

**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, 2021
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)

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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, 2021 51,668,315 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

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Introduction

Unless otherwise indicated, “argenx,” “argenx SE,” “the Company,” “our company,” “we,” “us” and “our” refer to argenx SE and its consolidated subsidiaries.

We own various trademark registrations and applications, and unregistered trademarks and service marks, including “VYVGART™” and our corporate logo. All other trademarks or trade names referred to in this Annual Report are the property of their respective owners. Trade names, trademarks and service marks of other companies appearing in this Annual Report are the property of their respective holders. Solely for convenience, the trademarks and trade names in this Annual Report may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend to use or display other companies’ trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us, any other companies.

Our audited consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (*IFRS*), as issued by the International Accounting Standards Board (*IASB*). On January 1, 2021, we adopted a change in our presentation currency from euros to U.S. dollars. Accordingly, our consolidated financial statements are presented in this Annual Report in U.S. dollars. All references in this Annual Report to “\$,” “US\$,” “U.S.\$,” “U.S. dollars,” “dollars” and “USD” mean U.S. dollars and all references to “€,” “EUR,” and “euros” mean euros, unless otherwise noted. Throughout this Annual Report, references to ADSs mean ADSs or ordinary shares represented by ADSs, as the case may be.

Cautionary Statement with Respect to Forward-Looking Statements

This Annual Report on Form 20-F, (*Annual Report*), contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the *Securities Act*), and Section 21E of the Securities Exchange Act of 1934, as amended (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 products and 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;
- the anticipated pricing and reimbursement of our products and product candidates, if approved;
- the timing or likelihood of regulatory filings and approvals for any products and product candidates;
- our ability to establish sales, marketing and distribution capabilities for any of our products and product candidates that achieve regulatory approval;

- our regulatory strategy and our ability to establish and maintain manufacturing arrangements for our products and product candidates;
- the scope and duration of protection we are able to establish and maintain for intellectual property rights covering our products and 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 products and 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, including various variants thereof, 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 Annual Report, 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 but one of our products and 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, and only VYVGART™ for the treatment of generalized myasthenia gravis (**gMG**) has obtained regulatory approval in the U.S. and in Japan. Our trials may fail and even if they succeed we may be unable to commercialize any or all of our products and 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 contract research organizations (**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 products and product candidates and our business could be substantially harmed.
- We rely on patents and other intellectual property rights to protect our products, 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

[Reserved]

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 (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.

Risk Factors Related to argenx’s 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 commercial-stage biopharmaceutical company with a limited operating history and we have only very recently commenced our transition from clinical-stage to a commercial-stage company. Only VYVGART™ (efgartigimod alfa fcab) for the treatment of gMG has obtained regulatory approval in the U.S. on December 17, 2021 and in Japan on January 20, 2022 and we do not currently have any approvals in any other jurisdictions or for any other product candidates. Since our inception, we have incurred significant operating losses, totaling USD 1,400.2 million of cumulative losses. Our losses resulted principally from costs incurred in research and development, preclinical testing, clinical development of our product and 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 U.S. and in Europe. In the future, we intend to continue to conduct research and development, preclinical testing, clinical trials and regulatory compliance activities as well as the commercialization of VYVGART™ for the treatment of gMG in the U.S. and in Japan and we intend to continue our efforts to establish and maintain 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 strategic objectives 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 and 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 though we have received approval of and commercialize VYVGART™ for the treatment of gMG in the U.S. and in Japan, 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 VYVGART™ 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 products and product candidates, but may not be available to us on acceptable terms or at all.

Notwithstanding our significant position of cash and cash equivalents of USD 1,334.7 million and current financial assets of USD 1,002.0 million as of December 31, 2021, as disclosed in our consolidated financial statements for the financial year ended December 31, 2021, we expect to require additional funding in the future to sufficiently finance our operations, to advance development of our products and product candidates and to continue our business activities relating to research and development and the commercialization of our products. Our future capital requirements for VYVGART™ and our current or any future product candidates will depend on many factors, including (i) the progress, timing and completion of preclinical testing and clinical trials for our current or any future product candidates, (ii) the number of potential new product candidates we identify and decide to develop, (iii) 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, (iv) selling and marketing activities undertaken in connection with the potential commercialization of our current products or product candidates or any future product candidates, if approved, and costs involved in the creation of an effective sales and marketing organization, (v) manufacturing activities undertaken ahead of the potential commercialization of our current products or product candidates or any future product candidates, if approved, and costs involved in the creation of an effective supply chain, (vi) the costs involved in growing our organization to the size needed to allow for the research, development and potential commercialization of our current products or product candidates or any future product candidates, (vii) the costs involved in filing patent applications and maintaining and enforcing patents or defending against claims or infringements raised by third parties, (viii) the maintenance of our existing collaboration agreements and entry into new collaboration agreements, (ix) the amount of revenues, if any, we may derive either directly or in the form of royalty payments from future sales of our current products or product candidates or any future product candidates, if approved, and (x) 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.

In preparation of our commercial launch of VYVGART™, our cash burn increased significantly in 2021 to approximately double from 2020 and, based on our current plans to expand our commercial infrastructure and differentiated pipeline of assets, we expect this to continue in 2022. The increased spend will support our transition to an integrated immunology company and is, in particular, expected to be used to build our commercial infrastructure to support the commercialization of VYVGART™ in the U.S. and in Japan for the treatment of gMG

and, if approved, for a rapidly growing number of indications in the U.S. and Japan and our other key territories (including the EU), to advance the development of efgartigimod to market regulatory approval for the treatment of primary immune thrombocytopenia (*ITP*), pemphigus vulgaris (*PV*), chronic inflammatory demyelinating polyneuropathy (*CIDP*), bullous pemphigoid (*BP*), myositis, COVID-19 mediated postural orthostatic tachycardia syndrome (*COVID-19 mediated POTS*), primary Sjögren's syndrome (*primary SjS*), membranous nephropathy (*MN*) and lupus nephritis (*LN*), to advance clinical development of ARGX-117 in multiple Phase 2 proof of concept trials in multifocal motor neuropathy (*MMN*) and delayed graft function in the context of kidney transplant, to advance ARGX-119 and early stage pipeline candidates in our commercial franchises, the neuromuscular, hematology, dermatology and nephrology franchises, to build out a commercial supply chain to support our global launches of any approved products, to expand our pipeline of future product candidates through the IIP, and to fund other current and future research and development activities and technology development and for working capital and other general corporate purposes.

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 products 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 products or 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, 2021, we had cash and cash equivalents and current financial assets of USD 2,336.7 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.

Risk Factors Related to the Development and Clinical Testing of argenx's Products and Product Candidates

All but one of our products and 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, and only VYVGART™ for the treatment of gMG has obtained regulatory approval in the U.S. and in Japan. Our trials may fail and even if they succeed we may be unable to commercialize any or all of our products and 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 products and 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 or product candidate.

We could encounter delays, for example if a clinical trial is suspended or terminated by us, by the institutional review boards (**IRBs**) of the institutions in which such trials are being conducted or ethics committees, by the Data Review Committee (**DRC**) or Data Safety Monitoring Board (**DSMB**) for such trial or by the EMA, FDA, Pharmaceuticals and Medical Devices Agency (**PMDA**) or other regulatory authorities. Such authorities may impose 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, PMDA 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 products and product candidates belong, failure to demonstrate a benefit from using products or 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 products or product candidates, the commercial prospects of our products and product candidates will be harmed, and our ability to generate product revenues from any of these products and 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 products and product candidates and impair our ability to commercialize our products and 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 products and product candidates produced under cGMP requirements and other regulations. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance. We depend on our collaborators and on medical

institutions and CROs to conduct our clinical trials in compliance with Good Clinical Practices (**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 U.S. 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, PMDA 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 IND applications in the U.S. or Japan, or a clinical trial applications (**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, PMDA 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, PMDA 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 products and product candidates or products and product candidates employing our technology. Many of our clinical trials are blinded, which may cause us to incur significant expenses without any visibility as to the likelihood of successful results. For instance, we expect to receive topline data for the Phase 3 ADVANCE trial of 10 mg/kg efgartigimod for the treatment of primary ITP in the second quarter of 2022. As such study results are blinded, we will not know whether such trial has been successful until we receive the data and cannot assure you that such data will contain positive results. 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, EMA, PMDA 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. Only VYVGART™ for the treatment of gMG has obtained regulatory approval in the U.S. and in Japan and we do not currently have any approvals for any other indication, in any other jurisdictions or for any other product candidates and it is possible that none of our other existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval in any other jurisdiction or indication. Approval by one regulatory authority does not guarantee approval by another regulatory authority on the basis of the same data or at all. 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 products and 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 launch of VYVGART™ for the treatment of gMG. An MAA for efgartigimod for the treatment of gMG is currently under review with the EMA with an anticipated decision in the second half of 2022 and we expect Zai Lab to be able to file for approval in Greater China by mid-2022 and Medison in Israel in the second quarter of 2022. If VYVGART™ is not approved in one or more jurisdictions other than the U.S. and Japan, or if such approvals are significantly delayed, it could have a material adverse effect on our business.

Business interruptions resulting from the COVID-19 pandemic could cause a disruption of the development of our products and 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 has already endured several waves and variants, and, as of the date of this Annual Report, 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 effectiveness of vaccines and other treatments against new variants or mutations of the disease, the duration and effect of business disruptions and the short-term effects and ultimate effectiveness of the travel restrictions, quarantines, social distancing requirements 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 COVID-19 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 as a result of the continued mutation of the virus and uncertainty as to the effectiveness of vaccines and treatments therefor. 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.

We and/or our respective partners evaluate the advancement of each clinical program on a continuous basis taking into account the trajectory of COVID-19. If we and/or one of our partners elect not to move forward

with some or all of these clinical programs as a result of the COVID-19 pandemic or otherwise, we would not be entitled to some or all of the future payments which we are eligible to receive under the collaboration agreement with such partner.

We have been informed by our drug substance and drug product manufacturing partners about potential limitations in the availability of critical manufacturing materials due to the demand outweighing the available manufacturing capacity for these materials and prioritizations imposed by the U.S. government on the manufacturing of COVID-19 vaccines and therapeutics. Therefore, we may experience limitations in manufacturing capacity which could impact our ability to build adequate inventory as we support the commercial launch of VYVGART™ in gMG, and as we prepare for the commercial launch of efgartigimod in additional indications, if approved. We are working closely with our manufacturing partners to mitigate those risks to the extent possible.

Since March 2020, when foreign and domestic inspections by the FDA of facilities were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. Since April 2021, the FDA has conducted limited inspections and employed remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates. The FDA is continuing to complete mission-critical work, prioritize other higher-tiered inspectional needs (e.g., for-cause inspections), and carry out surveillance inspections using risk-based approaches for evaluating public health. As of the date of this Annual Report, ongoing travel restrictions and other uncertainties continue to impact oversight operations. Should the FDA determine that an inspection is necessary for approval of a marketing application and an inspection cannot be completed during the review cycle due to restrictions on travel, the FDA has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. A complete response letter indicates that the review cycle of the application is complete and the application will not be approved in its present form, and usually describes all of the specific deficiencies in the new drug application identified by the FDA. The applicant may either resubmit the new drug application, addressing all of the deficiencies identified in the letter, withdraw the application, or request a hearing. In 2020 and 2021, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. Such restrictions and delays could adversely affect our ability to obtain regulatory approval for and to commercialize our products and product candidates and have a material adverse effect on our business and financial results.

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 worsening of the severity or spread of the 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 American Depositary Shares (**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 when and 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.

When and if the EMA, FDA, PMDA or a comparable regulatory authority approves any of our product candidates, the manufacturing processes, labelling, 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 Current Good Manufacturing Practices (**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 products and product candidates are classified as biologics in the U.S. and, therefore, can only be sold if we obtain a biologics license application (**BLA**) from the FDA and therefore cannot be sold in the U.S. 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 labelling 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 products and product candidates may have serious adverse, undesirable or unacceptable side effects or even cause death, and we or others may identify undesirable or unacceptable side effects caused by VYVGART™ or any of our product candidates after they receive marketing approval.

Undesirable side effects that may be caused by our product candidates or by the combination of our product candidates with other medical products 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, PMDA 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 (**TEAEs**) in our clinical studies to date, and we may see additional adverse events and TEAEs in our ongoing and future trials, which may be more serious than those observed to date, and as a result, our ongoing and future trials may 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, which have not yet received approval by at least one regulatory authority other than VYVGART™ for the treatment of gMG, 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 we or others identify undesirable or unacceptable side effects caused by VYVGART™ or any of our other product candidates after they receive marketing approval, a number of potentially significant negative consequences could arise, including:

- regulatory authorities may withdraw approvals or revoke licenses of such products and require us to take such products off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, or a contraindication or request the issuance of 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 (**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 a neonatal Fc receptor (**FcRn**) antagonist recently initiated a voluntary pause of its ongoing clinical trials after an observed signal of elevated total cholesterol and low-density lipoprotein (**LDL**) levels in one of its ongoing trials. We have evaluated VYVGART™ in over 600 subjects and patients and to date we have not seen evidence of elevation in cholesterol markers related to treatment with VYVGART™. 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. Further, the FDA or the PMDA could require a change of label or even revoke the license, which could harm our reputation and have a material adverse effect on our ability to commercialize VYVGART™.

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

The market for pharmaceutical products is highly competitive. Our competitors we face in the autoimmune field, the field of leukemia and lymphoma and the monoclonal antibody drug discovery field include many established pharmaceutical companies, biotechnology companies, universities and other research or commercial institutions, many of which have substantially greater financial, research and development resources than we have. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing pharmaceutical products. Smaller and early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, the development of our products.

The fields in which we operate are characterized by rapid technological change and innovation. There can be no assurance that our competitors are not currently developing, or will not in the future develop, technologies

and products that are equally or more effective or are more economically attractive than any of our current or future technology or product. Competing products or technology platforms may gain faster or greater market acceptance than our products or technology platforms and medical advances or rapid technological development by competitors may result in our products and 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 products and 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 (**TCL**) and acute myeloid leukemia (**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. In addition, a limited number of patients enrolled in our clinical trials are located in Russia or Ukraine. The conflict between Russia and Ukraine, see "Global economic uncertainty and weakening product demand caused by political instability, changes in trade agreements and conflicts, such as the conflict between Russia and Ukraine, could adversely affect our business and financial performance." may prevent their continued participation in such trials and may prevent us from enrolling new patients from such countries which, in turn, may cause delays in certain ongoing clinical trials. For example, a relevant minority of the patients in the ADDRESS trial of SC efgartigimod for PF and PV are participating in studies conducted in Ukraine or Russia. Accordingly, we expect that the conflict between Russia and Ukraine will delay our ADDRESS trials, with the timing of topline data for the ADDRESS trial of SC efgartigimod for PF and PV currently under review.

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.

Regional political instability, changes in trade agreements and conflicts, such as the conflict between Russia and Ukraine could cause a disruption of the development of our products and product candidates, by impairing regulatory approval processes, and could thereby adversely impact our business.

We are conducting certain clinical trials in a large number of jurisdictions, including in Russia and Ukraine. Global conflicts, including the conflict between Russia and Ukraine, as well as economic sanctions implemented by the U.S., the European Union and other countries against Russia in response thereto, may cause disruption of regulatory activities relating to clinical development activities performed in affected regions, including the ability of regulatory authorities to conduct inspections at our clinical trial sites. For example, study data collected at Russian or Ukrainian sites may not be fit for submission as part of a regulatory approval process due to incompleteness or due to the fact that auditing of the data was not (fully) possible. This could delay data read-out points for our studies although we are currently insufficiently certain if and by how much such delays would occur. While at the date of this Annual Report we have no indication that the conflict between Russia and Ukraine and the corresponding sanctions imposed on Russia will hinder regulatory activities relevant for our pending or expected approval requests, we cannot predict the effect the conflict may have on regulatory activities in affected areas in the near future, and we cannot predict the range of areas that will be ultimately affected, and the direct or indirect negative impact this may have on our business. For example, as of the date of this Annual Report, ongoing travel restrictions, the COVID-19 pandemic and other uncertainties continue to impact FDA's oversight operations including routine surveillance, bioresearch monitoring and pre-approval inspections. In addition, we perform development activities in a number of countries neighboring Russia and Ukraine. If the conflict between Russia and Ukraine would escalate further, neighboring and other countries may be impacted which could also have an impact on our development activities in those countries.

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 only VYVGART™ has been approved in the U.S. and in Japan for commercial sale for the treatment of gMG; however, the current and future use of product candidates by us and our collaborators in clinical trials, and the sale of any approved products, 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 products and product candidates or any prospects for commercialization of our products and 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, the coverage of which we have extended to include the sale of VYVGART™, and we expect to expand our insurance coverage further if we obtain marketing approval for any of our other 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.

Risk Factors Related to Commercialization of argenx's Products and Product Candidates

We will face significant challenges in successfully commercializing our products.

We are in the process of continuing to setup our sales and marketing infrastructure, have limited experience in the sale or marketing of pharmaceutical products and may not or not timely have the appropriate infrastructure in place (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. While we have established our own sales force in the U.S. and in Japan for VYVGART™ for the treatment of gMG, we plan to expand our own sales and marketing capabilities and promote our products and product candidates if and when regulatory approval has been obtained in the relevant jurisdictions and/or for other product candidates or other indications. There are risks involved should we decide to expand our own sales and marketing capabilities or enter into arrangements with third parties to perform these services. Even if we have established or expanded our own 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 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, e.g. such as our agreement with Medison in connection with the commercialization of VYVGART™ for gMG in Israel, 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. This includes the risk 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 comply with and complete its 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 products and 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 products and 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 and 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 products and 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 products and product candidates for which we have obtained or intend to seek approval as biological products may face competition sooner than anticipated.

The Biologics Price Competition and Innovation Act (**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 twelve years from the date on which the reference product was first licensed. During this twelve-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing

the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the twelve-year period of exclusivity, as was the case with VYVGART™. 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 products and product candidates and may affect the prices we may set.

In the U.S., 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 U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. 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 products and product candidates. See section titled “*Information on Company, Business Section, Coverage, Pricing, and Reimbursement.*”

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. 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 products and 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. See section titled “*Information on Company – Business Section – Coverage, Pricing, and Reimbursement.*”

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

Our ability to successfully commercialize VYVGART™ or any other products and product candidate approved for commercialization 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 products and product candidates. Moreover, increasing efforts by governmental and third-party payors in the European Union, the U.S., 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 VYVGART™ or any other of our products and product candidates approved for commercialization. Limitations on reimbursement and reimbursement levels may diminish or prevent altogether any significant demand for VYVGART™ or our other product candidates once approved 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 be subject to healthcare laws, regulation and enforcement. Our failure to comply with these laws could harm our results of operations and financial conditions.

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. 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 EU 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 remains applicable in the United Kingdom. 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. See section titled "*Information on Company – Business Section – Healthcare Law and Regulation.*"

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 limited experience in the sale or marketing of pharmaceutical products and we are building and, in light of any future approval and commercialization, will need to continue building an internal program to ensure compliance with the different health care laws and regulations. The establishment, expansion and maintenance of an internal compliance program will involve substantial costs and the program may not be successful in complying with the different reporting requirements.

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. 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. See section titled "*Information on Company – Business Section – Healthcare Reform*."

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs.

In addition, 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 U.S. federal and state levels that seek to reduce healthcare costs, including the cost of prescription drugs, and improve the quality of healthcare. If such legislative and/or regulatory initiatives and changes would lead to increased restrictions on the marketing of VYVGART™ or any of our products and product candidates approved for commercialization, 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 VYVGART™ or any of our products and product candidates approved for commercialization.

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

In Europe, 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, the ***e-Privacy Directive***) required the 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.

Since May 25, 2018, 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 (the ***GDPR***) imposes a broad range of strict requirements on companies, including requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the European Economic Area (***EEA***) including to the U.S. or China, 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 have been 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 EU Member States 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 U.S. and China, in compliance with EU 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 any EU data protection authority, we may face fines and other penalties. Any such investigation or charges by EU 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 EU 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 U.S., or a patient population greater than 200,000 in the U.S. where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the U.S. In the European Union, after a recommendation from the EMA's Committee for Orphan Medicinal Products (**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 U.S., 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 products and 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 and product candidate.

We may from time to time seek orphan drug designation in the U.S. or Europe for certain indications addressed by our products and product candidates. For example, in September 2017, the FDA granted orphan drug designation for the use of VYVGART™ for gMG, in January 2019, the FDA granted orphan drug designation for the use of efgartigimod for the treatment of ITP and for the use of cusatuzumab for the treatment of AML and in August 2021, the FDA granted orphan drug designation for the use of efgartigimod co-formulated with rHuPH20 for the treatment of CIDP. 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 U.S. 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 products and product candidates.

Even when and if our products and product candidates are approved for marketing, sales of such products and product candidates will depend, in part, on the extent to which third-party payors, including government health programs in the U.S. (such as Medicare and Medicaid) and other countries, commercial health insurers, and managed care organizations, provide coverage and establish adequate reimbursement levels for such products and product candidates. Moreover, increasing efforts by governmental and third-party payors in the European Union, the U.S., 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 products and product candidates. For instance, access to VYVGART™ for the treatment of gMG may be restricted by limited payer coverage due to treatment criteria, which may prevent us from realizing its full commercial potential.

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 products and 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. 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.

Risk Factors Related to argenx's Business and Industry

Nearly all aspects of our activities are subject to substantial regulation. No assurance can be given that any of our products and 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 industries are 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 products and 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, or withdrawal of, approval of a product candidate. Any failure or delay of any of our product candidates in clinical studies or to receive or maintain 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 EEA, the U.S., 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, FDA or 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, PMDA 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, PMDA or one or more other comparable foreign authority. The FDA, EMA, PMDA 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, the PMDA'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, PMDA 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, PMDA 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, PMDA or any other regulatory authority. For instance, we have submitted a request for approval of VYVGART™ in gMG to the EMA and anticipate receipt of such approval in the first quarter of 2022 and the second half of 2022, respectively, but can provide no assurances that such approval will be obtained on the timeline that we expect or at all. In addition, we anticipate to file requests for approval of VYVGART™ in new indications, but can provide no assurances that such requests will be accepted or that approval will be obtained on the timeline that we expect or at all. Furthermore, the FDA has resumed inspections of certain domestic clinical trial operations and trial sites. We cannot be sure to 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 substantial time and attention devoted by our personnel to the commercial launch of VYVGART™ for the treatment of gMG.

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, PMDA 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 VYVGART™ for the treatment of gMG in jurisdictions outside the U.S. and Japan or for other indications, which would significantly harm our business, results of operations and prospects.

In addition, even when and if we obtain approval, regulatory authorities may approve any of our products and 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 non-compliance 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, data manipulation (scientific fraud) or unauthorized activities that violate: (i) the regulations of the FDA, EMA, PMDA 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 U.S. 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.

When and 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.

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 have been threatened by state actors and private citizens as a method of potential international sabotage in furtherance of national or political goals. Cyber-attacks could include the deployment of harmful malware, ransom-ware, 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 cyber-security 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. This risk is further increased by the growing amount of data transferred by us between Europe, China and the U.S. 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 (**ERP systems**) in which we have limited experience and which may prove a complex process that could cause delays in our commercialization process.

