available in law or equity.

14.3. Accrued Rights; Surviving Obligations. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination or expiration. Such termination or expiration shall not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement. Without limiting the foregoing, ARTICLE 1 (to the extent the definitions are used in any surviving provisions), the first sentence of Section 3.5, Section 3.7.3 (with respect to any payment obligations accrued before termination or expiration of this Agreement), Sections 7.4, 7.5, 7.8.1 and 7.8.3, Sections 8.4.8 and 8.5 (with respect to any payment obligations accrued before termination or expiration of this Agreement), Sections 8.7, 8.8, 8.9, 8.10, Sections 9.1.1, 9.1.2, 9.1.4, 9.2.2, the first sentence of Section 9.6, Section 9.7, ARTICLE 10 (other than Section 10.5), Section 11.3.1, Section 11.5, ARTICLE 12, Section 13.1, ARTICLE 14 and ARTICLE 15 of this Agreement shall survive the termination or expiration of this Agreement for any reason.

ARTICLE 15

MISCELLANEOUS

15.1. Force Majeure. Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from events beyond the reasonable control of the non-performing Party, including fires, floods, earthquakes, hurricanes, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorist acts, insurrections, riots, civil commotion, strikes, lockouts, or other labor disturbances (whether involving the workforce of the non-performing Party or of any other Person), acts of God or acts, omissions or delays in acting by any governmental authority (except to the extent such delay results from the breach by the non-performing Party or any of its Affiliates of any term or condition of this Agreement). The non-performing Party shall notify the other Party of such force majeure within **[***]** days after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. Following this notification, the Parties shall enter into good faith discussions on how to limit the negative impact of any such force majeure to the extent possible. The suspension of performance shall be of no greater scope

and no longer duration than is necessary and the non-performing Party shall use commercially reasonable efforts to remedy its inability to perform. Without limitation to the foregoing, if Licensee is the non-performing Party and the force majeure event specifically impacts Licensee (i.e., it does not also impact all or substantially all competitors of Licensee in the Territory), and if the suspension of performance continues for a consecutive period of **[***]** after the date of the occurrence, Licensor shall have the right to terminate this Agreement **[***]** upon written notice to Licensee, in its sole discretion, and **[***]**. In the event that Licensor terminates this Agreement in accordance with the aforementioned sentence, the Parties shall enter into discussions on any compensation to be paid by Licensor to Licensee for such termination taking into account the harm/costs to the Parties as a result of such termination and force majeure, to the extent agreed between the Parties and for which agreement the Parties shall make reasonable good faith efforts.

15.2. Assignment. This Agreement may not be assigned or otherwise transferred by either Party without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed; provided that each of the Parties may, without such consent, but with notification, assign this Agreement and its rights and obligations hereunder to any of its Affiliates or to a successor, whether in a merger, sale of stock, sale of assets or any other transaction, of all or substantially all of the portion of its business to which this Agreement relates. In case of an assignment by Licensee to an Affiliate, such Affiliate must agree in writing that in case such Affiliates ceases to be an Affiliate of Licensee, the Agreement, or in case of an assignment of rights or obligations, such assigned rights shall automatically be re-assigned and transfer back to Licensee, and that the parties to such assignment agreement will do all acts that are required to effectuate such re-assignment and transfer back to Licensee. Any attempted assignment or delegation in violation of this Section 15.2 shall be void and of no effect. All validly assigned and delegated rights and obligations of the Parties hereunder shall be binding upon and inure to the benefit of and be enforceable by and against the successors and permitted assigns of Licensor or Licensee, as the case may be. The permitted assignee or transferee shall assume all obligations of its assignor or transferor under this Agreement.

15.3. Change of Control.

15.3.1. Change in Control of Licensee. If Licensee enters into an agreement that results or that, if the transaction contemplated thereby is completed would result, in a Change of Control of Licensee, Licensee shall provide Licensor with prompt written notice describing such Change of Control in reasonable detail. Licensee shall provide such notice prior to the execution of such agreement, or, if not permitted by Applicable Law or third party confidentiality obligations, as soon as practicable thereafter and in any event not later than **[***]** following the consummation of the transaction contemplated by such agreement.