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

Our products and 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 we are not able to deliver our product to our partner in China.

Also, certain raw materials or other products necessary for the manufacture and formulation of our products and 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 products and 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. Interruptions in the supply of these materials, products or services may result from international conflict, trade disputes or economic sanctions enacted by, or imposed on, the U.S., the European Union or any other country. 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 products and 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 products and 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 there are any changes in the regulation requirements, our clinical development or commercial activities may be delayed or interrupted.

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, PMDA 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.

Risk Factors Related to argenx's 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 products and 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, PMDA 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, PMDA 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 products and product candidates. As a result, our results of operations and the commercial prospects for our products and 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 programs and product candidates. If we fail to enter into new strategic relationships our business, financial condition, commercialization prospects and results of operations may be materially adversely affected.

We are, and expect to continue to be, dependent on partnerships with partners relating to the development and commercialization of our existing and future research programs and product candidates. We currently have collaborative research relationships with various pharmaceutical companies such as AbbVie S.Á.R.L. (**AbbVie**), Shire AG (**Shire**, now known as Shire International GmbH), Zai Lab Limited (**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 the 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. In addition, we may not be able to control our collaborative partners' compliance with all applicable requirements for the commercialization of our products, which could adversely affect such commercializing and the profitability of such products.

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 products and product candidates, and we expect to continue to rely on third parties to manufacture our products, if approved. The development of such products and product candidates and the commercialization of any products, when and 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 products or product candidates for use in the conduct of our clinical studies or for commercial supply, when and if our products are approved. Instead, we rely on, and expect to continue to rely on contract manufacturing organizations (CMOs). We are forced to rely on limited and single sources of manufacturing. We currently rely mainly on Lonza for the manufacturing of the drug substance of all our 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 products and 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 products and 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 was unable to meet our demand for any of our products and 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, PMDA 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 facilities. 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 products and 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. 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. If 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.

Risk Factors Related to argenx's Intellectual Property

We rely on patents and other intellectual property rights to protect our products and 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 products and 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 and our products and product candidates. 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 U.S. Patent and Trademark Office (*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 products and 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 twelve years from the date on which the reference product was approved.

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 be assured 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 a pending patent application. Even if patents do issue and even if such patents cover our products and 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 issue 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 or product candidate. Furthermore, as to the U.S., 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 U.S. 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 U.S. 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 products and 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 products and product candidates, or other attributes of our products and 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. One such third party patent family of potential relevance to cusatuzumab is scheduled to expire in 2028. 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 products and 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 are unaware to relevant patents or applications. For example, certain U.S. applications filed after November 29, 2000 that will not be filed outside the U.S. may remain confidential until patents issue. In general, patent applications in the U.S. 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, product candidates and/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 products and product candidates that are held to be infringing. We might, if possible, also be forced to redesign products and product candidates so that we no longer infringe the third-party intellectual property rights. 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 products and 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 operate or 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 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 U.S. 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 products and 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 preserve such license agreements could prevent us from commercializing products and product candidates covered by the licensed intellectual property. Several of our existing license agreements are sub-licenses 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 products and 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 products and 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 products and product candidates, our business may be materially harmed.

Patents have a limited duration. In the U.S., 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 products and 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 (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 (**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 products and 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 products or 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 U.S. and the European Union. These products may compete with our products and 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 U.S. 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 (**AIA**) has been enacted in the U.S., 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 U.S. 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 products and product candidates may prevent us from successfully monetizing such products and 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 products and product candidates, our competitors might be able to enter the market, which would have an adverse effect on our business.

Our trade secrets may be misappropriated or disclosed, and confidentiality agreements with employees, consultants, advisors and potential collaborators may not adequately prevent disclosure of trade secrets and protect other proprietary information.

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 are difficult to protect, and we have limited control over the protection of trade secrets used by our licensors, collaborators and suppliers.

To protect this type of information against disclosure or appropriation by competitors, our usual practice is to require our employees, consultants, advisors and potential collaborators to enter into confidentiality agreements. Moreover, we put in place appropriate procedures to identify confidential material and restrict access to documentation. However, current or former employees, consultants, advisers and potential collaborators may unintentionally or willfully disclose our confidential information to competitors. We have entered into, and may in the future enter into additional, collaborations with our competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known to our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements.

Enforcing a claim that a third party obtained illegally and is using trade secrets is expensive, time consuming and the outcome is unpredictable, and the enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. Moreover, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us.

Risk Factors Related to argenx's 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 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. For example, we are currently outsourcing certain development areas which we cannot cover ourselves due to limited personnel capacities, for example to Zai Lab in relation to proof-of-concept trials in two kidney indications, LN and MN or to IQVIA in relation to proof-of-concept trials in primary SjS and COVID-19-mediated POTS. As a result of our limited financial, manufacturing and management resources, we may forgo or delay pursuit of opportunities with potential product candidates that later prove to have greater market potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Further, we may relinquish rights to such product candidates through collaborations, licensing or royalty arrangements in circumstances where it would have been more advantageous for us to retain sole development and commercialization rights.

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 strategic objectives 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.

Global economic uncertainty and weakening product demand caused by political instability, changes in trade agreements and conflicts, such as the conflict between Russia and Ukraine, could adversely affect our business and financial performance.

Economic uncertainty in various global markets caused by political instability may result in weakened demand for our products and difficulty in forecasting our financial results. Global conflicts, including the conflict between Russia and Ukraine, as well as economic sanctions implemented by the U.S., the European Union and other countries against Russia in response thereto, may negatively impact markets, increase energy and transportation costs and cause weaker macro-economic conditions. Political developments impacting government spending and international trade may also negatively impact markets and cause weaker macro-economic conditions. While at the date of this Annual Report the conflict between Russia and Ukraine and the corresponding sanctions imposed on Russia, did not directly impact our operations, we cannot predict the effect the conflict may have on the European and global economic and thereby, indirectly or directly affect our operations.

The conflict between Russia and Ukraine increased recruitment costs for our ADDRESS trial of SC efgartigimod for PF and PV and is expected to cause delays in our ADDRESS trial. In addition, the sanctions imposed by many countries, ongoing developments in and uncertainty related to the conflict between Russia and Ukraine could adversely affect us in other ways. For example, it could lead to increasing manufacturing costs for our products by causing disruptions in the supply chain, including as a result of transportation restrictions, increased costs of raw materials, production costs as well as having an adverse effect on the availability of materials. The conflict between Russia and Ukraine may also result in declines in the global equity and debt capital markets, limiting our ability to access such markets to obtain financing to conduct our operations and growth.

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, which may be re-evaluated if our shareholder base changes significantly. 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 USD, 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.

Changing expectations for inflation and deflation and corresponding fluctuations in interest rates could decrease demand for our products and negatively affect our performance, as well as increase certain operating costs, such as employee compensation.

Demand for our products and our operating costs may be negatively impacted by adverse conditions in the U.S., the European Union and global economies. A number of factors may contribute to a decline in economic conditions, including, but not limited to, rising government debt levels, fiscal and central bank policy shifts, the withdrawal of government interventions into the financial markets, changing consumer spending patterns, and

changing expectations for inflation and deflation which may impact interest rates. For example, at its January 2022 the Federal Open Market Committee Meeting, the United States Federal Reserve Bank indicated it expects to raise benchmark interest rates in 2022, partially in response to increasing inflation and a strong labor market. Increased interest rates may decrease demand for our products, even as inflation places pressure on consumer spending, borrowing and saving habits as consumers evaluate their prospects for future income growth and employment opportunities in the current economic environment, and as borrowers face uncertainty about the impact of rising prices on their ability to repay a loan. A change in demand for our products and any steps we may take to mitigate such change could impact our overall growth. Furthermore, inflationary and other economic pressure could negatively affect our business, financial condition, results of operations, cash flows and future prospects.

Additionally, an inflationary environment, combined with the tight labor market, could make it more costly for us to attract or retain employees. In order to meet the compensation expectations of our prospective and current employees due to inflationary factors, we may be required to increase our operating costs or risk losing skilled workers to competitors.

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 products and product candidates in Europe, the U.S. 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, 2021, we had \$815.3 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 and ordinary shares 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 (*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, USD, British pound and Swiss franc. Our functional currency is the USD, and the majority of our operating expenses are paid in USD, and we also receive payments from our main business partners Janssen Pharmaceuticals, Inc. (*Janssen*), AbbVie and Shire in USDs and we regularly acquire services, consumables and materials in euro, Japanese Yen, 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 USDs, fluctuations in the exchange rate between the USD 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 USD 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 USD, 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 USD and the euro, the USD 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 USD 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, 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 (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 (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 (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 (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, 2022 (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, 2023 and would also trigger a 10-K filing for the year ended December 31, 2022. 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, 2022, 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 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, 2021.

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 2021 taxable year, and do not anticipate being classified as a PFIC for U.S. federal income tax purposes for the 2022 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 (**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 2021 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 2022 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, since 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 +31 (0) 10 70 38 441. Our website address is www.argenx.com. The information contained on, or that can be accessed through, our website is not a part of, and shall not be included elsewhere 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 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, 2021, 2020 and 2019 amounted to \$121.4 million, \$5.1 million and \$46.7 million respectively. These capital expenditures primarily consisted of Priority Review Voucher (“**PRV**”) 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, 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, including in connection with the commercialization of VYVGART™. We anticipate our capital expenditure in 2022 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 commercial-stage, global, fully-integrated biotechnology company developing a deep pipeline of differentiated therapies for the treatment of severe autoimmune diseases. By combining our suite of antibody engineering technologies with the disease biology expertise of our research collaborators, we aim to translate immunology breakthroughs into a pipeline of novel antibody-based medicines through our discovery engine, the Immunology Innovation Program (**IIP**). We have a particular focus on neuromuscular, hematology, dermatology and nephrology indications within our growing commercial franchises. Through the building and use of commercial franchises, we plan to leverage capabilities and an organizational footprint for subsequent potential launches across our broad immunology pipeline. On December 17, 2021, the FDA approved efgartigimod, which is being marketed as VYVGART™ (efgartigimod alfa-fcab), for the treatment of gMG in adult patients who are acetylcholine receptor (**AChR**) antibody positive. On January 20, 2022, the Japan PMDA approved VYVGART™ (efgartigimod alfa) for the treatment of adult patients with gMG who do not have sufficient response to steroids or

non-steroidal immunosuppressive therapies (*ISTs*). With these regulatory milestones, VYVGART™ is the first-and-only approved neonatal FcRn blocker in the U.S and Japan.

Immunology Innovation Program

Our IIP is a core business strategy of co-creation and innovation. The IIP also serves as our discovery engine to identify novel targets and together, in collaboration with our scientific and academic partners, to build potential new pipeline candidates. Every current pipeline candidate from both our wholly-owned and partnered pipeline emerged from an IIP collaboration. As part of our long-term strategy, we have committed to continued investment in the IIP. As at the date of this Annual Report, we have executed on our commitment and aim to continue to bring forth at least one new asset per year from the IIP.

Examples of key collaborations with scientific and academic partners:

- Efgartigimod emerged from a collaboration with Professor Sally Ward and UT Southwestern that later became one of the blueprints for our IIP. Professor Ward's research identified the crucial role that FcRn plays in maintaining and distributing IgGs throughout the body, in 2013. Efgartigimod is a human IgG1 Fc fragment that is equipped with ABDEG™ mutations, which we in-licensed from UT Southwestern. These proprietary mutations modified efgartigimod to increase its affinity for FcRn while retaining the pH-dependent binding that is characteristic of FcRn interactions with its natural ligand, endogenous IgG.
- ARGX-117 was built in collaboration with Broteio Pharma (***Broteio***) which was launched in 2017 with support from Professor Erik Hack and the University of Utrecht, to conduct research to demonstrate preclinical proof-of-concept of the mechanism of ARGX-117. Professor Hack has done renowned research in the role of inflammation in disease, specifically in the complement system, and has contributed research and expertise to the approval of two complement inhibitors. His understanding of the mild phenotype associated with a natural C2 deficiency and C2's unique positioning at the junction of the classical and lectin pathways led to our interest in engineering ARGX-117, which is equipped with our proprietary NHANCE™ mutations and LALA mutations.

Our Suite of Technologies

Through our IIP, we collaborate with scientific and academic partners to identify immunology breakthroughs and build potential pipeline candidates. This is done through co-creation where we bring to the collaboration our unique suite of antibody engineering technologies and experience in clinical development and our partners bring a wealth of disease and target biology expertise.

- ***SIMPLE Antibody™*** platform: Our proprietary SIMPLE Antibody™ platform, based on the powerful llama immune system, allows us to exploit novel and complex disease biology targets. The platform sources antibody V-regions from the immune system of outbred llamas, each of which has a different genetic background. 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. Our SIMPLE Antibody™ platform allows us to access and explore a broad target universe while potentially minimizing the long timelines associated with generating antibody candidates using traditional methods.
- ***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 from Chugai Pharmaceutical Co., Ltd. (***Chugai***) 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 Inc.'s (***Halozyme***) ***ENHANZE®*** SC drug delivery technology: we have exclusive access to ENHANZE® 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.

Recent Developments

On February 21, 2022, Russia announced that it proposed to recognise the so-called Donetsk People's Republic and Lugansk People's Republic as independent republics and on February 24, 2022, Russia further announced the commencement of what it described as a "special military operation" in Ukraine. Since such announcement, Russian forces have entered Ukraine and, as at the date of this Annual Report, there is an ongoing military conflict in Ukraine. In connection with these events, new sanctions have been imposed by the U.S. and European Union, as well as many other countries around the world, on certain Russian companies and Russian individuals, with the nature and extent of these sanctions evolving on an ongoing basis.

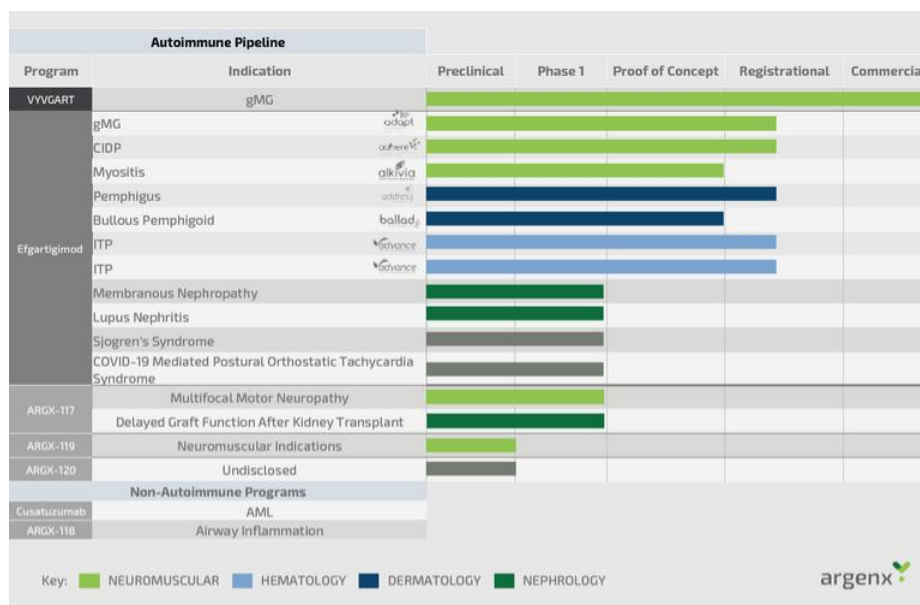
This ongoing conflict between Russia and the Ukraine has a direct, limited impact on our operations, given that we are conducting clinical trials in a large number of jurisdictions, including Russia and Ukraine. Due to the conflict, we are in some cases unable to ship samples from research sites to our third party central laboratory for analysis, recruited patients may no longer be able to participate in our clinical trials, and difficulties with recruiting patients in Russia and Ukraine might have an indirect limited impact on our business activities as we seek alternative recruitment options. Study data collected at Russian or Ukrainian sites may not be fit for submission due to incompleteness or due to practical limitations on auditability of the data. At this time we do not expect a material negative impact on our operations as a result of the crisis, but we do expect timing of topline data for the ADDRESS trial of SC efgartigimod for PF and PV may be delayed, although we currently cannot assess if this is the case and how significant such delay could be. We continue to assess the developments on a daily basis.

We do not generate revenues in Russia or the Ukraine and we do not expect the conflict as known to us at the date of this Annual Report to have a material impact on our future sales. Our supply chains have been directly affected in some cases, where we are unable to ship study drug to clinical sites, but as we are not supplying from Russia or the Ukraine but only to these countries for ongoing development activities, we expect the impact will be limited to ongoing clinical studies in these countries. In addition, we expect an overall increase in prices caused by the conflict and global inflation.

Our economic performance is, at the date of this Annual Report, not directly impacted by the conflict. We currently expect the additional costs for any delays and the opening of additional trial sites to be relatively limited and not material to our overall financial performance.

Our Products and Product Candidates

The following table summarizes key information on our portfolio of lead product and product candidates as of the date of this Annual Report.



Our programs

VYVGART™

Approval

On December 17, 2021, the FDA approved VYVGART™ (efgartigimod alfa-fcab) for the treatment of gMG in adult patients who are AChR antibody positive. These patients represent approximately 85% of the total gMG population (Behn et al. New Pathways and Therapeutics Targets in Autoimmune Myasthenia Gravis. J Neuromusc Dis 5. 2018. 265-277). On January 20, 2022, Japan's PMDA approved VYVGART™ (efgartigimod alfa) for the treatment of adult patients with gMG who do not have sufficient response to steroids or non-steroidal ISTs. With these regulatory milestones, VYVGART™ is the first-and-only approved neonatal FcRn blocker in the U.S. and Japan.

gMG is a rare and chronic neuromuscular disease characterized by debilitating and potentially life-threatening muscle weakness. VYVGART™ is a human IgG1 antibody fragment that binds to FcRn, resulting in the reduction of circulating IgG antibodies. The action of AChR autoantibodies at the neuromuscular junction is a key driver of gMG (Howard JF Jr, Utsugisawa K, Benatar M, et al. Safety and efficacy of efficacy of eculizumab in anti-acetylcholine receptor antibody-positive refractory generalised myasthenia gravis (REGAIN): a phase 3, randomised, double-blind, placebo-controlled, multicenter study. Lancet Neurol. 2017; 16: 976-86).

The approval of VYVGART™ is based on results from the global Phase 3 ADAPT trial, which were published in the July 2021 issue of The Lancet Neurology.

Input from the gMG community was integrated into the ADAPT trial design. Through listening to and learning from the gMG patient community, we understood that every gMG patient experiences the course of

disease differently. As a result, we designed a trial to reflect the individualized nature of gMG with a dosing approach that would be adapted to each patient’s individual response.

The Phase 3 ADAPT trial was a randomized, double-blind, placebo-controlled, multi-center, global trial evaluating the safety and efficacy of efgartigimod in patients with gMG. A total of 167 adult patients with gMG in North America, Europe and Japan enrolled in the trial and were treated. Patients were eligible to enroll in ADAPT regardless of antibody status, including patients with AChR antibodies (**AChR-Ab+**) and patients where AChR antibodies were not detected. Patients were randomized in a 1:1 ratio to receive efgartigimod or placebo for a total of 26 weeks. ADAPT was designed to enable an individualized treatment approach with an initial treatment cycle followed by a variable number of subsequent treatment cycles.

The ADAPT trial met its primary endpoint, demonstrating that significantly more anti-AChR antibody positive gMG patients were responders on the MG-ADL scale following treatment with VYVGART™ compared with placebo (68% vs. 30%; $p<0.0001$). Responders were defined as having at least a two-point reduction on the MG-ADL scale sustained for four or more consecutive weeks during the first treatment cycle.

Additionally, there were significantly more responders on the quantitative myasthenia gravis (**QMG**) scale following treatment with VYVGART™ compared with placebo (63% vs. 14%; $p<0.0001$). Responders were defined as having at least a three-point reduction on the QMG scale sustained for four or more consecutive weeks during the first treatment cycle.

As shown in figure 1, minimal symptom expression (**MSE**) is an increasingly important data point for physicians and patients because it is a measure of symptom-free status. In ADAPT, 40% of patients achieved MSE – or an MG-ADL score of 0 or 1 - at any time during cycle one. The right side shows depth of response. Over half of patients treated with efgartigimod experienced an improvement of five points or more on the MG-ADL scale by week four.

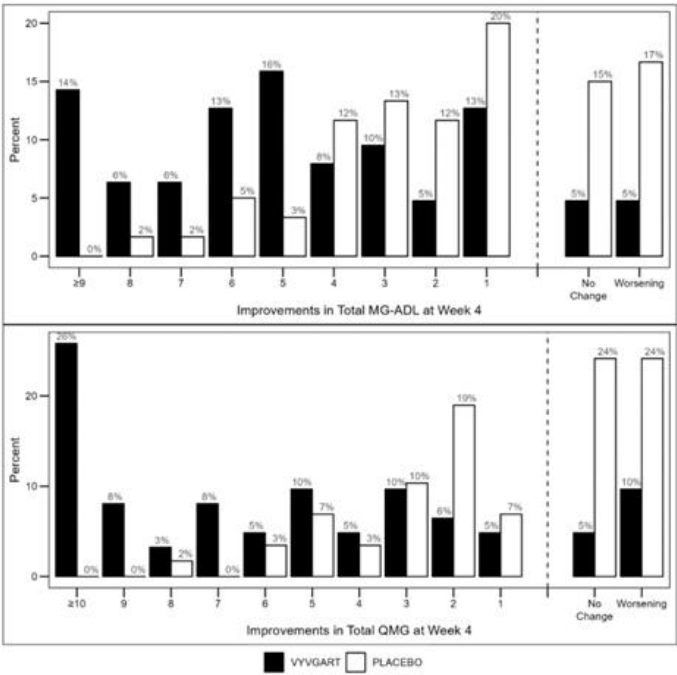


Figure 1: Percentage of patients with MG-ADL and QMG total score change four weeks after initial infusion of the first cycle in AChR-Ab positive population.

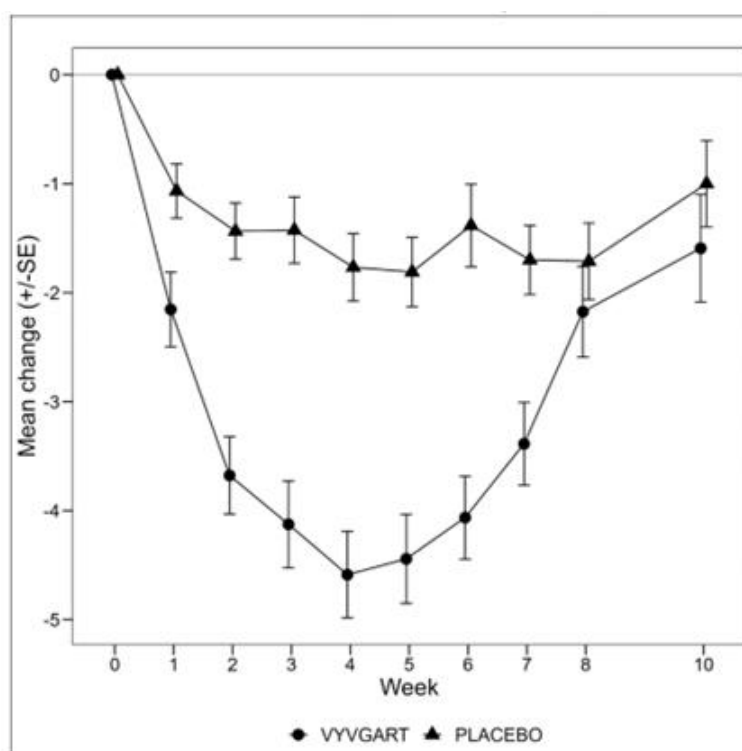


Figure 2: Mean change in total MG-ADL from cycle 1 baseline over time in AChR-Ab positive population.