15.3.2. Change in Control of Licensor. Patents and Information that are Controlled by an Acquiring Person prior to a Change of Control of Licensor or that become Controlled by an Acquiring Person after a Change of Control of Licensor (without use of any Licensed Technology existing prior to such Change of Control) shall not be included within the Licensed Patents or Licensed Know-How except to the extent (a) such Patents or Information cover technology used by Licensor or its Affiliates or their respective (sub)licensees in the

Development, Manufacture or Commercialization of Licensed Compounds or Licensed Products and (b) such Patents or Information are necessary or reasonably useful for the Development or Commercialization of the Licensed Compound or the Licensed Products in the Field in the Territory.

15.4. Severability. If any provision of this Agreement is held to be illegal, invalid, or unenforceable under any present or future law, and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid, or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid, or unenforceable provision or by its severance herefrom, and (d) in lieu of such illegal, invalid, or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid, and enforceable provision as similar in terms to such illegal, invalid, or unenforceable provision as may be possible and reasonably acceptable to the Parties. To the fullest extent permitted by Applicable Law, each Party hereby waives any provision of law that would render any provision hereof illegal, invalid, or unenforceable in any respect.

15.5. Governing Law, Jurisdiction and Service.

15.5.1. Governing Law. This Agreement or the performance, enforcement, breach or termination hereof shall be interpreted, governed by and construed in accordance with the laws of the State of New York, United States, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction; provided, however, that all questions concerning the construction or effect of Patent applications and Patents shall be determined in accordance with the laws of the jurisdiction in which the particular Patent application or Patent has been filed or granted, as the case may be. The Parties agree to exclude the application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods.

15.5.2. Dispute Resolution. Any dispute arising out of or in connection with this Agreement, including any question regarding its existence, validity or termination, shall be referred to and finally resolved by arbitration administered by the International Centre for Dispute Resolution in accordance with the provisions of its International Arbitration Rules for the time being in force, which rules are deemed to be incorporated by reference in this Section 15.5.2. The seat of the arbitration shall be New York, New York. The tribunal shall consist of three (3) arbitrators. The language of the arbitration shall be English.

15.5.3. Service. Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Section 15.6.2 shall be effective service of process for any action, suit, or proceeding brought against it under this Agreement in any such court.

15.6. Notices.

15.6.1. Notice Requirements. Any notice, request, demand, waiver, consent, approval, or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if (a) delivered by hand, (b) by internationally recognized overnight delivery service that maintains records of delivery, addressed to the Parties at their respective addresses specified in Section 15.6.2 or (c) to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Section 15.6.1. Such notice shall be deemed to have been given as of the date delivered by hand or on the second Business Day (at the place of delivery) after deposit with an internationally recognized overnight delivery service. This Section 15.6.1 is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

15.6.2. Address for Notice.

If to **Licensor**, to:

argenx BV
Industriepark Zwijnaarde 7
9052 Zwijnaarde (Ghent)
Belgium
Attention: Tim van Hauwermeiren (CEO)
with an electronic copy by email to: **[***]**

If to **Licensee**, to:

Zai Auto Immune (Hong Kong) Limited
4F, Bldg 1, Jinchuang Plaza
4560 Jinke Rd
Shanghai, China, 201210
Attention: Samantha Du (CEO)

with an electronic copy to **[***]**

With a copy to:

Cooley LLP
3175 Hanover Street
Palo Alto, CA 94303
USA
Attention: **[***]**
with an electronic copy to **[***]**

If to **Parent**, to:

Zai Lab Limited
4F, Bldg 1, Jinchuang Plaza
4560 Jinke Rd
Shanghai, China, 201210
Attention: Samantha Du (CEO)
With an electronic copy to **[***]**

With a copy to:

Cooley LLP
3175 Hanover Street
Palo Alto, CA 94303
USA
Attention: **[***]**
with an electronic copy to **[***]**

15.7. Entire Agreement; Amendments. This Agreement and Schedules attached hereto (including the Share Issuance Agreement) sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understandings, promises, and representations, whether written or oral, with respect thereto are superseded hereby (including the Confidentiality Agreement between the Parties dated 14 September 2020). No amendment, modification, release, or discharge shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

15.8. English Language. This Agreement shall be written and executed in, and all reports and other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

15.9. No Benefit to Third Parties. Except as provided in ARTICLE 12, covenants and agreements set forth in this Agreement are for the sole benefit of the Parties hereto and their successors and permitted assigns, and they shall not be construed as conferring any rights on any other Persons.