VYVGART™ had a demonstrated safety profile in the ADAPT clinical trial. The most common adverse events in ADAPT were respiratory tract infection (33% vs 29% placebo), headache (32% vs 29% placebo), and urinary tract infection (10% vs. 5% placebo).

There is a pre-approval access program (**PAA**) for gMG patients that remains open in the EU, the United Kingdom, Hong Kong and Canada for eligible patients.

Commercialization and Regulatory Plans

The U.S. commercial launch for VYVGART™ is ongoing following the December 17, 2021 FDA approval. The Japan commercial launch of VYVGART™ is intended to start after the National Health Insurance (**NHI**) drug price listing, expected approximately 90 days after the approval on January 20, 2022. We have established our own sales force in the U.S. and Japan for VYVGART™ for the treatment of gMG. We plan to expand our own sales and marketing capabilities and promote our product candidates if and when regulatory approval has been obtained in the relevant jurisdictions. An MAA for efgartigimod for the treatment of gMG is currently under review with the EMA with an anticipated decision in the second half of 2022. argenx Canada was established in first quarter of 2022 in preparation for a potential Health Canada approval request and if granted commercial launch in Canada.

Development and commercialization may also be done through collaborations with third parties. In January 2021, we entered into an exclusive license agreement with Zai Lab for the development and commercialization of efgartigimod in China, Taiwan, Hong Kong and Macau. We expect Zai Lab to be able to file for approval in Greater China by mid-2022. Under the terms of the strategic agreement with Zai Lab, we received a

\$75 million upfront payment in the form of 568,182 newly issued Zai Lab shares calculated at a price of \$132 per share and a \$75 million guaranteed development cost sharing payment and are entitled to a \$25 million milestone payment in connection with FDA approval of VYVGART™. We will also be eligible for tiered royalties based on annual net sales of efgartigimod in China, Taiwan, Hong Kong and Macau. In October 2021, we announced an exclusive distribution agreement with Medison to commercialize efgartigimod for gMG in Israel. Medison will also be responsible for seeking requisite regulatory approvals, and we expect Medison to be able to file for approval in Israel in the second quarter of 2022. We intend to sign additional distribution partnerships for other territories.

Efgartigimod (formerly ARGX-113) Development

Mechanism of Action

As shown in figure 2, efgartigimod is a human IgG1 Fc fragment equipped with our ABDEG™ mutations that is designed to target the FcRn and reduce IgG. FcRn is foundational to the immune system and functions to recycle IgG, extending its serum half-life over other immunoglobulins that are not recycled by FcRn. IgGs that bind to FcRn are rescued from lysosomal. By binding to FcRn, efgartigimod can reduce IgG recycling and increase IgG degradation.

Compared to alternative immunosuppressive approaches, such as B-lymphocyte (***B-cell***), depleting agents, efgartigimod acts in a highly selective manner. At the date of this Annual Report, Efgartigimod has been evaluated in over 600 subjects and has been observed to significantly reduce concentrations of all IgG subtypes without decreasing levels of other immunoglobulins or human serum albumin, which is also recycled by FcRn.

In a randomized, double-blind, placebo-controlled first-in-human study of 62 healthy volunteers, efgartigimod treatment resulted in rapid and specific clearance of serum IgG levels. Single administration of efgartigimod reduced IgG levels up to 50% while multiple dosing further lowered IgGs on average by 75% from baseline. Approximately eight weeks following the last administration, IgG levels returned to baseline. Efgartigimod did not alter homeostasis of albumin or immunoglobulins other than IgG and no serious adverse events related to efgartigimod infusion were observed.

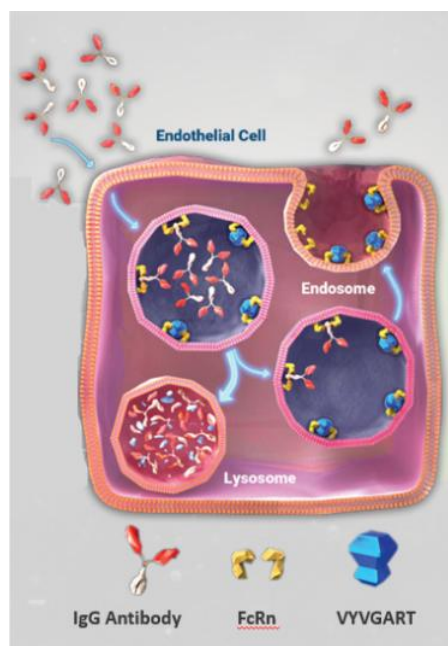


Figure 2: Efgartigimod's mechanism of action blocks the recycling of IgG antibodies and removes them from circulation

Based on its mechanism of action in targeting FcRn to selectively reducing IgGs, efgartigimod has the potential to address a multitude of severe autoimmune diseases where pathogenic IgGs are believed to be mediators of disease.

At the date of this Annual Report, we are evaluating efgartigimod in six autoimmune indications where significant unmet need exists despite the availability of commonly used therapies. These include gMG, CIDP and myositis within our neuromuscular franchise; ITP within our hematology franchise; and PV and PF and BP within our dermatology franchise. In 2022, we announced that we will expand into four additional autoimmune indications, including LN and MN within our nephrology franchise and primary SjS and post-COVID-19 mediated POTS.

Indication Selection Strategy

In selecting our indications for efgartigimod, we utilize the following strategy:

- We first start with a strong, unifying biological rationale. The indications in our pipeline are unified in that there exists a wide range of supportive evidence that demonstrates that each is IgG-mediated. This ranges from published literature, clinical trials with currently used therapies such as intravenous immunoglobulin (IVIg), PLEX, or Rituximab, and other experiments, such as passive transfer models.
- We also look at indications where a significant clinical or commercial opportunity exists. These are disease areas where there is a significant unmet need for innovation as patients are often not well-managed by current therapies and their respective side effects. For example, steroids and ISTs are often used to treat a multitude of autoimmune diseases, but for the indications in our pipeline thus far, these have been observed to be lacking in both safety and tolerability.

- Furthermore, for each indication, there is a defined path forward with established precedent for how to run proof-of-concept and registrational trials with generally accepted clinical and regulatory endpoints.
- Finally, as we work towards achieving our ‘argenx 2025’ vision, we select indications where there is a reasonable fit within our growing neuromuscular, hematology, dermatology, and nephrology franchises.

Formulations

Overview

We are developing two formulations of efgartigimod to address the needs of patients, physicians, and payors across indications and geographies, including IV efgartigimod and the ENHANZE® (licensed from Halozyme) SC formulation.

IV

We conducted a 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.

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 3. For all doses in the multiple ascending dose part of the Phase 1 clinical trial, 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 our proprietary ABDEG™ technology (detailed in section 1.8.2 “Platform Technologies”) on increasing the intracellular recycling of efgartigimod. In both the single and multiple ascending dose portions, no significant reductions in IgM, IgA or serum albumin were observed.

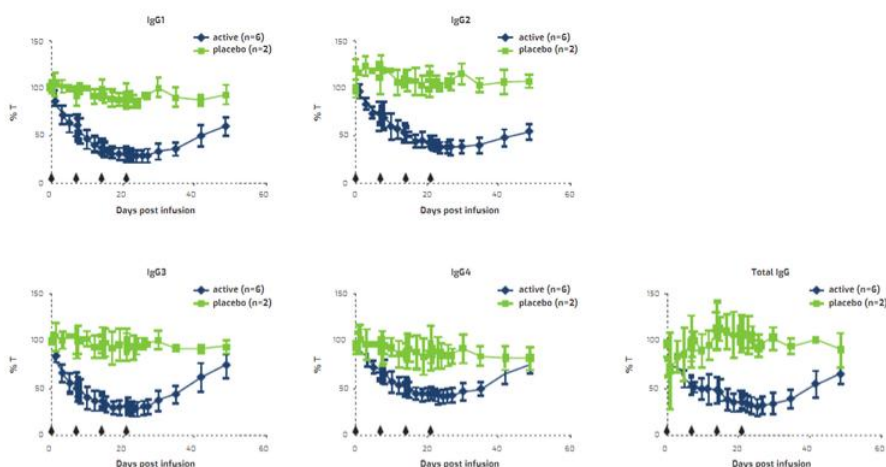


Figure 3: Reduction in the levels of four IgG antibody classes and total IgG levels in the multiple ascending dose part of our Phase 1 clinical trial of efgartigimod in healthy volunteers at a dose of 10 mg/kg every seven days.

SC - Partnership with Halozyme

In 2020, we and Halozyme expanded the existing global collaboration and license agreement that was signed in February 2019. Under the expansion, we gained the ability to access Halozyme’s ENHANZE® drug delivery technology for three additional exclusive targets upon nomination bringing the total to six potential targets under the collaboration. To date, two targets have been nominated including the human neonatal Fc receptor FcRn and complement component C2.

In July 2019, we evaluated a SC formulation of efgartigimod that incorporates Halozyme’s ENHANZE® drug delivery technology in a Phase 1 clinical trial in healthy volunteers, which demonstrated retained pharmacodynamic (*PD*) profile of IV-formulated efgartigimod.

ENHANZE® has demonstrated across multiple FDA-approved products the ability to remove traditional limitations on the volume of biologics that can be delivered subcutaneously, potentially shortening drug administration time, reducing healthcare practitioner time, and offering additional flexibility and convenience for patients.

SC – Partnership with Elektrofi

In April 2021, we entered into a collaboration and license agreement with Elektrofi to explore new SC formulations utilizing Elektrofi’s small volume injection technology for efgartigimod, and up to one additional target. See section “Our Exclusive License with Elektrofi for efgartigimod” for more information.

Efgartigimod (formerly ARGX-113) Indications

Generalized Myasthenia Gravis (gMG)

Overview

gMG is a rare and chronic autoimmune disease where IgG autoantibodies disrupt communication between nerves and muscles, causing debilitating and potentially life-threatening muscle weakness.

In myasthenia gravis (**MG**), IgG 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. The muscle weakness associated with MG usually presents initially in ocular muscles and can then spread into a generalized form affecting multiple muscles, known as gMG. Approximately 85% of people with MG progress to gMG within 24 months (source: Behn et al. New Pathways and Therapeutics Targets in Autoimmune Myasthenia Gravis. J Neuromusc Dis 5. 2018. 265-277). MG in the ocular form 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;

Patients with confirmed AChR antibodies account for approximately 85% of the total gMG population (Behn et al. New Pathways and Therapeutics Targets in Autoimmune Myasthenia Gravis. J Neuromusc Dis 5. 2018. 265-277).

ADAPT-SC Trial Design

In January 2021, we initiated ADAPT-SC, a registrational non-inferiority bridging study of SC efgartigimod for the treatment of gMG. The design of the bridging study is based on the demonstrated association between total IgG reduction and clinical benefit in gMG, and incorporates feedback from the FDA. The study is comparing the pharmacodynamic effect of 1000 mg SC efgartigimod with 10 mg/kg IV efgartigimod. The primary endpoint is the percent change from baseline of total IgG levels measured at day 29.

We expect to announce topline results for the ADAPT-SC trial in the first quarter of 2022.

Other trials

In addition, we are currently evaluating efgartigimod in IV formulation, in clinical trials exploring variations on dosing in the gMG, in children with gMG, as well as in a healthy volunteer trial evaluating the immune response after vaccination (PNEUMOVAX 23) while receiving efgartigimod.

Primary Immune Thrombocytopenia (ITP)

Overview

Primary ITP is an acquired autoimmune bleeding disorder, characterized by a low platelet count ($<100 \times 10^9/L$) in the absence of other causes associated with thrombocytopenia. In most patients, IgG autoantibodies directed against platelet receptors can be detected. They accelerate platelet clearance and destruction, inhibit platelet production, and impair platelet function, resulting in increased risk of bleeding and impaired quality of life. Primary ITP 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. Patients may suffer from depression and fatigue as well as side effects of existing therapies, impairing their quality of life. Current therapeutic approaches include non-specific immunosuppression (e.g. steroids and rituximab), inhibition of platelet clearance (e.g. splenectomy, IVIg, anti-D globulin, and Syk inhibitor fostamatinib¹³) or stimulation of platelet production (e.g. thrombopoietin receptor agonist TPO-RA). Splenectomy remains the only treatment that provides sustained remission off therapy for one year or longer for a high proportion of patients. 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).

Phase 3 ADVANCE Trials

In the fourth quarter of 2019, the first of two registrational trials, the ADVANCE Phase 3 trial, was initiated to evaluate 10 mg/kg IV efgartigimod for the treatment of primary ITP. The second registrational ADVANCE-SC trial of 1000mg SC efgartigimod for the treatment of primary ITP was initiated in the fourth quarter of 2020. We expect to enroll approximately 156 patients in each trial. Topline data are expected for the ADVANCE trial in the second quarter of 2022 and for the ADVANCE-SC trial in the first quarter of 2023, respectively. The primary endpoint of both trials is the proportion of chronic ITP patients with a sustained platelet count response, defined as achieving platelet counts of at least $50 \times 10^9/L$ for at least four of the six visits between weeks 19 and 24 of the trial.

Phase 2 Trial

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 had platelet counts lower than $30 \times 10^9/L$ while being on a stable dose of standard-of-care treatments consisting of corticosteroids, permitted immunosuppressants or thrombopoietin receptor agonists, or after having undergone a splenectomy or while being monitored under a 'watch & wait' approach. We conducted the clinical trial at 19 clinical centers across eight countries in the European Union. Patients were randomly assigned to three arms of twelve 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 $30 \times 10^9/L$.

Full results from the Phase 2 trial were published in the peer-reviewed American Journal of Hematology. Efgartigimod was well-tolerated and showed a correlation of reduced IgG levels, increased platelet counts and reduced bleeding in ITP patients.

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). There were no dose-related safety observations and the safety profile was consistent with previous observations in healthy volunteers and myasthenia gravis patients. No increased risk of infection was apparent in the efgartigimod-treated groups compared to the placebo group.

Targeting FcRn with efgartigimod resulted in rapid and selective IgG reduction, and a greater numerical reduction was observed in the efgartigimod 10 mg/kg group, without impacting the levels of other immunoglobulin isotypes. Efgartigimod administration did not result in a reduction of albumin levels, suggesting that the Fc fragment efgartigimod is not interfering with albumin binding or influencing the fate of FcRn.

Reduction in platelet-associated autoantibodies were observed in the majority of patients with clinically meaningful platelet increase.

Efgartigimod-treated groups achieved a higher maximum mean platelet count change from baseline compared to the placebo group. Post hoc analyses requiring greater frequency or duration of platelet count $\geq 50 \times 10^9/L$, or increased platelet count to $\geq 100 \times 10^9/L$, demonstrated the efficacy of efgartigimod. Six patients (46%) treated in both efgartigimod groups showed an increase in platelet count $> 50 \times 10^9/L$ on at least two occasions. Additionally, substantially more active-treated patients achieved a platelet count $\geq 50 \times 10^9/L$ for more than 10 cumulative days compared to the placebo group (10 [38%] vs. 0 [0%], respectively).

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 World Health Organization 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.

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.

Phase 3 - IV and SC Trials

In the fourth quarter of 2019, the first potential registrational Phase 3 trial of IV efgartigimod in ITP, the ADVANCE trial, was initiated 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. We expect to announce topline results for the ADVANCE and ADVANCE-SC trials in the second quarter of 2022 and first quarter of 2023, respectively.

Pemphigus Vulgaris (PV)

Overview

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 Pemphigus. Similar to MG and ITP, disease severity of Pemphigus 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. Several disease activity measurements exist for the clinical evaluation of PV patients, including the pemphigus disease area index (**PDAI**), autoimmune bullous skin disorder intensity score (**ABSI**), and the PV activity score (**PVAS**). The PDAI is reported to have the highest validity and is recommended for use in clinical trials of PV.

Phase 3 ADDRESS Trial

In the fourth quarter of 2020, the registrational ADDRESS trial was initiated of SC efgartigimod for the treatment of PV and PF. This is a randomized, double-blinded, placebo-controlled study, where the objective is to assess efficacy, safety and tolerability in up to 150 newly diagnosed or relapsing patients with moderate to severe pemphigus. Patients are randomized to receive either SC efgartigimod or placebo for 30 weeks. Patients start on concomitant steroids based on what we determine to be the optimized dosing regimen from the Phase 2 study. The primary endpoint will assess the proportion of patients who achieve complete remission on a minimal steroid dose at 30 weeks. 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. A relevant minority portion of the patients in the ADDRESS trial are participating in studies conducted in Ukraine or Russia. Due to the conflict between Russia and Ukraine, we may be unable to fully benefit from the study data collected to date and we may need to recruit additional patients which could delay data read-out points for our studies, although we are currently unable to assess if and by how much such delays would occur. Accordingly, timing of topline data for the ADDRESS trial of SC efgartigimod for PF and PV may be impacted but we are currently unable to assess the full impact due to the rapidly developing situation.

Phase 2 Trial

We completed an open-label Phase 2 adaptive trial in which, through sequential cohorts, 34 patients were dosed at 10 or 25mg/kg IV efgartigimod with various dosing frequencies, as monotherapy or add-on therapy to low

dose oral prednisone. The primary endpoint of the trial was safety and tolerability. The full Phase 2 trial results were published in *The British Journal of Dermatology*.

In this trial, we observed:

- a favorable tolerability profile, consistent with data from previous efgartigimod studies and those adverse events were mostly mild.
- a major decrease in serum total IgG and anti-desmoglein (**DSG**) autoantibodies and correlated with improved PDAI scores.
- that 90% (28/31) of patients demonstrated early disease control; median time to disease control for monotherapy and combination therapy was 17 days.
- complete clinical remission in 64% (14/22) of patients receiving optimized prolonged treatment with efgartigimod in combination with a median dose of 0.26mg/kg/day prednisone within 2-41 weeks.
- a favorable tolerability profile, consistent with data from previous efgartigimod studies.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

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.

Most CIDP patients require treatment and IVIg which is the preferred first-line therapy. Glucocorticoids and plasma exchange are used to a lesser extent as they are either limited by side effects upon chronic use, in the case of glucocorticoids, or invasiveness of the procedure and access, which is restricted to specialized centers in case of plasma exchange. Alternative immunosuppressant agents are typically reserved for patients ineligible for or refractory to IVIg, glucocorticoids or plasma exchange. While IVIg therapy can usually control CIDP, most patients require repeated treatments every two to six weeks for many years. This is due to the fact that IVIg monotherapy does not usually lead to long-term remission.

ADHERE Trial

At the end of 2019, we initiated the registrational ADHERE trial evaluating SC efgartigimod for the treatment of CIDP. The ADHERE trial is a randomized, withdrawal study evaluating 1000mg weekly SC efgartigimod expected to enroll approximately 130 patients. The trial consists of an open-label Stage A followed by a randomized, placebo-controlled Stage B with a planned interim responder analysis after the first 30 patients enroll in Stage A. In order to enter Stage A and receive efgartigimod, both patients who are treatment-naïve or on therapy must first receive a confirmed diagnosis of CIDP by an independent panel of experts and demonstrate active disease. To show active disease, patients who are on current CIDP therapy have to demonstrate a minimal clinically meaningful worsening after treatment withdrawal based on at least one CIDP clinical assessment tool, including Inflammatory Neuropathy Cause and Treatment (**INCAT**) Disability Score, Inflammatory Rasch-built Overall Disability Scale (**I-RODS**) or mean grip strength. To advance to Stage B, patients need to demonstrate a minimal clinically meaningful response to efgartigimod equivalent with the loss observed on the same efficacy scale on which worsening is observed during the withdrawal period. In Stage B, patients are randomized to either

SC efgartigimod or placebo for up to 48 weeks. The primary endpoint is event-driven and based on the adjusted INCAT efficacy score in Stage B.

Interim Analysis from ADHERE Trial

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. 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 interim analysis achieved 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.

We expect to announce the topline data of the ADHERE trial in the first quarter of 2023.

Idiopathic Inflammatory Myopathy (Myositis)

Overview of Myositis

Myositis are a rare group of autoimmune diseases that can be muscle specific or affect multiple organs including the skin, joints, lung, gastrointestinal tract and heart. Myositis can be very severe and disabling and have a material impact on quality of life. Initially these myopathies were classified as either dermatomyositis (**DM**) or polymyositis, but as the underlying pathophysiology of myositis has become better understood, including through the identification of characteristic autoantibodies, new polymyositis subgroups have emerged. Two of these subtypes are immune-mediated necrotizing myopathy (**IMNM**) and anti-synthetase syndrome (**ASyS**). Proximal muscle weakness is a unifying feature of each myositis subset.

- IMNM is characterized by skeletal muscle weakness due to muscle cell necrosis. The muscle weakness is typically symmetrical – on both sides of the body – and affects proximal muscles including hips, thighs, upper arms, shoulder and neck. The muscle weakness can be severe and lead to difficulty in completing daily tasks. Characteristic autoantibodies of IMNM, include anti-signal recognition particle (anti-SRP) and anti-3-hydroxy-3-methylglutaryl-coenzyme A reductase (anti-HMGCR) autoantibodies.
- ASyS is characterized by muscle inflammation, inflammatory arthritis, interstitial lung disease, thickening and cracking of the hands (mechanic’s hands) and Raynaud phenomenon. Autoantibodies associated with ASyS attack tRNA synthetase enzymes and include anti-Jo-1 and anti-PL1 and PL-12 most commonly.
- DM is characterized by muscle inflammation and degeneration and skin abnormalities, including heliotrope rash, Gottron papules, erythematous, calcinosis and edema. DM is associated with myositis-specific autoantibodies, including anti-Mi-2, anti-MDA-5, anti-TIF-1γ and others.

There are no current FDA-approved therapies for IMNM or ASyS. IVIg (Octagam 10%) was approved by the FDA for the treatment of dermatomyositis in July 2021. Myositis patients are most often treated with high-dose steroids.

ALKIVIA Trial

We intend to initiate the registrational ALKIVIA trial of SC efgartigimod for the treatment of myositis in the second quarter of 2022. We will enroll 180 patients dosed with 1000mg SC efgartigimod in three myositis subtype cohorts, IMNM, ASyS and DM. An interim analysis is planned after the first 30 patients of each myositis subtype.

The primary endpoint will be based on the mean total improvement score and additional key secondary endpoints will include time to response, durability of benefits, the quality of life and the individual components of the total improvement score.

Bullous Pemphigoid (BP)

Overview

BP is the most common autoimmune blistering disease and is driven by autoantibodies affecting the skin. The disease typically affects elderly people and early key symptoms are itch and rash and patients develop fluid-filled blisters during disease progression. The prevalence of bullous pemphigoid is twelve per 100,000 adults and the incidence increases with age. BP is associated with a high disease burden and can have a significant impact on the quality of life of patients. The mortality of BP in the U.S. is 2.4% or higher than the mortality in the general population of the same age. There are currently no approved therapies available for BP. First line treatment consists of topical or systemic corticosteroids, which result in substantial morbidity and increased mortality, conventional immunosuppressants as corticosteroid-sparing agents, rituximab and IVIg.

BP is a well characterized autoimmune disease in which the binding of autoantibodies to hemidesmosomal proteins, BP180 and BP230, initiates a cascade of inflammatory events resulting in blister formation. BP180 and BP230 are involved in the stable attachment of keratinocyte to the underlying matrix. The autoantibody actions include mechanical disruption of keratinocyte adhesion and cytokine release. Immune complex formation initiates complement activation leading to the recruitment mast cells, neutrophils, eosinophils and other immune cells and to the release of proteases and inflammatory mediators. All these effects, which start with the binding of the autoantibodies, induce the blistering observed in BP.

BALLAD Trial

We initiated the BALLAD registrational trial evaluating SC efgartigimod in BP in the second half of 2021, in which we will enroll 160 patients.

The study population will be newly diagnosed and relapsing patients within one year diagnosis. Patients will be randomized 1-to-1 to receive efgartigimod or placebo for total duration of 36 weeks. Standard of care concomitant medication will consist of prednisone at a starting dose of 0.5 milligram per kilogram per day, and the dose will be adjusted if the patient achieves sustained control of disease activity. The primary endpoint is the proportion of participants in complete remission while on minimal steroids ($\leq 0.1\text{mg/kg/day}$) for at least eight weeks at week 26. Secondary endpoints relate to cumulative steroid doses, IGA BP score, complete remission off steroids, average itch, control of disease activity, and quality of life measures. An interim analysis of the BALLAD trial is expected after the first 40 patients.

New Efgartigimod Indications

In January 2022, we announced that we will be initiating proof-of-concept trials in four new autoimmune indications through our partnership agreements with Zai Lab and IQVIA:

- Membranous Nephropathy (**MN**) is an autoimmune, glomerular disease and the most frequent cause of nephrotic syndrome. MN is characterized by thickening of the glomerular capillary walls caused by immune complex deposition. 70% of MN patients have IgG autoantibodies against PLA2R. In patients without PLA2R autoantibodies, there can be detectable anti-THSD7A or anti-NELL1 antibodies. 20-30% of patients progress to end-stage renal disease. There are no current approved therapies for MN.
- Lupus Nephritis (**LN**) is a glomerulonephritis and one of the most severe and common organ manifestations of the autoimmune disease systemic lupus erythematosus (**SLE**). LN is a substantial cause of morbidity and death among patients with SLE. Autoantibodies associated with LN include

anti-dsDNA and anti-nuclear antibodies. 5-20% of LN patients progress to end-stage renal disease. Oral corticosteroids and broad immunosuppressants are current standard of care but are not uniformly effective.

- Primary Sjögren's Syndrome (**primary SjS**) is a systemic autoimmune disease of the exocrine glands that can affect salivary and lacrimal glands, mostly, and result in severe dryness of mucosal surfaces, primarily in the eyes and mouth. In addition to sicca symptoms, patients can experience significant fatigue, chronic pain, major organ involvement, neuropathies and lymphomas. Autoantibodies are present in the majority of patients and include antinuclear antibodies and antibodies against SjS-related antigen A and B (anti-SSA Ro and SSB La). There are no current FDA-approved therapies and patients are most often treated with IVIg, in severe cases, or eyes drops and corticosteroids in more mild to moderate patients.
- COVID-19 mediated postural orthostatic tachycardia syndrome (**COVID-19 mediated POTS**) has been emerging after resolution of COVID-19 infection in previously healthy patients. POTS is a disorder of the autonomic nervous system that is characterized by a rise in heart rate when moving to a standing position and additional symptoms of shortness of breath, headache, fatigue, poor concentration, weakness and anxiety. The large majority of patients are women between 15 and 50 years of age. There is a strong association of POTS to activating autoantibodies to autonomic G-protein coupled receptors (**GPCR**), including the $\beta 1$ and $\beta 2$ -adrenergic receptors and M2 and M3 muscarinic receptors. There are no current FDA-approved therapies and symptomatic treatments focus on blood volume, kidney sodium levels, heart rate reduction and vessel constriction.

Zai Lab Limited

Our Zai Lab strategic collaboration, which was announced in January 2021, allows us to accelerate development of efgartigimod into new autoimmune indications with Zai Lab taking operational leadership of the Phase 2 proof-of-concept trials.

Zai Lab will initiate Phase 2 proof-of-concept trials in MN and LN, which both fall within our emerging nephrology franchise.

IQVIA

On December 2, 2021 we entered into a strategic asset development agreement (the **Asset Development Agreement**) with IQVIA. Pursuant to the Asset Development Agreement, IQVIA shall perform asset and indication development services for efgartigimod through an advanced outsourcing model. Such services include, but are not limited to, overall product indication development strategy, design of clinical trial protocol, set-up, execution and oversight of clinical development plans for an indication for efgartigimod selected by us.

To enable and encourage fast and innovative delivery of the services by IQVIA, the Asset Development Agreement contains an innovative earn-back and bonus plan based upon the performance of IQVIA.

Primary SjS and COVID-mediated POTS are the first indications identified by argenx to be further developed under the Asset Development Agreement.

ARGX-117 Development

ARGX-117 is a highly differentiated therapeutic monoclonal antibody targeting complement component C2 equipped with our proprietary NHANCE™ mutations. By addressing a novel target at the intersection of the complement and lectin pathways of the complement cascade, we believe ARGX-117 represents a broad pipeline opportunity across several severe autoimmune indications. Activation of the classical and lectin pathway of complement may contribute to tissue damage and organ dysfunction in a number of autoimmune inflammatory

diseases and ischemia-reperfusion conditions. Targeting C2 also leaves the alternative pathway of the complement system intact, which is an important component of the innate defense system

ARGX-117 exhibits both pH- and calcium dependent binding. These unique characteristics enable ARGX-117 to capture free C2 in circulation and release it in the endosome to be sorted for degradation in the lysosome. ARGX-117 is equipped with NHANCE mutations increasing its affinity for FcRn and allowing it to recycle back into circulation to capture more C2.

We obtained the rights to ARGX-117 as part of our Immunology Innovation Program. argenx and Broteio Pharma 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 exercised the exclusive option to license the program and assumed responsibility for further development and commercialization.

In addition to an intravenous formulation, we have exclusive access to Halozyme's ENHANZE® SC drug delivery technology for the C2 target.

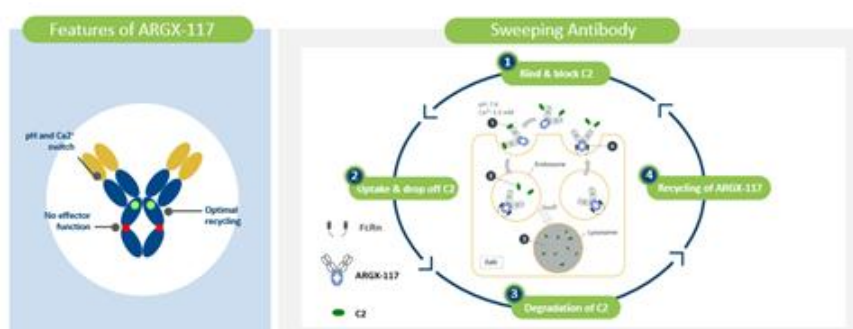


Figure 4

Phase 1 Data

We conducted a Phase 1 healthy volunteer trial of IV and SC ARGX-117. This first-in-human clinical study was a double-blind placebo-controlled study designed to assess the safety, tolerability, pharmacokinetics (**PK**) and PD of a broad dose range of ARGX-117 in 102 healthy subjects. In the single ascending dose (**SAD**) part, we evaluated 70 subjects and tested up to 80 mg/kg administered IV and up to 60mg/kg administered SC. In the multiple ascending dose (**MAD**) part of the study, we evaluated 32 subjects to understand the safety and tolerability of repeated administrations and in particular to generate a data-set to optimally inform a PK/PD model.

The majority of the observed TEAEs were categorized as grade 1 (or mild). Few grade 2 (or moderate) TEAE were observed and, in the MAD part of the study, no grade 2 or higher TEAEs were observed. Overall, we concluded that single and multiple administrations of ARGX-117 or placebo have a favorable safety and tolerability profile supporting the investigation of study drug in patient studies.

We observed a dose-dependent reduction of free C2 levels. After one dose of 30mg/kg ARGX-117, free C2 levels were reduced by 95% for more than 100 days. In the MAD part of the study, we could reach full complement blockade with more than 99% reduction of free C2 levels.

Following analysis of Phase 1 data, and the observed favorable safety and tolerability profile and consistent PK/PD profile, we launched a Phase 2 proof-of-concept trial in multifocal motor neuropathy in the fourth quarter of 2021 within our neuromuscular franchise.

Overview of Multifocal Motor Neuropathy and Current Treatment

Multifocal Motor Neuropathy (**MMN**) is a debilitating neuromuscular autoimmune disorder that is characterized by slowly progressive muscle weakness due to motor neuron degeneration. It mainly affects hands and forearms, mainly in males, and the median age of diagnosis is around 40 years. Diagnosis takes about 1.5 years and is usually misdiagnosed as amyotrophic lateral sclerosis (**ALS**). There are estimated to be around 13,000 patients with MMN in the U.S. and this number is increasing.

Specific pathophysiologic characteristics of MMN include the presence of immunoglobulin M (**IgM**) autoantibodies against the ganglioside GM1 and conduction block, i.e., impaired propagation of action potentials along the axon. GM1 is widely expressed in the nervous system by neurons, particularly around the nodes of Ranvier, and Schwann cells.

IVIg is the only approved treatment for MMN and needs to be dosed regularly to address the disease's progressive nature.

Delayed graft function and/or allograft failure

A second proof-of-concept trial will be initiated in the second half of 2022 evaluating ARGX-117 for the prevention of delayed graft function (n) and/or allograft failure after kidney transplantation. This occurs in up to 40% of kidney transplant recipients, and is often a result of ischemia reperfusion injury.

There is compelling evidence from kidney biopsies of mannose-binding lectin and C4d co-staining indicating involvement of both the classical and lectin pathways, making C2 an ideal target. Furthermore, there is a well-established process to measure kidney function and establish proof-of-concept and achieve registration. On this basis, combined with the significant unmet medical need, we have chosen delayed graft function (**n**) and allograft failure after kidney transplantation as second indication for ARGX-117.

Strategy and objectives

Company's Strategies

Our goal is to deliver therapies that are either first-in-class or best-in-class to patients suffering from neuromuscular, hematology, dermatology and nephrology indications for which a significant unmet medical need exists. We focus on attaining this goal in a manner that is disciplined for a company of our size. We plan to:

- *Execute our global launch.* With the approval of VYVGART™ as the first-and-only approved neonatal FcRn blocker in the U.S and Japan, we have already taken the first steps in executing our plans for a global launch for VYVGART for the treatment of gMG. We expect the EMA's decision on approval in the second half of 2022 and aim for further approvals in other jurisdictions in the course of the year. We have already built our commercial infrastructure to support the launch of VYVGART in the U.S. and in Japan as well as build out additional commercialization infrastructure to support a rapidly growing number of indications in the U.S., Japan, Europe and our other key territories, including Canada.
- *Expand applications for our lead product efgartigimod.* 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. We are further developing our lead product, efgartigimod, to market regulatory approval for the treatment of gMG, ITP, PV, CIDP, BP, myositis, COVID-19 mediated POTS, SJS, MN and LN. By the end of 2024, we aim to be ready for four additional commercial launches of gMG (with SC efgartigimod), ITP, PV and CIDP. We expand the use of our products and product candidates in existing indications by developing new formulations, such as a subcutaneous version of efgartigimod, that may reach

more patient groups by capturing different patient preferences and providing additional optionality with regards to dosing.

- *Advance our pipeline of assets.* In addition to new indications for efgartigimod, we plan to advance our other product candidates. In particular, we plan to advance the clinical development of ARGX-117 in multiple Phase 2 proof of concept trials in MMN and delayed graft function in the context of kidney transplant; to advance ARGX-119 and early stage pipeline candidates in our strategic franchise indications, the neuromuscular, hematology, dermatology and nephrology franchises; and to expand our pipeline of future product candidates through the IIP.
- *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 but fall outside our commercial franchises or are better served by the resources of larger biopharmaceutical companies. In addition to collaborating on our products and product candidates, we may also elect to enter into collaborations for access to partner technology platforms or capabilities from which we can develop differentiated potential pipeline assets.
- *Implement our “argenx 2025” vision.* We hope to make efgartigimod globally available to patients across our expanding commercial franchises. We aspire to make efgartigimod either commercially available or in clinical development in fifteen active indications. We plan to make progress across our broader immunology pipeline with ARGX-117 in multiple late-stage trials and demonstrate proof-of-concept with ARGX-119. Finally, we will invest in the continued expansion of our differentiated pipeline through the IIP and aim to continue to generate one new asset into the pipeline each year.
- *Continue to build innovation into every step of our development, highlighted by our collaborative IIP translating immunology breakthroughs into medicines.* The 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.

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 (**GSK**) (Benlysta/lupus); F. Hoffman-La Roche AG (**Roche**) (Rituxan/often used off label); and Janssen (Remicade/rheumatoid arthritis and Stelera/psoriasis). 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 AstraZeneca PLC is selling Soliris for the treatment of adult patients with gMG who are AChR antibody positive and that GSK, Roche, Novartis AG, CSL Behring, Grifols, S.A., BioMarin Pharmaceutical Inc., Curavac, UCB S.A./RA Pharma, DAS Therapeutics, Takeda, RemeGen, Immunovant, Cartesian Therapeutics, Horizon Therapeutics, AstraZeneca PLC, Chugai Pharma/Genentech, Regeneron/Alnylam and Johnson & Johnson Innovation Inc., among others, are developing drugs that may have utility for the treatment of MG. Competition for other (potential) future indications is also fierce, with significant development activities in almost all of the indications where we are currently developing or planning to develop our product or product candidates.

Our Competitive Strengths

We believe that the combination of our technologies, expertise and 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, neuromuscular, hematology, dermatology and nephrology diseases for which the current treatment paradigm is inadequate.

Productive discovery capabilities through our IIP 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. Leveraging our technology suite and clinical expertise, we have advanced several candidates and believe this level of productivity affords us a breadth of options with regard to independently advancing or partnering on our pipeline assets.

In November 2020, we announced the agreement to acquire an FDA Priority Review Voucher (**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 biologic license application (**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 for another indication.

Immunology Innovation Program

Overview

Our IIP is a core business strategy of co-creation and innovation. The IIP also serves as our discovery engine to identify novel targets and together, in collaboration with our scientific and academic partners, to build potential new pipeline candidates. The IIP has been foundational in building our pipeline, and every current pipeline candidate from both our wholly-owned and partnered pipeline emerged from an IIP collaboration. As part of our long-term strategy, we have committed to continued investment in the IIP. As at the date of this Annual Report, we have executed on our commitment and aim to continue to bring forth at least one new asset per year from the IIP.

Our Suite of Technologies

Through our IIP, we collaborate with scientific and academic partners to identify immunology breakthroughs and build potential pipeline candidates. This is done through co-creation where we bring to the collaboration our unique suite of antibody engineering technologies and experience in clinical development and our partners bring a wealth of disease and target biology expertise.

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:

Antibody Engineering and Other Technology Capabilities

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™, POTELLIGENT® and DHS mutations – 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. In addition, we obtained a non-exclusive research license and option for the SMART-Ig® and ACT-Ig® technologies. 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 (**NK**) cells. These NK cells can destroy the target cell, resulting in enhanced antibody-dependent cell-mediated cytotoxicity (**ADCC**). NHance® and ABDEG™: Modulation of Fc Interaction with FcRn.

An illustration of the FcRn-mediated antibody recycling mechanism is shown in figure 5. [1] Serum proteins, including IgG antibodies, are routinely removed from the circulation by cell uptake. [2] Antibodies can bind to FcRn, which serves as a dedicated recycling receptor in the endosomes, which have an acidic environment, and then [3A] return to the circulation by binding with their Fc region to FcRn. [3B] Unbound antibodies end up in the lysosomes and are degraded by enzymes. Because this Fc/FcRn interaction is highly pH-dependent, antibodies tightly bind to FcRn at acidic pH (pH 6.0) in the endosomes but release again at neutral pH (pH 7.4) in the circulation.

Figure 2: The FcRn-mediated recycling mechanism.

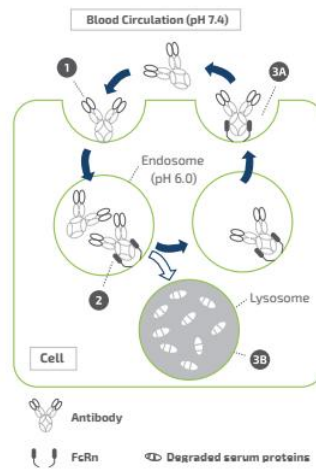


Figure 5: The FcRn-mediated recycling mechanism

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 6, [1] NHance® antibodies bind to FcRn with higher affinity, specifically under acidic pH conditions. [2] Due to these tighter bonds, NHance® FcRn-mediated antibody recycling is strongly favored over lysosomal degradation, although some degradation does occur. [3] NHance® allows a greater proportion of antibodies to return to the circulation potentially resulting in increased bioavailability and reduced dosing frequency. ARGX-111, ARGX-109, ARGX-117 and a number of our discovery-stage programs utilize NHance®.

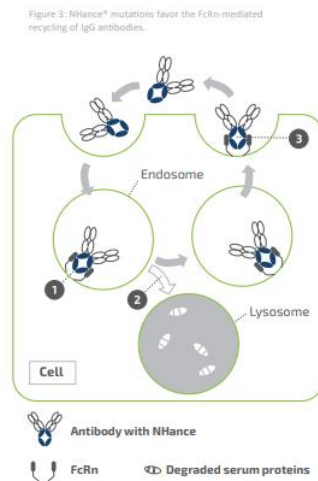


Figure 6

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

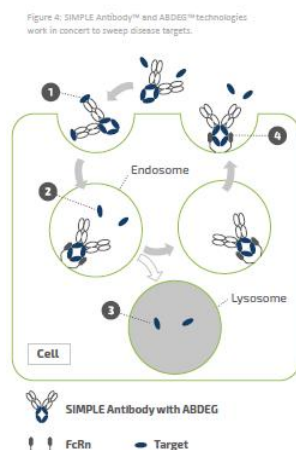


Figure 7: SIMPLE Antibody™ and ABDEG™ technologies work in concert to sweep diseases targets.

POTELLIGENT®

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>).

Chugai and Clayton

In 2020, we entered into a research license and option agreement with Chugai under which we may access Chugai's SMART-Ig® ("Recycling Antibody" and part of "Sweeping Antibody" technology) and ACT-Ig® (Antibody half-life extending technology). In 2020, we also entered into a non-exclusive research agreement with the Clayton Foundation under which we may access the Clayton Foundation's proprietary DHS mutations to extend the serum half-life of therapeutic antibodies.

Subcutaneous drug delivery technologies

We have exclusive access to Halozyme's ENHANZE® SC drug delivery technology 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.

In addition, in April 2021, we entered into a collaboration and license agreement with Elektrofi to explore new SC formulations utilizing Elektrofi's small volume injection technology for efgartigimod, and up to one additional target.

For more information on our collaborations, see section "Collaboration Agreements".

Other wholly-owned IIP Programs

Cusatuzumab (formerly ARGX-110)

In June 2021, we announced that we regained worldwide rights to our anti-CD70 antibody cusatuzumab from Cilag GmbH International (**Cilag**).

Following termination of our collaboration, we have elected that Cilag continues to operationally support the treatment and follow-up of patients enrolled in ongoing cusatuzumab clinical trials. Cusatuzumab is being

developed for the rare and aggressive hematological cancer AML, as well as high risk MDS. The CULMINATE trial and ELEVATE trial, described below, remain ongoing.

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.

A set of interim data from the 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, has been presented at American Society of Hematology in December 2021. Final results from the ELEVATE trial will be presented in a peer reviewed forum.

ARGX-119

In January 2022, we announced that ARGX-119 is an antibody that targets muscle-specific tyrosine kinase (**MUSK**), a protein located at the neuromuscular junction, in an agonistic or activating manner. We intend to develop ARGX-119 in a range of neuromuscular diseases, potentially including congenial MG, a rare hereditary subtype of myasthenia gravis, MUSK MG, a rare autoimmune subtype of myasthenia gravis, spinal muscular atrophy (**SMA**) and ALS, both rare, severe neuromuscular 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:

- it acts on a novel target intended to address mucus plugging, a large unmet need in airway inflammation;
- it has a unique mechanism of action with observed crystal-dissolving properties; and
- its 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. Lead optimization work on ARGX-118 for airway inflammation will continue in 2022.

ARGX-120

In addition, we are developing ARGX-120, an antibody against an undisclosed target with application in autoimmune diseases.

Other Partnered Programs

See sections “Collaboration Agreements” and “License Agreements” for a description of collaboration and license agreements that we have entered into to further leverage our IIP.

Manufacturing and Supply

We utilize third-party contract manufacturers who act in accordance with the FDA’s good laboratory practices (**GLP**) and current good manufacturing practices (**cGMP**) for the manufacture of drug substance and drug product. At the date of this Annual Report, we contract with Lonza based in Slough, the United Kingdom, Portsmouth, U.S. and Singapore for all activities relating to the development of our cell banks, development of our manufacturing processes and the manufacturing 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, ARGX-117, ARGX-119 and LP0145 are each manufactured using the System, which includes 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. See section “Our non-exclusive license with Lonza for Multi-product GS Xceed-License”.

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 to ensure 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 in part upon our ability to obtain and maintain patent and other proprietary protection for commercially important technologies, inventions and know-how related to our business, defend and enforce our intellectual property rights, particularly our patent rights, preserve the confidentiality of our trade secrets and operate without infringing valid and enforceable intellectual property rights of others. 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: Our Wholly-Owned Programs” and “Product Candidates: Our Partnered Programs.”

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, 2022, our patent portfolio (which includes both proprietary and in-licensed patent families) comprises approximately 300 granted patents and approximately 308 pending patent applications, including approximately 35 issued U.S. patents, approximately 15 granted European patents and approximately 250 issued patents in other jurisdictions.

Platform Technologies

With regard to our platform technologies, we own or have intellectual property rights 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, the 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, the 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 a variant immunoglobulin Fc region having an increased affinity for an Fc gamma receptor relative to a wild-type IgG1 Fc region, and method of use claims directed to a method of using such an FcRn-antagonist to treat certain antibody mediated disorders. The U.S. parent patent expires in 2036 (including patent term adjustment). In addition, in this patent family, we also have granted patents in Australia, China, Eurasia, Europe, Japan, Macao, 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 intellectual property rights that relate to different aspects of the POTELLIGENT® platform.

Product Candidates: Our Wholly-Owned Programs

Efgartigimod

With regard to efgartigimod, efgartigimod incorporates the ABDEG™ platform technology.