15.10. Waiver and Non-Exclusion of Remedies. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party hereto of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available except as expressly set forth herein.

15.11. Further Assurance. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

15.12. Relationship of the Parties. It is expressly agreed that Licensor, on the one hand, and Licensee, on the other hand, shall be independent contractors and that the relationship between the Parties shall not constitute a partnership, joint venture, or agency. Neither Licensor, on the one hand, nor Licensee, on the other hand, shall have the authority to make any statements, representations, or commitments of any kind, or to take any action, which shall be binding on the other, without the prior written consent of the other Party to do so. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

15.13. Counterparts; Facsimile Execution. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed by facsimile or electronically transmitted signatures and such signatures shall be deemed to bind each Party hereto as if they were original signatures.

15.14. References. Unless otherwise specified, (a) references in this Agreement to any Article, Section or Schedule shall mean references to such Article, Section or Schedule of this Agreement, (b) references in any Section to any clause are references to such clause of such Section, and (c) references to any agreement, instrument, or other document in this Agreement refer to such agreement, instrument, or other document as originally executed or, if subsequently amended, replaced, or supplemented from time to time, as so amended, replaced, or supplemented and in effect at the relevant time of reference thereto.

15.15. Construction. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend, or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including," "include," or "includes" as used herein shall mean including, without limiting the generality of any description preceding such term. Any reference to "demonstrable" costs and expenses means those costs and expenses can be evidenced in writing. Whenever this Agreement refers to a "jurisdiction", (a) the PRC, (b) Hong Kong, (c) Macau, and (d) Taiwan shall each be deemed a separate jurisdiction and any part of (a), (b), (c) or (d) shall not be deemed a separate jurisdiction. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party hereto. Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provisions.

15.16. Parent Guarantee. Parent (a) hereby unconditionally guarantees the due and punctual payment and performance of all of Licensee's obligations and commitments under this Agreement, and (b) without limiting the foregoing, hereby covenants to procure and cause Licensee and its Affiliates to take such actions that may be necessary to support and duly complete the performance of Licensee's obligations and commitments under this Agreement. Parent agrees that such obligations of Licensee and this Agreement may be extended, modified or renewed, in whole or in part, in accordance with the terms of this Agreement (without notice or further assent from Parent). This guaranty is an irrevocable guaranty of payment and performance (and not just of collection) by Licensee and shall continue in effect until **[***]**, notwithstanding any extension, modification or renewal of the terms of this Agreement. This guarantee is primary and is in no way conditioned upon any requirement that Licensor first attempt to collect or enforce any guaranteed obligation from or against Licensee. The obligations of Parent hereunder shall be absolute and unconditional, and shall not be affected by or contingent upon (i) the liquidation or dissolution of,

or the merger or consolidation of Licensee with or into any corporation, any sale or transfer by Licensee or all or any part of its or their property or assets, or any assignment of this Agreement, (ii) the bankruptcy, receivership, insolvency, reorganization or similar proceedings involving or affecting Licensee, or (iii) any modification, alteration, amendment or addition of or to the Agreement; provided that, if Licensee is no longer an Affiliate of Parent, Parent has approved any such alteration, amendment or addition which would materially impact Parent's obligations hereunder. Parent's obligations under this Section 15.16 shall terminate upon **[***]**. Parent acknowledges that each of the waivers set forth in this Section 15.16 is made with full knowledge of its significance and consequences and under the circumstances the waivers are reasonable and not contrary to public policy. If any of said waivers is determined to be contrary to any applicable law or public policy, such waivers shall be effective only to the extent permitted by law.

[SIGNATURE PAGE FOLLOWS.**]**

THIS AGREEMENT IS EXECUTED by the authorized representatives of the Parties as of the Effective Date, 6 January 2020.