Our ARGX-117 Product Candidate

With regard to the ARGX-117 product candidate, we own or have rights in three patent families (including one in-licensed patent family from Broteio) 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 has granted patents in Australia, China, Europe, Hong Kong, Mexico and U.S. (two issued patents in U.S.), which have a basic expiry date in 2034. The other two patent families have basic expiry dates in 2039 and 2040.

Our ARGX-119 Product Candidate

With regard to the ARGX-119 product candidate, we in-licensed two patent families from/with NYU Langone Health, a U.S. medical center based in New York, and three patent families from/with the Leiden University Medical Center (**LUMC**), a Dutch University Hospital based in Leiden, with one U.S. granted patent and several pending applications in multiple jurisdictions.

Our ARGX-118 Product Candidate

With regard to the ARGX-118 product candidate, we co-own one patent family with VIB vzw (**VIB**), an inflammation research center in Ghent, Brussels, and Universiteit Gent, with one U.S. granted patent and pending patent applications in multiple jurisdictions in North America, South America, Europe and Asia. The patent family has a basic expiry date in 2039.

Our Cusatuzumab Product Candidate

With regard to the cusatuzumab product candidate, we have four issued U.S. patents, and one allowed U.S. patent application, including, one U.S. granted patent with composition of matter claims directed to the cusatuzumab antibody, one U.S. granted patent with claims directed to the epitope cusatuzumab binds to, one U.S. granted patent with claims directed to a polynucleotide that encodes antibodies that bind to the epitope cusatuzumab binds to, and, one U.S. granted patent and one U.S. allowed patent application 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, without taking a potential patent term extension into account. In addition, we have patents that have been granted in Australia, China, Europe, Indonesia, Israel, India, Japan and Russia and patent applications pending in Brazil and Canada. Cusatuzumab incorporates or employs the SIMPLE Antibody™ and POTELLIGENT® platform technologies.

Product Candidates: Our Partnered Programs

Our ARGX-115 (ABBV-151) Product Candidate

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. patent has 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. (continuation-in-part) and various other countries and regions in North America, South America, Europe and Asia. Further, we co-own with, and exclusively license from, the Université Catholique de Louvain two 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 as well as method of use claims directed to the use of such an antibody in the treatment of cancer. These two patent families have basic expiry dates in 2036 and 2038. Furthermore, ARGX-115 (ABBV-151) incorporates or employs the SIMPLE Antibody™ platform technology.

Our ARGX-109 Product Candidate

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, Chile, China, Colombia, Hong Kong, Israel, Japan, Mexico, New Zealand, Russia, U.S. and South Africa, and pending patent applications in Brazil, India and U.S. (divisional application). The patent family has a basic expiry date in 2033. Furthermore, ARGX-109 incorporates or employs the SIMPLE Antibody™ platform technology and the NHance® platform technology.

Our ARGX-112 (LP-0145) Product Candidate

With regard to the ARGX-112 (LP-0145) 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 (LP-0145) incorporates the SIMPLE Antibody™ platform technology.

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 U.S., 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 if granted, the length of such extensions.

Trade Secret Protection

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 follow a disciplined strategy to maximize the value of our pipeline by planning to retain all development and commercialization rights to those products and product candidates that we believe we can ultimately commercialize successfully, if approved.

We have partnered, and plan to continue to partner, products and product candidates that we believe have promising utility in disease areas or have patient populations that may benefit from resources of other biopharmaceutical companies. We expect to continue to collaborate selectively with pharmaceutical and biotechnology companies to leverage our platform technology and accelerate product candidate development. We have entered into multiple collaboration agreements with pharmaceutical partners, which are described below.

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

In April 2016, we entered into a collaboration agreement with AbbVie S.Á.R.L. (**AbbVie**) to develop and commercialize ARGX-115 (ABBV-151) as a cancer immunotherapy against the novel target GARP (the **AbbVie Collaboration Agreement**). 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. Under the terms of the AbbVie Collaboration Agreement, we are responsible for conducting and funding all ARGX-115 (ABBV-151) research and development activities up to completion of IND-enabling studies.

We have granted AbbVie an exclusive option, for a specified period following completion of IND-enabling studies, to obtain a worldwide, exclusive license to the ARGX-115 (ABBV-151) program to develop and commercialize products. Following the exercise of the option, AbbVie will be 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.

In August 2018, AbbVie exercised its option to develop and commercialize ARGX-115 (ABBV-151) and has now assumed development obligations, including the sole responsibility 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.

Pursuant to the AbbVie Collaboration Agreement, we have the right, on a product-by-product basis, to co-promote ARGX-115 (ABBV-151)-based products in the EEA and Switzerland and to combine the product with our own future oncology programs (if any). 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 AbbVie Collaboration Agreement, the term of the option and license agreement ends, with respect to the ARGX-115 (ABBV-151) program, upon the earliest of (i) a technical failure of the IND-enabling studies which is outside of our control, (ii) AbbVie's election to not exercise its option, or (iii) following AbbVie's exercise of the option, fulfillment of all payment obligations under the agreement.

AbbVie may terminate the AbbVie Collaboration 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) ten years after the first commercial sale of such product sold in that country under the AbbVie Collaboration Agreement.

Our Strategic Partnership with Zai Lab for efgartigimod

In January 2021, we entered into a collaboration agreement with Zai Lab, a commercial-stage biopharmaceutical company, relating to an exclusive out-license for the development and commercialization of efgartigimod in Greater China, including mainland China, Hong Kong, Taiwan and Macau (the ***Zai Lab Agreement***). Pursuant to the Zai Lab Agreement, Zai Lab obtains the exclusive right to develop and commercialize efgartigimod in Greater China. Zai Lab will also contribute Chinese patients to our global Phase 3 trials of efgartigimod. Additionally, the Zai Lab Agreement is expected to accelerate efgartigimod global development by initiating multiple Phase 2 proof-of-concept trials in new autoimmune indications under our supervision. In particular, Zai Lab will launch proof-of-concept trials in two new kidney conditions in 2022: LN and MN.

Pursuant to the Zai Lab Agreement, we have received \$150.0 million in collaboration payments, comprised of a \$75.0 million upfront payment in the form of 568,182 newly issued shares in Zai Lab at a price of \$132.00 per share, and a \$75.0 million as a guaranteed non-creditable, non-refundable development cost-sharing payment, and we triggered an additional \$25.0 million milestone payment following the approval of efgartigimod in the U.S. We are 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.

Our Collaboration with Genor Biopharma for ARGX 109

In October 2012, we entered into an exclusive license agreement with Bird Rock Bio, Inc. (***Bird Rock Bio***, formerly known as RuiYi Inc. and Anaphore, Inc.), to develop and commercialize ARGX-109, which employs our SIMPLE Antibody™ and NHance® technologies and blocks interleukin 6 (IL 6), a cell signaling protein that is an important driver of inflammatory response implicated in the transition from acute to chronic inflammation. In 2018, we and Bird Rock Bio mutually agreed to terminate this exclusive license agreement. Following the termination of our agreement with Bird Rock Bio, we agreed a direct licensing agreement with Genor Biopharma Co. Ltd (***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 (**LEO Pharma**) to develop and commercialize LP0145 for the treatment of dermatologic indications involving inflammation (the **LEO Pharma Collaboration Agreement**). LP0145 employs our SIMPLE Antibody™ technology and blocks the interleukin-22 receptor (IL-22R) in order to neutralize the signaling of cytokines implicated in autoimmune diseases of the skin. Pursuant to the LEO Pharma Collaboration Agreement, 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, which was achieved in April 2018. Since then, LEO Pharma has been solely responsible for funding the clinical development of the program. In May 2021, CTA approval of a Phase 2a clinical trial for LP0145 was received.

Up through specified periods, LEO Pharma may, against payment of an option fee to us, exercise an option to obtain an exclusive, worldwide license to further develop and commercialize a product, following which LEO Pharma will assume full responsibility for the continued development, manufacture and commercialization of such product and be subject to diligence obligations in respect of continuation of development and commercialization of such product. We are eligible to receive additional development, regulatory and commercial milestone payments in aggregate amount of up to €120.0 million, 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 the option is not exercised, if LEO Pharma does not meet agreed development diligence obligations within a specified time, or if the LEO Pharma Collaboration Agreement is terminated other than for reasons of our breach or insolvency, 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.

Unless earlier terminated, the term of the LEO Pharma Collaboration Agreement ends upon the later of (i) the expiration of the option period, (ii) the expiration of the last license granted under the agreement, and (iii) the fulfillment of all payment obligations under the agreement. LEO Pharma may terminate the LEO Pharma Collaboration 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, upon the later of (i) a time when no valid claims covering such product, and (ii) (a) in major market countries with no composition of matter patent covering such product, the expiration of the data exclusivity period or (b) 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.

In 2021, we signed two amendments to the LEO Pharma Collaboration Agreement, to extend LEO Pharma's option period with six months, to allow LEO Pharma to undertake chemistry, manufacturing and control (CMC) development work in advance of the exercise by LEO Pharma of its option, and updating the provisions regarding the management of patents.

Our Research Collaboration with Staten for STT-5058

In January 2015, we entered into a collaboration agreement with Staten Biotechnology B.V. (**Staten**) to develop and commercialize products in the area of dyslipidemia therapy (the **Staten 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 and commence further research programs for targets with therapeutic relevance in these areas. The first research program under the Staten Collaboration Agreement identified STT-5058 for the treatment of dyslipidemia as the initial product candidate. STT-5058 employs our SIMPLE Antibody™ technology and blocks APOC3, a metabolic target involved in triglyceride metabolism. Staten initiated dosing in first-in-human clinical trial of STT-5058. Staten exercised its exclusive option to license STT-5058 in March 2017.

Pursuant to the Staten Collaboration Agreement, 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 responsible for additional clinical development.

On a research program-by-research program basis, we have granted Staten an option to obtain an exclusive, worldwide, permanent license to research, develop and commercialize products identified in that program within a specified period of time. If Staten exercises this option for a product (as it has for STT-5058), it will be obligated to pay us a percentage of any payments payable to or on behalf of Staten's shareholders in certain events, including the change of control, any licensing, sale, disposition or similar transaction of such product, or otherwise from the research, development or commercialization of that product, in each case, depending on the stage of development and ranging 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 such product candidate. Staten is under the diligence obligation to continue to develop and commercialize at least one product during the term of the Staten Collaboration Agreement.

The Staten Collaboration Agreement ended automatically in 2021. In addition, we terminated the research program in connection with the Staten Collaboration Agreement since no targets have been selected within 24 months of the effective date of the relevant research program 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 (***Shire***, now known as Shire International GmbH) to discover, develop and commercialize novel human therapeutic antibodies against up to three targets to address diverse, rare and unmet diseases (the ***Shire Collaboration Agreement***). Pursuant to the Shire Collaboration Agreement, 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, we have granted Shire an exclusive option, against payment of a one-time option fee, 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 such exercise, Shire has the diligence obligation to continue to develop and commercialize at least one licensed product.

Shire may exercise exclusive options to develop and commercialize programs arising under our expanded agreement against an option fee. In July 2018, Shire exercised such an exclusive option to in-license an antibody discovered and developed using our licensed technologies, triggering a milestone payment by Shire to us.

In addition to option fees, Shire is 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. Accordingly, 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 Shire Collaboration Agreement. For products generated against additional targets, 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.

If Shire does not exercise its option with respect to any discovered antibody within a specified period, 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, or (ii) exercises its option but later abandons development of such antibody or (iii) the Shire Collaboration 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, 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, the collaboration term ends with the expiry of the last royalty term under the Shire Collaboration 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) ten years after the first commercial sale of such product sold in that country under the Shire Collaboration Agreement. Shire may terminate the agreement for any reason upon prior written notice to us.

Our Strategic Partnership with Janssen for cusatuzumab

In December 2018, we entered into a collaboration agreement with Cilag, an affiliate of Janssen Pharmaceuticals, Inc. (***Janssen***), a subsidiary of Johnson & Johnson, to jointly develop and commercialize cusatuzumab (the ***Janssen Collaboration Agreement***).

We were notified of Janssen's decision to discontinue the collaboration agreement during a regularly scheduled steering committee meeting on June 4, 2021. Following termination of our collaboration, we have elected that Cilag continue to operationally support the treatment and follow-up of patients enrolled in ongoing cusatuzumab clinical trials. See "Immunology Innovation Program".

License Agreements

We are 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. License agreements can relate to research and development and/or commercialization of the relevant product candidates (and technologies) or products. 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 Elektrofi for efgartigimod

In April 2021, we entered into a collaboration and license agreement with Elektrofi, to explore new SC formulations for therapeutic products directed at the human FcRn, including efgartigimod, and up to one additional target (the ***Elektrofi Agreement***). The Elektrofi-enabled formulations are aimed to promote additional optionality for patients through at-home and self-administration capabilities.

Under the terms of the Elektrofi Agreement, we will make an upfront payment and future milestones payments across both targets pending achievement of pre-defined development, regulatory, and commercial milestones. Elektrofi will also receive a mid-single digit royalty on sales of commercialized products.

Our Non-Exclusive Research License with Chugai for SMART-Ig® and ACT-Ig®

In September 2020, we entered into a non-exclusive research license and option agreement with Chugai Pharmaceutical Co., Ltd. (***Chugai***) allowing us access Chugai's SMART-Ig® and ACT-Ig® Fc engineering technologies for conducting feasibility studies. 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.

Our Non-exclusive License with the Clayton Foundation for DHS mutations

In October 2020, we entered into a non-exclusive research agreement with the Clayton Foundation relating to the non-exclusive in-license for the Clayton Foundation's proprietary DHS mutations to extend the serum half-life of therapeutic candidates.

Our Exclusive License with Halozyme for ENHANZE®

In February 2019, we entered into an in-license agreement with Halozyme Inc. (**Halozyme**) for the use of certain patents, materials and know-how owned by Halozyme and relating to its ENHANZE® technology (ENHANZE®), for application in the field of prevention and treatment of human diseases (the **ENHANZE® License Agreement**). Pursuant to the ENHANZE® License Agreement, we were granted exclusive rights to apply ENHANZE® to biologic products against pre-specified targets, in order to research, develop and commercialize SC formulations of our therapeutic antibody-based product candidates.

Our first therapeutic target for which we have received an exclusive license from Halozyme is FcRn, which allows us to apply ENHANZE® to efgartigimod and any other product 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 C2 associated with the product candidate ARGX-117, which is being developed to treat severe autoimmune diseases. Pursuant to the ENHANZE® License Agreement, we also have the right to nominate future targets 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 ENHANZE® 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 achieving the first patient dosed for efgartigimod -113 Ph3 for ITP we made a \$15 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 million for the first product that uses ENHANZE® and is specific for a given target. Throughout the term of the ENHANZE® License 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 ten years from the first commercial sale of the product in a country, the last valid claim within the licensed ENHANZE® patent(s) expires. 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.

Pursuant to the ENHANZE® License Agreement, 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 ENHANZE®. Halozyme provides dedicated specialist support to us which it has accrued over ten years of licensing ENHANZE® to its collaborators.

We may terminate the ENHANZE® 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 ENHANZE® License Agreement will automatically expire upon the expiry of our royalty payment obligations under the agreement. In

the event the ENHANZE[®] License 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 ENHANZE[®] License 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 this, our entering into the ENHANZE[®] 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 argenx or Halozyme. Mr. Daly did not participate in any discussions and decision making relating to the ENHANZE[®] License Agreement. Consequently, no further disclosures regarding Halozyme have been added in “*Related Party Transactions*”.

Our Exclusive License with AgomAb for ARGX-114 (AGMB-101)

In March 2019, we entered into an exclusive out-license with AgomAb Therapeutics NV (**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 (AGMB-101), 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 investigational new drug (**IND**) and is subject to further adjustment upon the occurrence of certain financings). Upon the occurrence of a qualified initial public offer of AgomAb, the profit-sharing certificate will automatically be converted into the equivalent number of ordinary shares in 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 for ARGX-117

In March 2017, we entered into a collaboration with Broteio in connection with our immunology innovation program, to develop an antibody against a novel target in the complement cascade, ARGX-117 (the **Broteio Agreement**). Under the terms of the Broteio 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 in-license the program in March 2018 and assumed responsibility for further development and commercialization. Pursuant to the Broteio 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 the Broteio Agreement for convenience upon 90 days prior written notice. The Broteio Agreement is also subject to mutual termination for material breach or insolvency and automatically expires upon the expiration of our financial obligations thereunder.

Our Exclusive License with VIB for ARGX-118

In November 2016, we entered into a collaboration under our immunology innovation program with VIB to develop antibodies against Galectin-10, the protein of Charcot-Ley-den Crystals, which play a major role in severe asthma and the persistence of mucus plugs, including ARGX-118 (the **VIB Agreement**). Pursuant to the VIB 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 in-license the program and assumed responsibility for further development and commercialization. Under the VIB Agreement, including as amended in November 2018, 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 the VIB Agreement for convenience upon 90 days prior written notice. The VIB 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 for NHance® and ABDEG™

In February 2012, we entered into an exclusive in-license with The Board of Regents of The University of Texas System (**UoT**) for use of certain patents rights relating to the NHance® platform for any use worldwide (the **UoT Agreement**). The UoT 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 the UoT Agreement, but in any event does not exceed 1%. In addition, we must make annual license maintenance payments to UoT until termination of the UoT Agreement and we have assumed certain development and commercial milestone payment and reimbursement obligations. We also have diligence requirements with respect to development and commercialization of products which use the in-licensed patent rights.

Pursuant to the UoT Agreement, 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 the UoT Agreement.

We may unilaterally terminate the UoT Agreement for convenience upon prior written notice. Absent early termination, the UoT Agreement will automatically expire upon the expiration of all issued patents and filed patent applications within the patent rights covered by the UoT 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 for POTE LLIGENT®

In October 2010, we entered into a non-exclusive in-license agreement with BioWa, Inc. (**BioWa**) for use of certain patents and know-how owned by BioWa and relating to its POTE LLIGENT® platform technology, for use in the field of prevention and treatment of human diseases (the **POTE LLIGENT® License Agreement**). Pursuant to the POTE LLIGENT® License Agreement, we are granted a non-exclusive right to use POTE LLIGENT® to research, develop and commercialize antibodies and products containing such antibodies using POTE LLIGENT®. BioWa retains a right of first negotiation for the exclusive right to develop and commercialize, in certain countries only, any product we develop using POTE LLIGENT®. We successfully applied POTE LLIGENT® to cusatuzumab, an anti-CD70 mAb, and ARGX-111, an anti-c-Met mAb, under the POTE LLIGENT® License Agreement.

Upon commercialization of our products developed using POTE LLIGENT®, 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 ten 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.

Pursuant to the POTE LLIGENT® License Agreement, we have the right to grant sublicenses to third parties.

We may terminate the POTE LLIGENT® License Agreement at any time by sending BioWa prior written notice. Absent early termination, the POTE LLIGENT® License Agreement will automatically expire upon the

expiry of our royalty obligations under the POTELLIGENT® License Agreement. In the event the POTELLIGENT® License 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 POTELLIGENT® License 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 for 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 in-license agreements for cusatuzumab and ARGX-111 with BioWa and Lonza Sales AG (**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® platform 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 the POTELLIGENT® License Agreement, which continues to govern our research, development and commercialization of products utilizing POTELLIGENT®. 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. 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® License Agreement or the agreement in relation to POTELLIGENT® CHOK1SV, but not both. The BioWa royalty is tiered, ranging in the low single digits and is reduced by half if during the following ten 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 ten 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® License Agreement or the agreement in relation to POTELLIGENT® CHOK1SV, 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 per product, also depending on such product being manufactured by Lonza, us or one of our affiliates or strategic partners or otherwise.

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.

We may terminate any of the non-exclusive commercial license agreements at any time by sending BioWa and/or 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 respective 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) ten 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 non-exclusive license with Lonza for Multi-product GS Xceed-License

On February 4, 2015 we entered into a non-exclusive multi-product in-license agreement with Lonza (the **Multi-Product Agreement**) for use of Lonza's proprietary glutamine synthetase gene expression system known as GS Xceed™ consisting of Chinese hamster ovary cell line and the vectors for the manufacturing of drug substance (the **System**). The System is used for the manufacturing of efgartigimod, cusatuzumab ARGX-117, ARGX-119 and LP0145.

Pursuant to the Multi-Product Agreement, we have the right to grant sublicenses to certain pre-approved third parties without prior written consent of Lonza, but otherwise must obtain Lonza's prior written consent.

We have assumed certain development, regulatory and commercial milestone payment obligations to Lonza. We are required to pay such milestones only in respect of the first product manufactured using the System. We are obligated to make development, regulatory and commercial milestone payments to Lonza in aggregate amounts of up to £575,000 for the first product manufactured by Lonza, us or one of our affiliates or strategic partners. Through December 31, 2021, we have paid Lonza an aggregate amount of £0.4 million, which includes milestone payments made under the Multi-Product Agreement. Upon commercialization of our products developed using the System, we will be obligated to pay Lonza a percentage of net sales as a royalty for each product manufactured. The Lonza royalty is tiered, ranging in the low single digits and is reduced by half if the product in a country is not protected by a valid claim.

We may terminate the Multi-Product Agreement on a product-by-product basis by giving Lonza prior written notice. Lonza may terminate the Multi-Product Agreement solely in case of breach or insolvency events. Absent early termination, the Multi-Product Agreement will automatically expire upon the expiry of the last valid claim for such product. We or our strategic partners would retain the right to sell the respective products then on hand post-termination.

Our Collaboration with UCL and Sopartec for GARP

In January 2013, we entered into a collaboration and exclusive product license agreement with Université Catholique de Louvain (**UCL**) and its technology transfer company Sopartec S.A. (**Sopartec**) to discover and develop novel human therapeutic antibodies against GARP (the **GARP Agreement**). Pursuant to the GARP Agreement, 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 under the GARP Agreement to enter into an exclusive, worldwide commercial in-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 (the **GARP License**). Upon the expiration of the GARP Agreement, the GARP 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.

Pursuant to the GARP 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 in connection with AbbVie Collaboration Agreement, 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.

Our Exclusive License with NYU Langone Health and LUMC for ARGX-119

In 2019 and 2020, we entered into collaboration and exclusive license agreements with NYU Langone Health (**NYU**) and LUMC under our immunology innovation program to develop antibodies targeting the MuSK, for the treatment neuromuscular diseases, which play a major role at the neuromuscular junction (the **NYU and LUMC Agreements**). Pursuant to the NYU and LUMC Agreements, we, NYU and LUMC jointly developed antibodies against MUSK using our proprietary suite of technologies. Under the NYU and LUMC Agreements, as amended, we are obligated to make milestone payments upon the occurrence of certain development milestones, commercialization milestones and pay tiered royalties on net sales in the low single digits.

Distribution Agreements

Our Exclusive Distribution Agreement with Medison for efgartigimod

In October 2021, we announced an exclusive distribution agreement with Medison Pharma Ltd. (**Medison**) to commercialize efgartigimod for gMG in Israel; under the agreement, Medison will also be responsible for seeking requisite regulatory approvals.

Our Exclusive Distribution Agreement with Genpharm for efgartigimod

On January 18, 2022, we entered into a partnership agreement with Genpharm Services FZ-LLC (**Genpharm**), under which Genpharm shall purchase VYVGART™ from us for resale in the Gulf Cooperation Council (**GCC**) on an exclusive basis for Genpharm's own account and own name (the **Genpharm Agreement**).

Regulatory Framework

Government authorities in the U.S., 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 U.S. 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 U.S.

In the U.S., our product candidates and products are regulated as biological products, or biologics, under the Public Health Service Act (**PHSA**), and the Federal Food, Drug, and Cosmetic Act (**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, 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 U.S. generally must satisfactorily complete each of the following steps:

- nonclinical laboratory tests, animal studies and formulation studies all performed in accordance with applicable regulations, including the 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 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 GCP;
- preparation and submission to the FDA of a 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 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 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 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 U.S. 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 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. If the FDA determines the BLA is not sufficiently complete, it

will refuse the BLA. 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 (**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 reviews. The review process may be significantly extended by FDA requests for additional information or clarification. The review process and the PDUFA goal date may also 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, 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 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 (**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 patient 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. Such regulatory reviews can result in denial or modification of the planned changes, or requirements to conduct additional tests or evaluations that can substantially delay or increase the cost of the planned changes.

Such regulatory reviews can result in denial or modification of the planned changes, or requirements to conduct additional tests or evaluations that can substantially delay or increase the cost of the planned changes.

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 ten 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 or on a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality (**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, radio-graphic 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. Unless otherwise informed by the FDA, all promotional materials for product candidates approved under accelerated regulations are subject to prior review by the agency.

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 other parties involved in the drug supply chain for prescription drug and biological products must also comply with product tracking and tracing requirements and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the U.S. 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. Any distribution of prescription biological products and pharmaceutical samples must comply with the U.S. PDMA and the PHSA.

Once an approval is granted, the FDA may revoke or suspend the approval of the BLA 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. Although physicians may prescribe legally available products for unapproved uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), company's with approved products may not market or promote such off-label uses. The FDA does not regulate the behavior of physicians in their choice of treatments, but the FDA regulations do impose stringent restrictions on manufacturers' communications regarding off-label uses. 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, including investigation by federal and state authorities. Prescription biological product promotional materials must be submitted to the FDA in conjunction with their first use or first publication.

Orphan Drug Designation

Orphan drug designation in the U.S. is designed to encourage sponsors to develop products intended for rare diseases or conditions. In the U.S., a rare disease or condition is statutorily defined as a condition that affects fewer than 200,000 individuals in the U.S. or that affects more than 200,000 individuals in the U.S. 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 U.S.

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 and if it is the first FDA approval for that product for the disease for which it has such designation. 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 (**OOPD**) at the FDA based on an acceptable confidential request made under the regulatory provisions. After the FDA grants orphan drug designation, the generic identity of the product and its potential orphan use are disclosed publicly by the FDA. 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 sponsor 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 of the product.

Pediatric Studies and Exclusivity

Under the Pediatric Research Equity Act of 2003 (as amended, **PREA**), 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 sub-populations, 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 U.S. 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 (**BPCIA**) established a regulatory scheme authorizing the FDA to approve biosimilars and interchangeable biosimilars.

Under the BPCIA, an applicant 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 twelve 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 (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 the United Kingdom

In order to market any medicinal product outside of the U.S., 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 U.S. 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 an MAA and granting of a marketing authorization by these authorities before the product can be marketed and sold in the European Union. Following the United Kingdom's departure from the European Union, a separate marketing authorization will be required in order to place medicinal products on the market in the United Kingdom (under the Northern Ireland 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

In April 2014, the European Union adopted the new Clinical Trials Regulation (EU) No 536/2014, which replaced the Clinical Trials Directive 2001/20/EC effective as of January 31, 2022. The transitory provisions of the new Regulation offer sponsors the possibility to choose between the requirements of the previous Directive and the new Regulation if the request for authorization of a clinical trial is submitted in the year after the new Regulation became applicable. If the sponsor chooses to submit under the previous Directive, the clinical trial continues to be governed by the Directive until three years after the new Regulation became applicable. If a clinical trial continues for more than three years after the Regulation became applicable, the new Regulation will at that time begin to apply to the clinical trial. The new Regulation (EU), which is directly applicable in all European Union Member States, aims at simplifying and streamlining the approval of clinical trials in the European Union. The main characteristics of the new Regulation include: a streamlined application procedure via a single-entry point through the Clinical Trials Information System (**CTIS**); a single set of documents to be prepared and submitted for the

application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts (Part I contains scientific and medicinal product documentation and Part II contains the national and patient-level documentation). Part I is assessed by a coordinated review by the competent authorities of all European Union Member States in which an application for authorization of a clinical trial has been submitted (**Concerned Member States**) of a draft report prepared by a Reference Member State. Part II is assessed separately by each Concerned Member State. Strict deadlines have also been established for the assessment of clinical trial applications.

The United Kingdom has implemented Directive 2001/20/EC into national law through the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended). The extent to which the regulation of clinical trials in the United Kingdom will mirror the new European Union Clinical Trials Regulation that has come into effect is not yet known, however the Medicines and Healthcare products Regulatory Agency (**MHRA**), the United Kingdom medicines regulator, has opened a consultation on a set of proposals designed to improve and strengthen the United Kingdom clinical trials legislation. Such consultation is open until 14 March 2022.

Orphan 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: (1) that the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) 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 (ii) without incentives it is unlikely that the marketing of the product in the European Union would generate sufficient return to justify the necessary investment in its development; and (3) 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 product has to be of a significant benefit compared to products available for the condition.

An orphan designation provides a number of benefits, including fee reductions and, regulatory assistance. If a marketing authorization is granted for an orphan medicinal product, 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 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 for the authorized orphan product consents to the second orphan application; or (iii) the marketing authorization holder for the authorized orphan product cannot supply enough orphan medicinal product. Orphan designation must be requested before submitting an application for marketing approval. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Since January 1, 2021, a separate process for orphan designation has applied in Great Britain. There is now no pre-marketing authorization orphan designation (as there is in the European Union) and the application for orphan designation will be reviewed by the MHRA, at the time of an MAA for a United Kingdom or Great Britain marketing authorization. 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, as opposed to the European Union, and the prevalence of the condition must be no more than 5 in 10,000 persons in Great Britain).

Marketing Authorization

To obtain a marketing authorization for a product under the European Union regulatory system, an applicant must submit an MAA, either to the EMA using the centralized procedure or to competent authorities in the EU 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 EU. Regulation (EC) No. 1901/2006 provides that prior to obtaining a marketing authorization in the EU, an applicant must demonstrate compliance with all measures included in an EMA-approved pediatric investigation plan (**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 the EU and the additional Member States of the European Economic Area (Iceland, Liechtenstein and Norway) (**EEA**). 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 medicinal products (gene therapy, somatic cell therapy or tissue engineered 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 and other immune dysfunctions and neurodegenerative disorders. The centralized procedure is optional for products that contain a new active substance for any other indications, which are a significant therapeutic, scientific or technical innovation and whose authorization would be in the interest of public health in the European Union.

Under the centralized procedure, the Committee for Medicinal Products for Human Use (**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 asked by 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 United Kingdom has left the European Union, Great Britain will no longer be covered by centralized marketing authorizations (under the Northern Ireland 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 United Kingdom 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.

European Data and Market Exclusivity

In the European Union, innovative medicinal products, approved on the basis of a complete independent data package, qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. The data exclusivity, if granted, prevents generic or biosimilar applicants from referencing the innovator's preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the European Union, for a period of eight years from the date on which the reference product was first authorized in the European Union. During the additional two-year period of market exclusivity a generic or biosimilar MAA can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be marketed in the European Union until the expiration of the market exclusivity period. The overall ten year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains a marketing authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are determined to

bring a significant clinical benefit in comparison with currently approved therapies. There is no guarantee that a product will be considered by the EMA to be an innovative medicinal product, and products may not qualify for data exclusivity. Even if a product is considered to be an innovative medicinal product so that the innovator gains the prescribed period of data exclusivity, another company nevertheless could also market another version of the product if such company obtained a marketing authorization based on an MAA with a complete independent data package of pharmaceutical tests, preclinical tests and clinical trials.

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. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any authorization that is not followed by the placement of the drug on the European Union market (in the case of the centralized procedure) or on the market of the authorizing Member State (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 products 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 products and/or the general public, are strictly regulated in the European Union under Directive 2001/83EC, as amended. The aforementioned European Union rules are generally applicable in the EEA.

Brexit and the Regulatory Framework in the United Kingdom

In June 2016, the electorate in the United Kingdom voted in favor of leaving the European Union (commonly referred to as “**Brexit**”), and the United Kingdom officially withdrew from the European Union on January 31, 2020. Pursuant to the formal withdrawal arrangements agreed between the United Kingdom and the European Union, the United Kingdom was subject to a transition period until December 31, 2020, or Transition Period, during which European Union rules continued to apply. However, the European Union and the United Kingdom have concluded a trade and cooperation agreement, or TCA, which was provisionally applicable since January 1, 2021 and has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not foresee wholesale mutual recognition of United Kingdom and European Union pharmaceutical regulations. At present, 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 therefore largely aligns with current European Union regulations, however it is possible that these regimes will diverge in future now that Great Britain's regulatory system is independent from the European Union and the TCA does not provide for mutual recognition of United Kingdom and European Union pharmaceutical legislation. For example, the new Clinical Trials Regulation which became effective in the European Union on January 31, 2022 has not been implemented into United Kingdom law, and a separate application will need to be submitted for clinical trial authorization in the United Kingdom.

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 (the ***Minister***), 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 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 PMDA, 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 PMDA, 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 PMDA, 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 GLP and 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 PMDA.

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 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 U.S. (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 U.S. 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 U.S. and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. 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.

Factors payors consider in determining reimbursement are based on whether the product is (i) a covered benefit under its health plan; (ii) safe, effective and medically necessary; (iii) appropriate for the specific patient; (iv) cost-effective; and (v) neither experimental nor investigational.

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 (**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 (**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 have needed and 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. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any future product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price (**ASP**) and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. 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 U.S. 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 U.S., 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) 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. Historically, products launched in the European Union do not follow price structures of the U.S. and generally prices tend to be significantly lower.

Outside the U.S., 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 U.S., the reimbursement for our products may be reduced compared with the U.S. 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 (**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 (**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. 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 (**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 (**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 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 (**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 were extended to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners;
- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs;
- 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 U.S.

Some state laws require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals, in addition to requiring pharmaceutical manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state and require the registration of pharmaceutical sales representatives. State and foreign laws, including for example the European Union General Data Protection Regulation, which became effective May 2018, 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. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties.

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

In the U.S., to help patients afford our approved product, we may utilize programs to assist them, including patient assistance programs and co-pay coupon programs for eligible patients. Government enforcement agencies have shown increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. In addition, at least one insurer has directed its network pharmacies to no longer accept co-pay coupons for certain specialty drugs the insurer identified. Our co-pay coupon programs could become the target of similar insurer actions. In addition, in November 2013, the CMS issued guidance to the issuers of qualified health plans sold through the ACA's marketplaces encouraging such plans to reject patient cost-sharing support from third parties and indicating that the CMS intends to monitor the provision of such support and may take regulatory action to limit it in the future. The CMS subsequently issued a rule requiring individual market qualified health plans to accept third-party premium and cost-sharing payments from certain government-related entities. In September 2014, the OIG of the HHS issued a Special Advisory Bulletin warning manufacturers that

they may be subject to sanctions under the federal anti-kickback statute and/or civil monetary penalty laws if they do not take appropriate steps to exclude Part D beneficiaries from using co-pay coupons. Accordingly, companies exclude these Part D beneficiaries from using co-pay coupons. It is possible that changes in insurer policies regarding co-pay coupons and/or the introduction and enactment of new legislation or regulatory action could restrict or otherwise negatively affect these patient support programs, which could result in fewer patients using affected products, and therefore could have a material adverse effect on our sales, business, and financial condition.

Third party patient assistance programs that receive financial support from companies have become the subject of enhanced government and regulatory scrutiny. The OIG has established guidelines that suggest that it is lawful for pharmaceutical manufacturers to make donations to charitable organizations who provide co-pay assistance to Medicare patients, provided that such organizations, among other things, are bona fide charities, are entirely independent of and not controlled by the manufacturer, provide aid to applicants on a first-come basis according to consistent financial criteria and do not link aid to use of a donor's product. However, donations to patient assistance programs have received some negative publicity and have been the subject of multiple government enforcement actions, related to allegations regarding their use to promote branded pharmaceutical products over other less costly alternatives. Specifically, in recent years, there have been multiple settlements resulting out of government claims challenging the legality of their patient assistance programs under a variety of federal and state laws. It is possible that we may make grants to independent charitable foundations that help financially needy patients with their premium, co-pay, and co-insurance obligations. If we choose to do so, and if we or our vendors or donation recipients are deemed to fail to comply with relevant laws, regulations or evolving government guidance in the operation of these programs, we could be subject to damages, fines, penalties, or other criminal, civil, or administrative sanctions or enforcement actions. We cannot ensure that our compliance controls, policies, and procedures will be sufficient to protect against acts of our employees, business partners, or vendors that may violate the laws or regulations of the jurisdictions in which we operate. Regardless of whether we have complied with the law, a government investigation could impact our business practices, harm our reputation, divert the attention of management, increase our expenses, and reduce the availability of foundation support for our patients who need assistance.

On December 2, 2020, the HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers (PBMs), 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 PBMs and manufacturers. Implementation of this change and new safe harbors for point-of-sale reductions in price for prescription pharmaceutical products and PBM service fees are currently under review by the current U.S. presidential administration and may be amended or repealed. Further, on December 31, 2020, CMS published a new rule, effective January 1, 2023, requiring manufacturers to ensure the full value of co-pay assistance is passed on to the patient or these dollars will count toward the Average Manufacturer Price and Best Price calculation of the drug. On May 21, 2021, PhRMA sued the HHS in the U.S. District Court for the District of Columbia, to stop the implementation of the rule claiming that the rule contradicts federal law surrounding Medicaid rebates. It is unclear how the outcome of this litigation will affect the rule. We cannot predict how the implementation of and any further changes to this rule will affect our business. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the current U.S. presidential administration may reverse or otherwise change these measures, both the current U.S. presidential administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

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. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance 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 the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment, reputational harm, and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, 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. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected.

Healthcare Reform

In the U.S., 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 U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the ACA entered into force. 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 (**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 its enactment, there have been judicial, Congressional and executive challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact our business.

Prior to the Biden administration, 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 U.S. 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. It is unclear what effect this will have on our business.

In addition, CMS published a final rule that would give states greater flexibility as of 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.

On December 20, 2019, former President Trump signed into law the Further Consolidated Appropriations Act (H.R. 1865), which repeals the Cadillac tax, the health insurance provider tax, and the medical device excise tax. It is impossible to determine whether similar taxes could be instated in the future.

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, included aggregate reductions of Medicare payments to providers of 2% per financial 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, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022

due to the COVID-19 pandemic. Following the suspension, a 1% payment reduction will occur beginning April 1, 2022 through June 30, 2022, and the 2% payment reduction will resume on July 1, 2022. 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.

On May 23, 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.

At a federal level, President Biden signed an Executive Order on July 9, 2021 affirming the administration's policy to (i) support legislative reforms that would lower the prices of prescription drug and biologics, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and, by supporting the development and market entry of lower-cost generic drugs and biosimilars; and (ii) support the enactment of a public health insurance option. Among other things, the Executive Order also directs HHS to provide a report on actions to combat excessive pricing of prescription drugs, enhance the domestic drug supply chain, reduce the price that the Federal government pays for drugs, and address price gouging in the industry; and directs the FDA to work with states and Indian Tribes that propose to develop section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and the FDA's implementing regulations. FDA released such implementing regulations on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. On September 25, 2020, CMS stated drugs imported by states under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. If implemented, importation of drugs from Canada may materially and adversely affect the price we receive for any of our product candidates. Further, on November 20, 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation (*MFN*) Model under which Medicare Part B reimbursement rates would have been calculated for certain drugs and biologics based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. However, on December 29, 2021 CMS rescinded the MFN rule. Additionally, on November 30, 2020, HHS published a regulation removing 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 court order, the removal and addition of the aforementioned safe harbors were delayed and recent legislation imposed a moratorium on implementation of the rule until January 1, 2026. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

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 U.S. 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 U.S. 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, 2021, we had seven 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
argenx France SAS	France	100.00 %	Pharmaceuticals and pharmacy supplies merchant wholesalers
argenx Germany GmbH	Germany	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, Tokyo, Japan, Geneva, Switzerland, Munich Germany and Issy Les Moulineaux, France.

In January 2021, we 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 \$1.9 million, which would be operational in the second quarter of 2025, 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.

We have an annual lease in Breda, the Netherlands in relation to office space, with an initial term of 1 year. In January 2021, we have entered into an annually renewing lease agreement in relation to office space located in Geneva, Switzerland for an initial term of 1 year including 2 office spaces. In September 2021, we have entered into a lease agreement in relation to office space located in Munich, Germany for an initial term of 1 year including 2 office spaces. In May 2021, we have entered into a lease agreement in relation to office space located in Issy Les Moulineaux, France for an initial term of 1 year including 1 office space.

We have following material facilities worldwide owned or leased as of December 31, 2021, 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 31 st , 2025
Boston, Massachusetts (leased)	Office Space	813	August 31 st , 2025
Tokyo, Japan (leased)	Office Space	546	January 17 th , 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 several candidates into late-stage clinical development and we currently have multiple programs in the discovery stage. Through December 31, 2021, we have raised an aggregate gross proceeds of \$3,514.4 million, including:

- (i) an aggregate of \$65.3 million (€46.0 million) from the private placement of equity securities in 2008, 2009 and 2011,
- (ii) \$56.9 million (€41.8 million) from our initial public offering on the Euronext Brussels in 2014,
- (iii) \$50.9 million (€46.0 million) from the private placement of equity securities, primarily to U.S. based institutional investors, in 2016,
- (iv) \$114.7 million from our initial U.S. public offering on the Nasdaq Global Select Market in May 2017,
- (v) \$265.5 million from our second U.S public offering on the Nasdaq Global Select Market in December 2017,
- (vi) \$300.6 million from our third U.S public offering on the Nasdaq Global Select Market in September 2018,
- (vii) \$200.9 million (€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) \$556.3 million (€502.2 million) from a global offering in November 2019,
- (ix) \$590.5 million from our U.S. public offering on the Nasdaq Global Select Market and \$222.8 million (€200.4 million) from a concurrent private placement in May 2020, and
- (x) \$1,090.1 million from from our U.S. public offering on the Nasdaq Global Select Market in January 2021.

In addition, as of December 31, 2021, we have received upfront payments, milestone payments and research and development service fees from our collaborators totaling \$578.9 million. As of December 31, 2021, we had cash, cash equivalents and current financial assets of \$2,336.7 million.

Our balance sheet shows our total assets accumulate to \$2,850.3 million for the year ended December 31, 2021, compared to \$2,279.4 million for the year ended December 31, 2020 and \$1,610.2 million for the year ended December 31, 2019. 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. On December 17, 2021, the FDA approved efgartigimod, which is marketed as VYVGART™ (efgartigimod alfa-fcab), for the treatment of gMG in adult patients who are AChR antibody positive. On January 20, 2022, the Japan PMDA approved VYVGART™ (efgartigimod alfa) for the treatment of adult patients with gMG who do not have sufficient response to steroids or non-steroidal ISTs. These are the only approved products we currently have and we have not generated any revenue from product sales until the end of the financial year ended December 31, 2021.

Our ability to generate revenue sufficient to achieve profitability will depend significantly upon the successful commercialization of the approved product and development and eventual commercialization of one or more of our product candidates. For the years ended December 31, 2021 and 2020, we incurred total comprehensive losses of \$450.6 million and \$446.2 million, respectively. As of December 31, 2021, we had accumulated losses of \$1,400.2 million.

We expect our expenses to increase substantially in connection with our transition to an integrated immunology company, including the build-out of global commercial infrastructure and drug product inventory for the commercial launch of VYVGART™ for the treatment of gMG, the advancement of our clinical-stage pipeline, including ongoing registrational trials across four indications of efgartigimod, and continued investment in our IIP. In addition, we expect to continue to incur significant costs associated with operating as a public company in the U.S. 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, CIDP, PF and in PV;
- execute the Phase 2/3 clinical trials of efgartigimod in BP and myositis 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; 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 VYVGART™ for which we obtained the regulatory approval from FDA and the PMDA and any product candidate for which we may obtain approval; 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.

Information pertaining to the year ended December 31, 2019 was included in our Annual Report on Form 20-F for the year ended December 31, 2020 under Item 5, “Operating and Financial Review and Prospects,” which was filed with the SEC on March 30, 2021.

Basis of Presentation

Foreign Currency Transactions

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. As of January 1, 2021, and for all periods thereafter, the consolidated financial statements are presented in USD (\$), which is the Company’s presentation currency.

2. Change in functional and presentation currency as of January 1, 2021

As of January 1, 2021, the Company changed its functional and presentation currency from EUR to USD. The change in functional currency was made to reflect that USD has become the predominant currency for the Company, representing a significant part of the Company’s cash flows and financing. The change has been implemented with prospective effect.

The change in presentation currency, effective January 1, 2021, from EUR to USD is retroactively applied to comparative figures according to IAS 8 and IAS 21, as if USD had always been the presentation currency of the consolidated financial statements. The change was made to better reflect the economic footprint of the Company’s business going forward. The Company believes that the presentation currency change will give investors and other stakeholders a clearer understanding of the Company’s performance over time.

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 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, the 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 products/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.

For our material ongoing collaboration and license agreement (i.e. the Zai Lab Agreement), the Company has assessed that there is more than one distinct performance obligation, being the transfer of a license and supply of clinical and commercial product.

This is because the Company considers the performance obligations is distinct in the context of the contract as the license has stand-alone value without the Company being further involved in the research and development collaboration and that there is no interdependence between the license and the clinical and commercial supply to be provided.

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

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 distinct from the other promises to transfer goods and/or services; the Company utilizes judgement to assess the nature of the performance obligation to determine whether the 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 collaboration and license agreement (i.e. the Zai Lab agreement) contains more than one performance obligation, the Company assesses to allocate the transaction price to all performance obligations identified.

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 collaboration and license agreement (i.e. the Zai Lab agreement) contains more than one performance obligation, the Company recognized revenue at the point in time of the transfer of license and the Company recognizes revenue over time for supply of clinical and commercial products as the customer simultaneously receive the benefits provided by the Company's performance, satisfied over time.

Other ongoing collaboration and license agreements 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.

Changes in fair value on non-current financial assets

- 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 Immunology Innovative Program. In exchange for granting this license, the Company received a profit share in AgomAb Therapeutics NV.

In March 2021, AgomAb Therapeutics NV secured \$74.0 million in Series B financing by issuing 286,705 Preferred B Shares. argenx used the post-money valuation of Series B financing round and the number of outstanding shares in determining the fair value of the profit-sharing instrument, which results in a change in fair value of non-current financial assets of \$11.2 million recorded through profit or loss. The fair value of non-current financial assets is updated at the end of each reporting period.