ZAI AUTO IMMUNE (HONG KONG) LIMITED

By: /s/ Samantha Du

Name: Samantha Du

Title: Chief Executive Officer

ARGENX BV

By: /s/ Tim Van Hauwermeiren

Name: Tim Van Hauwermeiren

Title: Chief Executive Officer

ARGENX BV

By: /s/ Dirk Beeusaert

Name: Dirk Beeusaert

Title: General Counsel

Solely with respect to Section 15.16:

ZAI LAB LIMITED

By: /s/ Samantha Du

Name: Samantha Du

Title: Chief Executive Officer

Schedule 1.22
Cost of Goods Sold

[***]

Schedule 1.65
Licensed Compound

[***]

Schedule 1.69
Licensed Patents

argenx Efgartigimod Patent portfolio listing in the Territory

People's Republic of China, Hong Kong, Macau and Taiwan

[***]

Schedule 3.2.1
Development Plan

[***]

Schedule 4.8
Pharmacovigilance

[***]

Schedule 5.3
Best estimate of COGS

[***]

Schedule 6.2.1
Form of Commercialization Plans

[***]

Schedule 7.3
Authorized Subcontractors

[***]

Schedule 7.7.1
Certain In-License Agreement Terms

[***]

Schedule 8.1
Share Issuance Agreement

[Omitted]

Schedule 10.4
Form of Press Release

[Omitted]

Exhibit 8.1

SUBSIDIARIES

Subsidiary	Jurisdiction of Incorporation
argenx BV	Belgium
argenx IIP BV	Belgium
argenx US, Inc.	United States
argenx Japan KK	Japan
argenx Switzerland SA	Switzerland

Exhibit 12.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
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 registrant as of, and for, the periods presented in this report;

4. The registrant'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 registrant 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 registrant, 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 registrant'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 registrant's internal control over financial reporting that occurred during the registrant's period covered by the Annual Report that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant'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 registrant'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 registrant's internal control over financial reporting.

Date: March 30, 2021

/s/ Tim Van Hauwermeiren
Name: Tim Van Hauwermeiren
Title: Chief Executive Officer
(Principal Executive Officer)

Exhibit 12.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
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 registrant as of, and for, the periods presented in this report;

4. The registrant'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 registrant 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 registrant, 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 registrant'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 registrant's internal control over financial reporting that occurred during the registrant's period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant'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 registrant'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 registrant's internal control over financial reporting.

Date: March 30, 2021

/s/ Eric Castaldi
Name: Eric Castaldi
Title: Chief Financial Officer
(Principal Financial Officer)

Exhibit 13.1

CERTIFICATION 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 on Form 20-F of argenx SE (the "Company") for the fiscal year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(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 result of operations of the Company.

Date: March 30, 2021

/s/ Tim Van Hauwermeiren
Name: Tim Van Hauwermeiren
Title: Chief Executive Officer
(Principal Executive Officer)

Exhibit 13.2

CERTIFICATION 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 on Form 20-F of argenx SE (the "Company") for the fiscal year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(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 result of operations of the Company.

Date: March 30, 2021

/s/ Eric Castaldi
Name: Eric Castaldi
Title: Chief Financial Officer
(Principal Financial Officer)

Exhibit 15.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement No. 333-225375 on Form S-8 and Registration Statement No. 333-225370 on Form F-3 of our reports dated March 31, 2021, relating to the financial statements of argenx SE and the effectiveness of argenx SE's internal control over financial reporting, appearing in this Annual Report on Form 20-F for the year ended December 31, 2020.
We consent to the incorporation by reference in the Registration Statement No. 333-225375 on Form S-8 and Registration Statement No. 333-225370 on Form F-3 of our reports dated March 30, 2021, relating to the financial statements of argenx SE and the effectiveness of argenx SE's internal control over financial reporting, appearing in this Annual Report on Form 20-F for the year ended December 31, 2020.

Deloitte Accountants B.V.

Rotterdam

March 30, 2021

/s/ Deloitte Accountants B.V.

P.J. Seegers