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 agreement with AbbVie, our own research and development expenses were not reimbursed. Under our agreement with Janssen, we assumed certain development obligations, and were 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 ARGX-117 and further advance the research and development of our other early stage pipeline candidates. 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 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) 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) costs associated with preparation of commercial launch of VYVGARTTM for the treatment of gMG in the U.S. and promotional activities (v) costs associated with the preparation of the commercial launch in Japan and EMEA and continued investment in supply chain, (vi) allocated facilities costs and (vii) 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 U.S. 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 and marketing expenses to increase significantly due to marketing and promotional activities with respect to the commercial launch of VYVGARTTM in the U.S. and Japan.

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 Euro, 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 USD, which is our functional and presentation currency since January 1, 2021 and therefore the presentation currency throughout this Annual Report. 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 Expense

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 incur costs for the commercial launch of VYVGART™, following the recent regulatory approval by the FDA and the PMDA. Consequently, we do not have any deferred tax asset regarding unused tax losses on our consolidated statements of financial position.

We are incurring current income tax expense on the profit generated in various subsidiaries in view of the transfer price agreements set up between argenx BV and these subsidiaries.

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.

Critical estimates in applying accounting policies

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.

Research and development cost accruals

The Company recognizes costs of \$163.7 million, as specified in note 15 to the consolidated 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.

Results of Operation

Comparison of Years Ended December 31, 2021 and 2020

	Year ended December 31,		
	2021	2020	% Change
	(In thousands)		
Revenue	\$ 497,277	\$ 41,243	1,106 %
Other operating income	42,141	23,668	78 %
Total operating income	539,418	64,911	731 %
Research and development expenses	(580,520)	(370,885)	57 %
Selling, general and administrative expenses	(307,644)	(171,643)	79 %
Total operating expenses	(888,164)	(542,528)	64 %
Operating loss	(348,746)	(477,617)	(27)%
Financial income/(expenses)	(944)	(1,501)	(37)%
Exchange gains (losses)	(50,053)	(126,234)	(60)%
Loss before taxes	\$ (399,743)	\$ (605,352)	(34)%
Income tax expense	(8,522)	(3,103)	175 %
Loss for the period and total comprehensive loss	\$ (408,265)	\$ (608,455)	(33)%
Weighted average number of shares outstanding	51,075,827	45,410,442	
Basic and diluted loss per share (in \$)	(7.99)	(13.40)	

Revenue

	Year ended December 31,		
	2021	2020	% Change
	(In thousands)		
Zai Lab	\$ 151,903	\$ —	100 %
Janssen	292,279	33,759	766 %
AbbVie	121	565	(79) %
Agomab	—	—	%
Other	—	38	(100) %
Upfront payments	444,303	34,362	1,193 %
Zai Lab	25,634	—	100 %
Janssen	22,865	2,641	766 %
AbbVie	102	762	(87) %
Other	1,214	19	6,289 %
Milestone payments	49,815	3,422	1,356 %
Janssen	2,028	3,175	(36) %
Other	298	284	5 %
Research and development service fees	2,326	3,459	(33) %
Zai Lab	833	—	100 %
Other revenues	833	—	100 %
Total revenue	\$ 497,277	\$ 41,243	1,106 %

Our revenue increased by \$456.1 million to \$497.3 million for the year ended December 31, 2021, compared to \$41.2 million for the year ended December 31, 2020, a result of a recognition of the transaction price from Janssen as a consequence of the termination of the collaboration agreement and the closing of the strategic collaboration for efgartigimod with Zai Lab.

The increase in revenue recognition from upfront payments is primarily driven by the recognition of the upfront payment received from Zai Lab upon strategic collaboration for efgartigimod and the recognition of the upfront payment received under the collaboration agreement with Janssen upon termination of the agreement.

The increase in revenue recognition from milestone payments is mainly due to recognition of \$25.0 million from Zai Lab upon regulatory approval of efgartigimod by FDA in the U.S. and recognition of \$22.9 million as a result of the termination of the collaboration agreement with Janssen.

The decrease in revenue recognition from research and development service fees of \$1.1 million is primarily driven by the decrease due to the termination of the collaboration agreement with Janssen.

Other Operating Income

	Year ended December 31,		
	2021	2020	% Change
		(In thousands)	
Grants	\$ 4,398	\$ 1,365	222 %
Research and development incentives	13,970	10,257	36 %
Payroll tax rebates	12,621	9,095	39 %
Change in fair value on non-current financial assets	11,152	2,951	278 %
Total	\$ 42,141	\$ 23,668	78 %

Other operating income increased by \$18.4 million to \$42.1 million for the year ended December 31, 2021, compared to \$23.7 million for the year ended December 31, 2020. The increase is primarily driven by:

- the increase in research and development incentives, as a result of the increased research and development costs incurred;
- 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, and
- the increase in fair value on our profit share in AgomAB Therapeutics NV.

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,		
	2021	2020	% Change
		(In thousands)	
Personnel expense	\$ 160,464	\$ 86,036	87 %
External research and development expenses	382,902	259,943	47 %
Materials and consumables	2,735	3,562	(23)%
Depreciation and amortization	3,742	2,835	32 %
Other expenses	30,677	18,509	66 %
Total	\$ 580,520	\$ 370,885	57 %

Our research and development expenses totaled \$580.5 million and \$370.9 million for the years ended December 31, 2021 and 2020, respectively. The increase of \$209.6 million compared to 2020 primarily results

from an increase in external research and development expenses and personnel expenses, primarily related to the efgartigimod program in various indications and other clinical and preclinical programs. Furthermore, the personnel expenses increased due to a planned increase in headcount.

The increase of \$74.4 million in personnel expense for the year ended December 31, 2021 corresponded primarily to (i) an increase of \$49.2 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 349.7 full time equivalents in our research and development functions in the year ended December 31, 2021, compared to 213.0 in the year ended December 31, 2020.

Our external research and development expenses for the year ended December 31, 2021 totaled \$382.9 million, compared to \$259.9 million for the year ended December 31, 2020. 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,		
	2021	2020 (In thousands)	% Change
efgartigimod	\$ 311,038	\$ 182,511	70 %
cusatuzumab	24,630	48,796	(50)%
Other programs	47,234	28,636	65 %
Total	<u>\$ 382,902</u>	<u>\$ 259,943</u>	<u>47 %</u>

External research and development expenses for our lead product candidate efgartigimod totaled \$311.0 million for the year ended December 31, 2021, compared to \$182.5 million for the year ended December 31, 2020. This increase of \$128.5 million corresponds primarily to increased manufacturing and clinical development activities in relation to:

- the execution of two Phase 3 clinical trials in MG ;
- the execution of the bridging study for ENHANZE® efgartigimod in MG;
- the execution of two Phase 2 clinical trials and initiation of the Phase 3 clinical trial in CIDP;
- the execution of two Phase 3 clinical trials in ITP;
- the execution of the Phase 2 clinical trial and initiation of the Phase 3 clinical trial in PV and PF;
- the execution of Phase 2 clinical trial in BP; and
- the execution of Phase 1 clinical trial in Myositis.

External research and development expenses for cusatuzumab totaled \$24.6 million for the year ended on December 31, 2021 compared to \$48.8 million for the year ended December 31, 2020. This decrease of \$24.2 million is the result of the termination of the collaboration agreement with Janssen.

External research and development expenses on other programs increased by \$18.6 million to \$47.2 million for the year ended December 31, 2021, compared to \$28.6 million for the year ended December 31, 2020. 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,	
	2021	2020	% Change
		(In thousands)	
Personnel expense	\$ 164,646	\$ 108,507	52 %
Professional fees	102,674	48,681	111 %
Supervisory board	12,958	4,838	168 %
Other expenses	27,366	9,617	185 %
Total	\$ 307,644	\$ 171,643	79 %

Our selling, general and administrative expenses totaled \$307.6 million and \$171.6 million for the years ended December 31, 2021 and 2020, respectively. The increase in our selling, general and administrative expenses for the year ended December 31, 2021 was principally due to an increase of personnel expense and professional 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 commercial launch of VYVGART™ in the U.S;
- increased professional fees, primarily in preparation of the commercial launch of VYVGART™ in the U.S; and
- Promotional and marketing cost associated with the commercial launch of VYVGART™, following the approval by FDA in the U.S.

We employed on average 264.4 full time equivalents in our selling, general and administrative functions in the year ended December 31, 2021, compared to 119.5 in the year ended December 31, 2020.

Financial Income (Expense)

For the year ended December 31, 2021, financial expense amounted to \$0.9 million compared to \$1.5 million for the year ended December 31, 2020. The decrease of \$0.6 million in 2021 related primarily to higher financial expenses incurred in 2020 as a result of a decrease in net asset value on 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 \$50.1 million for the year ended December 31, 2021, compared to exchange losses of \$126.2 million for the year ended December 31, 2020. The decrease was mainly attributable to unrealized exchange rate losses on the cash, cash equivalents and current financial assets position in Euro during the year ended December 31, 2021 as compared to unrealized exchange rate losses on the cash, cash equivalents and current financial assets position in USD during the year ended December 31, 2020.

B. LIQUIDITY AND CAPITAL RESOURCES

Sources of Funds

Since our inception in 2008, we have invested most of our resources in developing our product candidates, building our intellectual property portfolio, developing our supply chain, conducting business planning, raising capital and providing general and administrative support for these operations. We currently have only one approved product but have not generated any significant 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, 2021, we have raised gross proceeds of \$3,514.4 million from private and public offerings of equity securities and, received \$578.9 million in revenue from our collaborators.

Our cash flows may fluctuate and are difficult to forecast and will depend on many factors. On December 31, 2021, we had cash, cash equivalents and current financial assets of \$2,336.7 million, compared to \$1,996.5 million on December 31, 2020.

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, 2021 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, 2021 and which are incorporated herein by reference.

Cash Flows

Comparison for the Years Ended December 31, 2021 and 2020

The table below summarizes our cash flows for the years ended December 31, 2021 and 2020.

	Year ended December 31,		
	2021	2020	Variance
	(In thousands)		
Cash and cash equivalents at beginning of the period	\$ 1,216,803	\$ 372,162	\$ 844,641
Net cash flows (used in) / from operating activities	(606,812)	(398,463)	(208,349)
Net cash flows (used in) / from investing activities	(347,070)	344,692	(691,762)
Net cash flows (used in) / from financing activities	1,121,342	833,003	288,339
Effect of exchange rate differences on cash and cash equivalents	(49,587)	65,409	(114,996)
Cash and cash equivalents at end of the period	\$ 1,334,676	\$ 1,216,803	\$ 117,873

Net Cash Used in Operating Activities

Net cash outflow from our operating activities increased by \$208.3 million to a net outflow of \$606.8 million for the year ended December 31, 2021, compared to a net outflow of \$398.5 million for the year ended December 31, 2020. The net cash outflow from operating activities for the year ended December 31, 2021 resulted primarily from (i) the research and development expenses incurred in relation to the manufacturing and clinical development activities of efgartigimod and the advancement of other clinical, preclinical and discovery-stage product candidate, (ii) the personnel expenses and consulting expenses incurred in preparation of the commercial launch of efgartigimod in the U.S. and Japan, and (iii) the manufacturing of inventory ahead of the commercial launch of efgartigimod in the U.S. The net cash outflow of \$398.5 million for the year ended December 31, 2020 was primarily influenced by (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..

Net Cash Used in / from Investing Activities

Investing activities for the year ended December 31, 2021, consists primarily of the divestment of current financial assets and the purchase of intangible assets. Cash flow from investing activities represented a net outflow of \$347.1 million for the year ended December 31, 2021, compared to a net inflow of \$344.7 million for the year ended December 31, 2020. The net outflows for the year ended December 31, 2021 related primarily to (i) the net investment of \$228.2 million in current financial assets, including money market funds and term deposit accounts, compared to a net divestment of \$341.9 million for the year ended December 31, 2020 and (ii) the cash outflow of \$98.0 million during 2021 in relation to the purchase of a U.S. FDA Priority Review Voucher from Bayer Healthcare Pharmaceuticals.

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 \$1121.3 million for the year ended December 31, 2021, compared to a net cash inflow of \$833.0 million for the year ended December 31, 2020. The net cash inflows were attributed to (i) \$1,091.7 million net cash proceeds from our global offering in February 2021, compared to \$812.6 million net cash proceeds from our global offering and concurrent private placement in May 2020 and (ii) \$33.4 million proceeds received from the exercise of stock options in 2021, compared to \$22.9 million for the year ended 2020.

Operating and Capital Expenditure Requirements

We have never achieved profitability and, as of December 31, 2021, we had accumulated losses of \$1,400.2 million. We expect to continue to incur significant operating losses for the foreseeable future as we continue our research and development efforts, incur higher costs for commercialization of efgartigimod in the U.S. and Japan, and seek to obtain regulatory approval and commercialization of our product candidates in Europe.

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 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 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 commercialization of VYVGART™ or potential commercialization of any 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 commercialization of VYVGART™ or potential commercialization of any 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, 2021 to December 31, 2021 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.”

Following the approval of VYVGART™ for the treatment of gMG in the U.S. by the FDA on December 17, 2021, we transitioned from a clinical-stage to a commercial-stage biotechnology company and are working on the ongoing launch of the commercialization of VYVGART™.

There has been no significant change in the financial performance or the financial position of the Group since the balance sheet date of December 31, 2021 up to the date of this Annual Report.

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, 2021

Lease obligations

	Payments due by period				
	Total	Less than 1 year	1–3 years (In thousands)	3–5 years	More than 5 years
Lease liabilities	\$ 12,004	\$ 3,509	\$ 6,331	\$ 2,164	\$ —
Lease commitments not commenced	\$ 19,155	\$ —	\$ —	\$ 1,437	\$ 17,718

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, Plants and Equipment.”

In January 2021, we 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 \$1.9 million, which would be operational in the second quarter of 2025, 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, 2021 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 executive and non-executive directors, and a senior management team responsible for the day-to-day operations. We have opted for this structure to allow for a division of responsibilities between our Board of Directors and our senior management team, keeping our Board of Directors at a manageable size whilst being able to involve some or all members of our senior management team in discussions of the Board of Directors if and when necessary.

In practice, all members of our senior management team are regularly involved in the discussions of our Board of Directors and its committees, in order to provide information and context to the various issues the board needs to decide on. In addition to being present at meetings from time to time, regular contact (face to face or via electronic means) is kept between the members of the Board of Directors and its committees and the members of the senior management team as well as other senior leaders in the organization.

Our board of directors is currently comprised of one executive director and seven non-executive directors, each of whom 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, 2021:

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	63	Non-Executive Director (chairperson)	BE	May 8, 2018	2022
Werner Lanthaler	53	Non-Executive Director (vice chairperson)	AT	May 8, 2018	2022
J. Donald deBethizy	71	Non-Executive Director	US	May 7, 2019	2023
Pamela Klein	60	Non-Executive Director	US	May 12, 2020	2024
A.A. Rosenberg	68	Non-Executive Director	UK	May 11, 2021	2025
James M. Daly	60	Non-Executive Director	US	May 8, 2018	2022
Yvonne Greenstreet	58	Non-Executive Director	UK	May 11, 2021	2025

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

Tim Van Hauwermeiren, Peter K.M. Verhaeghe, Werner Lanthaler and James M. Daly are expected to be nominated for re-appointment at the General Meeting to be held in 2022.

Our board of directors has determined that all of the non-executive members of the board of directors are independent under 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. Tim Van Hauwermeiren serves on the board of directors of iTeos Pharmaceuticals and Aelin Therapeutics where he is chairman. Mr. Van Hauwermeiren currently holds the positions set out in the table "Our Senior Management" below.

Peter K. M. Verhaeghe has served as a member and chairperson of the 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, U.S. 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 on 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 (J.D.) from the University of Leuven and an LL.M degree from Harvard Law School.

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 SE, a global drug discovery and development organization, a position he has

held since March 2009. He also serves on the supervisory Board of AC Immune SA (Switzerland). 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 and Innovent LLC, board and CEO coaching consultancies. 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., LigoCyte Pharmaceuticals 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. He has been a Diplomate of the American Board of Toxicology.

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 several board of director's including F-Star Therapeutics, Jiya Acquisition Corps, I-Mab and Patry's; as well as various scientific advisor boards. Previously, Dr. Klein spent seven years at the National Cancer Institute as Research Director of the NCI-Navy Breast Center, after which she joined Genentech and was VP, Development until 2001. She served as Chief Medical Officer for Intellikine which was acquired by Takeda. She was previously Vice President, Development for Genentech. Dr. Klein holds a Bachelor's degree in biology from California State University and an M.D. from Stritch School of Medicine, Loyola University Chicago and is trained in internal medicine and medical oncology.

Msc. A.A. Rosenberg has served as a member of our Board of Directors since April 2017. He currently serves as CEO of TR Advisory Services GmbH, his own consultancy firm advising on business development, licensing and mergers and acquisitions. 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. Mr. Daly currently serves as a director of Acadia Pharmaceuticals Inc., Halozyme Therapeutics, Inc., Bellicum Pharmaceuticals, Inc. and Madrigal Pharmaceuticals, all Nasdaq-listed companies. Mr. Daly holds a Bachelor in Science and a Master in Business Administration from the University at Buffalo, State University of New York.

Dr. Yvonne Greenstreet has served as a member of our Board of Directors since May 2021. She was appointed Chief Executive Officer of Alnylam Pharmaceuticals effective January 1, 2022 and before was serving as is President and Chief Operating Officer at Alnylam Pharmaceuticals. Dr. Greenstreet has more than 25 years of

experience in the Biopharmaceutical industry, driving strategy and innovation, bringing transformative medicines to patients and building successful businesses in the U.S., Europe and globally. Dr. Greenstreet serves on the board of directors of Pacira Pharmaceuticals, American Funds, the Scientific Advisory Committee of the Bill and Melinda Gates Foundation and is a member of the Discovery Council of Harvard Medical School. Between 2011 and 2013, Dr. Greenstreet was Senior Vice President and Head of Medicines Development at Pfizer serving on the executive team leading a rapidly growing \$16 billion division. Prior to Pfizer, she was at GlaxoSmithKline plc for 18 years, where she was Senior Vice President and Chief of Strategy for Research and Development. Dr. Greenstreet had previously been in various positions of increasing responsibility at GSK, including Senior Vice President for Medicines Development and Chief Medical Officer for Europe. Dr. Greenstreet is trained as a physician and earned her medical degree from Leeds University in the United Kingdom and her MBA degree from INSEAD, France. On March 3, 2022, Dr. Greenstreet stepped down from her position as member of our Board of Directors due to time constraints following her appointment as Chief Executive Officer at Alnylam.

Our Senior Management

The following table sets forth certain information with respect to the current members of our senior management, including their ages as of December 31, 2021:

Name	Age	Position	Nationality	Date of appointment
Tim Van Hauwermeiren	49	Chief Executive Officer and Executive Director	Belgium	July 15, 2008
Karl Gubitz	52	Chief Financial Officer	Germany	June 1, 2021
Keith Woods	54	Chief Operating Officer	US	April 5, 2018
Hans de Haard	62	Chief Scientific Officer	The Netherlands	July 1, 2008
Wim Parys	62	Chief Medical Officer	Belgium	July 1, 2019
Arjen Lemmen	37	Vice President Corporate Development & Strategy	The Netherlands	May 1, 2016
Dirk Beeusaert	57	General Counsel	Belgium	April 1, 2017
Malini Moorthy	52	General Counsel	Canada	February 14, 2022
Andria Wilk	49	Global Head of Quality	UK	January 13, 2020

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

The following is a brief summary of the biographical information of those members of our senior management who do not also serve on our board of directors:

Karl Gubitz has served as Chief Financial Officer in June 2021. Mr. Gubitz worked at Pfizer for nearly 20 years, most recently as vice president of finance within the global oncology business. During his tenure at Pfizer, he successfully negotiated the commercialization model for tanezumab with Eli Lilly in all non-U.S. markets as well as the Myovant co-commercialization agreement for Orgovyx™. Within Pfizer, Mr. Gubitz held country, regional, and global positions, and consistently delivered top-line growth. He managed teams of over 250 colleagues in financial leadership roles within the global internal medicine and global innovative products businesses. Prior to joining Pfizer in 2003, Mr. Gubitz held various management roles at PricewaterhouseCoopers. He holds an M.B.A. from Henley Management College in the United Kingdom, Bachelor's degree in computing from the University of South Africa, and Bachelor of commerce from the University of Pretoria.

Keith Woods has served as our Chief Operating Officer since April 2018. Mr. Woods has over 30 years of experience in the biopharmaceutical industry. He most recently served as senior vice president of North American operations for Alexion Pharmaceuticals Inc., 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 UK 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.

Prof. Hans de Haard is a co-founder of argenx and 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.

Wim Parys joined argenx as Chief Medical Officer in 2019. He has over 25 years of experience leading successful clinical programs in biopharma, including the development and regulatory submission of seven now-approved drugs. Prior to argenx, Mr. Parys was the R&D head of the newly established Global Public Health group at Janssen (Johnson & Johnson) responsible for a portfolio including programs in HIV (developing first long-acting therapy), TB, dengue fever and malaria. Before this, Mr. Parys was the head of development of the infectious disease therapeutic area of Janssen and Tibotec where he developed and launched innovative drugs for HIV (Prezista™, Intelence™ and Edurant™), Hepatitis C (Incivo™, Olysio™/Sovriad™), and TB (Sirturo™). Mr. Parys started his career within the Johnson & Johnson organization at the Janssen Research Foundation in Belgium where he led the R&D team developing galantamine (Reminyl™/Razadyne™) for Alzheimer's disease. Mr. Parys obtained his medical degree from the Katholieke Universiteit in Leuven, Belgium and worked in private practice for nine years prior to joining industry. Mr. Parys will retire with effect from March 31, 2022 and will be succeeded by Luc Truyen as of April 1, 2022.

Luc Truyen joined argenx at the end of September 2021. Prior to this, Dr. Truyen was with Johnson & Johnson for over 20 years holding various leadership positions, primarily within neuroscience. In his most recent position prior to joining argenx, Dr. Truyen was global head of development and external affairs – neuroscience for neuroscience managing strategy and delivery of the early and late portfolio of assets for mood disorders and schizophrenia, and neurodegenerative and neuroinflammatory disorders. Besides Dr. Truyen's strong track record in clinical development resulting in several global innovative drug approvals, his broad-based experience also includes leading global clinical development operations for the whole Johnson & Johnson pharmaceutical group as well as serving as head of R&D and chief medical officer of Janssen Alzheimer Immunotherapy, an internal spin-out from Johnson & Johnson. Dr. Truyen holds an M.D. and Ph.D. in Neurology from the University of Antwerp. Luc Truyen will succeed Wim Parys with effect as of April 1, 2022 as a member of our senior management team.

Arjen Lemmen joined argenx in 2016 and serves as Vice President of Corporate Development & Strategy at argenx since 2019. He has successfully executed several transactions including a number of programs within the Immunology Innovation Program and the strategic collaboration with Janssen for cusatuzumab. Prior to joining argenx, Mr. Lemmen 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. He holds a B.Sc. in Life Science & Technology from the University of Groningen and a Master of Engineering Management from Duke University.

Dirk Beeusaert has served as General Counsel of argenx since 2017. He has 20 years of 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 on the boards of Cubigo NV and The Fourth Law NV. Dirk holds a Bachelor of Law, Master of Law from Ghent University and a Master in tax legislation and accountancy from Vlerick Leuven-Gent Management School. Mr. Beeusaert has retired per December 31, 2021 and has since been succeeded by Malini Moorthy as from February 14, 2022.

Malini Moorthy joined argenx as General Counsel in 2022. She has over 25 years of legal experience with extensive experience in the biopharmaceutical and medical device sectors, including as senior vice president & chief deputy general counsel, legal, compliance & government affairs at Medtronic, vice president & associate general counsel, head of global litigation & investigations at Bayer Corporation, vice president & assistant general counsel, head of civil litigation at Pfizer Inc. Malini Moorthy began her career as a law firm associate, first with McCarthy Tétrault and Genest Murray Desbrisay Lamek in Toronto, Canada and then Salans (now Dentons) in New York City.

She holds a Bachelor of Arts in political science and economics from the University of North Carolina at Chapel Hill and a Bachelor of Laws from the Faculty of Law at Queen's University in Canada.

Andria Wilk joined argenx as Global Head of Quality in 2020. Ms. Wilk has more than 20 years of experience in quality assurance (**QA**) within the pharmaceutical industry. Most recently, Ms. 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, U.S. and Asia. In this role, she was responsible for the global audit programs 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. Ms. 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 Senior Management

As of the date of this Annual Report, none of the members of our board of directors and senior management has a family relationship with any other member of our board of directors or senior 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 senior 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, liquidation or of such company being put into administration;
- 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 Senior 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 May 11, 2021, the shareholders approved an amendment to the Remuneration Policy, discussed in more detail below. For a discussion of our employment arrangements with our senior management, see the section of this Annual Report titled "Item 7.B.—Related Party Transactions—Agreements with Our Senior Management."

Except for the arrangements described in the section of this Annual Report titled "Related-Party Transactions—Agreements with Our Senior 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 Senior Management

The remuneration of our senior management (including our executive director, Mr. Tim Van Hauwermeiren) 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 and restricted stock units;
- severance arrangements; and
- pension and fringe benefits.

Fixed base compensation. The base compensation of our senior management is determined on the basis of a benchmarking analysis completed by an independent consulting firm. The fixed cash compensation levels are set at or around the 50th percentile of U.S. companies in our reference group for U.S. based executives, and at or around the 75th percentile of EU companies in our reference group for EU based executives. The final determination of an executive director's fixed pay is made considering this benchmark, the individual's skills, experience and performance, the remuneration practices and conditions across the wider organization and our interactions with key stakeholders to secure broad public support for our remuneration practices.

Short-term variable compensation. The objective of our short-term annual incentive compensation is to ensure that our senior management team is incentivized to achieve performance targets in the shorter term. Variable cash incentives are granted for achieving predetermined specific performance targets. At the start of each financial year, the Board of Directors will determine our key priorities and will set specific, challenging performance targets in line with these priorities. The Board of Directors will determine the relative weight of each target and the metrics used for measuring their achievement. Our senior management team is eligible for an annual short-term variable incentive of their annual base compensation. The target percentage for this purpose was set to 55% of the annual base compensation of a member of the senior management team except for our executive director. The target variable cash incentive for our executive director shall be 60% of the fixed cash compensation if 100% of targets are achieved. In case of significant overachievement, the Board of Directors may decide to award higher variable pay to fairly reflect the individual's value contribution to argenx, but the variable pay will not exceed 120% of the fixed cash compensation.

Financial performance targets relate to building the business and typically make up 60% of the overall variable cash incentive targets and are aimed at significantly progressing our product candidates towards market approval and ultimately to the generation of sales and revenues to further enhance shareholder value and enable and support our further research and development activities.

Non-financial targets relate to building the organization and typically make up 40% of overall targets and are aimed at building and developing our organization into a sustainable, commercial stage, fully integrated global biopharmaceutical company in line with our identity and our core values.

Long-term incentive awards. Our Board of Directors intends to incentivize our senior management team by issuing stock options and/or restricted stock units from time to time to be able to attract and retain well-qualified senior management in connection with the Equity Incentive Plan, as set out below. Typically, stock options and restricted stock units are granted annually in accordance with our equity incentive grant allocation 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 senior management team, 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 Senior Management".

Pension and fringe benefits. Our senior management team participates in a defined contribution pension scheme operated by a third-party pension insurance organization. Our senior management team 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, 2021:

Tim Van Hauwermeiren

	Compensation (\$)
Base salary	651,986
Option awards (1)	3,895,370
Restricted Stock Units	2,084,509
Employer social security contribution stock options (2)	—
Non-equity incentive plan compensation	586,787
Pension contributions	26,894
Social security costs	3,456
Other (3)	14,827
TOTAL	7,263,828

- (1) Amount shown represents the expenses with respect to the option awards granted in 2021 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) argenx incurs employer social security costs with respect to the option awards granted to the members of our senior 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, argenx makes a calculation of the exposure.
- (3) Consists of \$14,626 attributable to the lease of a company car and \$201 in employer-paid medical insurance premiums.

The following table sets forth information regarding aggregate compensation paid by us for the members of our senior management (excluding Tim Van Hauwermeiren) during the year ended December 31, 2021:

	Compensation (\$)
Base salary	2,812,668
Option awards (1)	11,165,679
Restricted Stock Units	5,940,183
Employer social security contribution stock options (2)	4,171,822
Non-equity incentive plan compensation	1,433,378
Termination benefits	381,522
Pension contributions	123,002
Social security costs	785,489
Other (3)	258,950
TOTAL	27,072,693

- (1) Amount shown represents the expenses with respect to the option awards granted in 2021 to Mr. Karl Gubitz, Mr. Keith Woods, Prof. Hans de Haard, Mr. Arjen Lemmen and Miss. Andria Wilk 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 elsewhere in this Annual Report. These amounts do not reflect the actual economic value realized by these members of our senior management.
- (2) The Company incurs employer social security costs with respect to the option awards granted to the members of our senior 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 \$78,181 attributable to the leases of company cars, \$136,893 in car, housing and other allowances and \$43,876 in employer-paid medical insurance premiums.

The following table sets forth information regarding option awards granted to our senior management during the year ended December 31, 2021:

Name	Stock options	Expiration date	Exercise price
Tim Van Hauwermeiren (1)	25,000	24/12/2031	\$ 350.20
Karl Gubitz	24,000	01/07/2031	\$ 288.93
Hans de Haard (1)	16,000	24/12/2031	\$ 350.20
Keith Woods	16,000	24/12/2031	\$ 350.20
Dirk Beeusaert	—	—	\$ —
Wim Parys	—	—	\$ —
Arjen Lemmen (1)	16,000	24/12/2031	\$ 350.20
Andria Wilk (1)	4,446	24/12/2031	\$ 350.20

(1) On December 24, 2021, 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 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.

Following our annual remuneration and benchmarking exercise the base amount of equity for the CEO was adjusted downward (from the approved remuneration policy 2021) to 32,000 stock options and 7,200 restricted stock units. The Remuneration and Nomination Committee discussed a recommendation of 130% of this base amount based on performance (being 41,600 stock options and 9,360 restricted stock units). However, following consultation of the CEO in line with best practice principle 3.2.2. of the Dutch Corporate Governance Code, at the request of the CEO, the Board of Directors agreed to grant only 25,000 stock options and 5,700 restricted stock units to the CEO and to recommend placing the difference (being 16,600 stock options and 3,660 restricted stock units) at the disposition of the CEO for distribution to key individuals in the April 1, 2022 equity grant.

The table below shows the stock options held at the start of the year ended December 31, 2021 and the stock options granted to our senior management which have vested during the year ended December 31, 2021, as well as the stock options scheduled to vest in the years ending December 31, 2022, December 31, 2023 and

December 31, 2024 (in number of stock options and restricted stock units), and the respective exercise price of such stock options:

Name	Total options held on January 1, 2021	Options granted in 2021	Options forfeited in 2021	Options exercised in 2021	Total options held on December 31, 2021	Exercise price	Options vested through 2020	Options vested in 2021	Options to vest in 2022	Options to vest in 2023	Options to vest in 2024
Tim Van Hauwermeiren	290,000	25,000	—	—	315,000	\$ 23.98	80,000				
						\$ 97.77	53,333	26,667			
						\$ 153.75	26,667	26,666	26,667		
						\$ 280.43		16,667	16,666	16,667	
						\$ 350.20			8,333	8,334	8,333
Total	290,000	25,000	—	—	315,000		160,000	70,000	51,666	25,001	8,333
Eric Castaldi (1)	171,400	—	—	(46,400)	125,000	\$ 23.98	25,000				
						\$ 97.77	50,000				
						\$ 153.75	50,000				
Total	171,400	—	—	(46,400)	125,000		125,000	—	—	—	—
Keith Woods	155,000	16,000	—	(30,000)	141,000	\$ 97.77	8,333	16,667			
						\$ 153.75	16,667	16,666	16,667		
						\$ 280.43		16,667	16,666	16,667	
						350.20			5,333	5,334	5,333
Total	155,000	16,000	—	(30,000)	141,000		25,000	50,000	38,666	22,001	5,333
Hans De Haard	545,975	16,000	—	—	561,975	\$ 2.76	144,822				
						\$ 8.12	109,000				
						\$ 10.72	28,200				
						\$ 12.99	28,200				
						\$ 16.01	28,200				
						\$ 20.85	14,353				
						\$ 23.98	43,200				
						\$ 97.77	33,333	16,667			
						\$ 153.75	16,666	16,668	16,666		
						\$ 280.43		16,667	16,666	16,667	
						350.20			5,333	5,334	5,333
Total	545,975	16,000	—	—	561,975		445,974	50,002	38,665	22,001	5,333
Wim Parys	225,000	—	—	—	225,000	\$ 97.77	83,333	41,667			
						\$ 153.75	16,667	16,666	16,667		
						\$ 280.43		16,667	16,666	16,667	
Total	225,000	—	—	—	225,000		100,000	75,000	33,333	16,667	—
Arjen Lemmen	136,211	16,000	—	(6,430)	145,781	\$ 20.85	4,306				
						\$ 23.98	6,328				
						\$ 91.54	2,361	834			
						\$ 97.77	8,452	7,500			
						\$ 153.75	24,963	12,519	12,518		
						\$ 280.43		16,667	16,666	16,667	
						\$ 350.20			5,333	5,334	5,333
Total	136,211	16,000	—	(6,430)	145,781		46,410	37,520	34,517	22,001	5,333
Dirk Beusaert (2)	204,682	—	—	(54,682)	150,000	\$ 91.54	23,500	4,700			
						\$ 97.77	14,533	7,267			
						\$ 128.53	30,757	19,243			
						\$ 222.16	12,756	37,244			
Total	204,682	—	—	(54,682)	150,000		81,546	68,454	—	—	—
Andria Wilk	19,300	4,446	—	—	23,746	\$ 153.75	4,693	2,353	2,354		
						\$ 280.43		4,575	2,663	2,662	
						\$ 350.20			1,482	1,482	1,482
Total	19,300	4,446	—	—	23,746		4,693	6,928	6,499	4,144	1,482
Karl Gubitz	—	24,000	—	—	24,000	\$ 288.93			11,333	8,000	4,667
Total	—	24,000	—	—	24,000		—	—	11,333	8,000	4,667

(1) Eric Castaldi resigned from his position as chief financial officer on our senior management in June 2021 and was succeeded by Karl Gubitz.

(2) Dirk Beusaert retired effective December 31, 2021 and was succeeded by Malini Moorthy effective February 14, 2022.

The table below shows the restricted stock units held at the start of the year ended December 31, 2021 and the restricted stock units granted to our senior management which have vested during the year ended December 31, 2021, as well as the restricted stock units scheduled to vest in the years ending December 31, 2022, December 31, 2023, December 31, 2024 and December 31, 2025:

Name	Total RSUs held on January 1, 2021	RSUs granted in 2021	RSUs forfeited in 2021	RSUs exercised in 2021	Total RSUs held on December 31, 2021	RSUs vested through 2021	RSUs to vest in 2022	RSUs to vest in 2023	RSUs to vest in 2024	RSUs to vest in 2025
Tim Van Hauwermeiren	—	5,700	—	—	5,700	—	1,425	1,425	1,425	1,425
Total	—	5,700	—	—	5,700	—	1,425	1,425	1,425	1,425
Keith Woods	—	3,600	—	—	3,600	—	900	900	900	900
Total	—	3,600	—	—	3,600	—	900	900	900	900
Hans De Haard	—	3,600	—	—	3,600	—	900	900	900	900
Total	—	3,600	—	—	3,600	—	900	900	900	900
Arjen Lemmen	—	3,600	—	—	3,600	—	900	900	900	900
Total	—	3,600	—	—	3,600	—	900	900	900	900
Andria Wilk	—	988	—	—	988	—	247	247	247	247
Total	—	988	—	—	988	—	247	247	247	247
Karl Gubitz	—	5,400	—	—	5,400	—	1,350	1,350	1,350	1,350
Total	—	5,400	—	—	5,400	—	1,350	1,350	1,350	1,350

The table below shows the remaining term of the stock options and restricted stock units held by our senior management during the year ended December 31, 2021.

Name	Number of stock options	Remaining term on December 31, 2021 (rounded up)	Number of restricted stock units (4)
Tim Van Hauwermeiren	80,000	6 years	5,700
	80,000	7 years	
	80,000	8 years	
	50,000	9 years	
	25,000	5 years / 10 years (1)	
Eric Castaldi (2)	17,360	2 years	
	18,120	3 years	
	25,000	6 years	
	32,640	7 years	
	31,880	8 years	
Keith Woods	25,000	7 years	3,600
	50,000	8 years	
	50,000	9 years	
	16,000	10 years	
Hans De Haard	108,996	0,5 years	3,600
	35,826	3 years	
	109,000	3 years	
	28,200	4 years	
	28,200	4,5 years	
	28,200	5 years	
	14,353	5,5 years	
	43,200	6 years	
	50,000	7 years	
	50,000	8 years	
	50,000	9 years	
	16,000	5 years / 10 years (1)	
Wim Parys	125,000	2 years	
	50,000	4 years	
	50,000	8 years	
Arjen Lemmen	2,500	1,5 years	3,600
	50,000	3 years	
	4,306	5,5 years	
	6,328	6 years	
	695	6,5 years	
	15,952	7 years	
	50,000	9 years	
	16,000	5 years / 10 years (1)	
Dirk Beeusaert (3)	28,200	1,5 years	
	21,800	2 years	
	50,000	2,5 years	
	50,000	3,5 years	
Andria Wilk	9,400	3 years	988
	9,900	4 years	
	4,446	5 years / 10 years (1)	
Karl Gubitza	24,000	10 years	5,400

- (1) On December 24, 2021, 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.

- (2) Eric Castaldi resigned from his position as chief financial officer on our senior management in June 2021 and was succeeded by Karl Gubitz.
- (3) Dirk Beeusaert retired effective December 31, 2021 and was succeeded by Malini Moorthy effective February 14, 2022.
- (4) In accordance with the equity plan, RSUs, once vested, will be settled against the issuance of ordinary shares in argenx SE. Such shares have no expiry date and may be held by the participant without limitation.

The table below shows the stock options exercised by our senior management during the year ended December 31, 2021 and the exercise price of those stock options. Per exercised option, one share was issued.

Name	Number of stock options	Exercise price
Eric Castaldi (1)	28,200	\$ 16.01
Eric Castaldi (1)	18,200	\$ 23.98
Keith Woods	5,000	\$ 23.98
Keith Woods	25,000	\$ 97.77
Arjen Lemmen	3,215	\$ 12.99
Arjen Lemmen	3,215	\$ 16.01
Dirk Beeusaert (2)	39,682	\$ 20.85
Dirk Beeusaert (2)	15,000	\$ 23.98
Total	137,512	

- (1) Eric Castaldi resigned from his position as chief financial officer on our senior management in June 2021 and was succeeded by Karl Gubitz.
- (2) Dirk Beeusaert retired effective December 31, 2021 and was succeeded by Malini Moorthy effective February 14, 2022.

Compensation of Our Non-Executive Directors

The remuneration of the individual members of the Board of Directors is determined by the Board of 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 remuneration policy approved by our General Meeting held on May 11, 2021.

Pursuant to the Remuneration Policy, the remuneration of the non-executive directors consists of the following fixed and variable components:

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

Fixed fee. The Board of Directors has set the annual base remuneration, the annual remuneration for members of the audit and compliance committee, the research and development committee, the remuneration and nomination committee and the commercial committee and, in each case, the additional remuneration for the respective chairperson as follows:

Name	Position	Fees in USD	Fees in EUR
Board of Directors	Chairperson	76,878	65,000
	Member	41,396	35,000
Audit & Compliance committee/R&D committee	Chairperson	17,741	15,000
	Member	8,871	7,500
Remuneration & Nomination committee/Commercial committee	Chairperson	11,827	10,000
	Member	5,913	5,000

Long-term incentive plan. The Board of Directors intends to incentivize the non-executive directors by issuing stock options and/or restricted stock units from time to time to be able to attract and retain well-qualified non-executive directors in connection with the Equity Incentive Plan. The Board of Directors grants stock options and restricted stock units to the non-executive directors on the recommendation of the remuneration and nomination committee. Such stock option and restricted stock unit grants are based on an equity incentive grant allocation scheme established by the Board of Directors pursuant to the Option Plan. The conditions of our Equity Incentive Plan apply to our non-executive directors, as set forth below in “Equity Incentive 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, 2021:

Name	Fees earned or paid in cash (\$)	Option awards \$(1)	RSU awards \$(2)	Total
Peter K.M. Verhaeghe	91,662	392,743	210,120	\$ 694,526
David L. Lacey	19,712	392,743	210,120	622,576
Werner Lanthaler	65,051	392,743	210,120	667,914
Pamela Klein	50,266	392,743	210,120	653,130
J. Donald deBethizy	62,094	392,743	210,120	664,957
A.A. Rosenberg	56,180	392,743	210,120	659,044
James M. Daly	59,137	392,743	210,120	662,000
Yvonne Greenstreet	30,459	514,154	260,034	804,647

(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 2021 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 “Share-based payments” to our consolidated financial statements for the year ended December 31, 2021, included elsewhere in this Annual Report.

(2) These amounts do not reflect the actual economic value realized by the non-executive director. Amount shown represents the expenses with respect to the RSU awards granted in 2021 to the non-executive directors. For a description of the assumptions used in valuing these awards, see note 14 “Share-based payments” to our consolidated financial statements for the year ended December 31, 2021, included elsewhere in this annual report.

The table below shows the stock options held at the start of the year ended December 31, 2021 and the stock options granted to the non-executive directors which have vested during the year ended December 31, 2021,

as well as the stock options scheduled to vest in the years ending December 31, 2022, December 31, 2023 and December 31, 2024 (in number of stock options), and the respective exercise price of such stock options:

Name	Total options held on January 1, 2021	Options granted in 2021	Options exercised in 2021	Total options held on December 31, 2021	Exercise price	Options vested through 2020	Options vested in 2021	Options to vest in 2022	Options to vest in 2023	Options to vest in 2024
Peter Verhaeghe	58,595	2,700	—	61,295	\$ 2.76	11,626				
					\$ 4.47	1,969				
					\$ 8.12	5,000				
					\$ 12.89	10,000				
					\$ 97.77	6,667	3,333			
					\$ 153.75	3,333		3,333		
					\$ 280.43		3,333	3,334	3,333	
					\$ 350.20					2,700
Total	58,595	2,700	—	61,295		38,595	10,000	6,667	3,333	2,700
David L. Lacey	67,800	2,700	(5,000)	65,500	\$ 8.12	7,800				
					\$ 12.89	10,000				
					\$ 23.98	15,000				
					\$ 97.77	6,667	3,333			
					\$ 153.75	3,333		3,333		
					\$ 280.43		3,333	3,334	3,333	
					\$ 350.20					2,700
Total	67,800	2,700	(5,000)	65,500		42,800	10,000	6,667	3,333	2,700
Werner Lanthaler	30,000	2,700	(4,420)	28,280	\$ 97.77	6,667	3,333			
					\$ 153.75	2,247	3,333			
					\$ 280.43		3,333	3,334	3,333	
					\$ 350.20					2,700
Total	30,000	2,700	(4,420)	28,280		8,914	9,999	3,334	3,333	2,700
J. Donald deBethizy	47,500	2,700	(7,500)	42,700	\$ 12.89	10,000				
					\$ 97.77	6,667	3,333			
					\$ 153.75	3,333	3,334	3,333		
					\$ 280.43		3,333	3,334	3,333	
					\$ 350.20					2,700
Total	47,500	2,700	(7,500)	42,700		20,000	10,000	6,667	3,333	2,700
Pamela Klein	50,000	2,700	(7,500)	45,200	\$ 12.96	2,500				
					\$ 12.89	10,000				
					\$ 97.77	6,667	3,333			
					\$ 153.75	3,333		3,333		
					\$ 280.43		3,333	3,334	3,333	
					\$ 350.20					2,700
Total	50,000	2,700	(7,500)	45,200		22,500	10,000	6,667	3,333	2,700
A.A. Rosenberg	45,000	2,700	(1,160)	46,540	\$ 16.00	15,000				
					\$ 97.77	6,667	3,333			
					\$ 153.75	2,173		3,333		
					\$ 280.43		3,333	3,334	3,333	
					\$ 350.20					2,700
Total	45,000	2,700	(1,160)	46,540		23,840	10,000	6,667	3,333	2,700
James M. Daly	35,000	2,700		37,700	\$ 90.97	2,500	2,500			
					\$ 97.77	6,667	3,333			
					\$ 153.75	3,333		3,333		
					\$ 280.43		3,333	3,334	3,333	
					\$ 350.20					2,700
Total	35,000	2,700	—	37,700		12,500	12,500	6,667	3,333	2,700
Yvonne Greenstreet	—	4,050	—	4,050	\$ 288.93			1,350	1,350	1,350
Total	—	4,050	—	4,050		—	—	1,350	1,350	1,350

The table below shows the restricted stock units held at the start of the year ended December 31, 2021 and the restricted stock units granted to the non-executive directors which have vested during the year ended December 31, 2021, as well as the restricted stock units scheduled to vest in the years ending December 31, 2022, December 31, 2023, December 31, 2024 and December 31, 2025:

Name	Total RSUs held on January 1, 2021	RSUs granted in 2021	RSUs forfeited in 2021	RSUs exercised in 2021	Total RSUs held on December 31, 2021	RSUs vested until 2021	RSUs vested in 2022	RSUs to vest in 2023	RSUs to vest in 2024	RSUs to vest in 2025
Peter Verhaeghe	—	600	—	—	600	—	150	150	150	150
Total	—	600	—	—	600	—	150	150	150	150
David L. Lacey	—	600	—	—	600	—	150	150	150	150
Total	—	600	—	—	600	—	150	150	150	150
Werner Lanthaler	—	600	—	—	600	—	150	150	150	150
Total	—	600	—	—	600	—	150	150	150	150
J. Donald deBethizy	—	600	—	—	600	—	150	150	150	150
Total	—	600	—	—	600	—	150	150	150	150
Pamela Klein	—	600	—	—	600	—	150	150	150	150
Total	—	600	—	—	600	—	150	150	150	150
A.A. Rosenberg	—	600	—	—	600	—	150	150	150	150
Total	—	600	—	—	600	—	150	150	150	150
James M. Daly	—	600	—	—	600	—	150	150	150	150
Total	—	600	—	—	600	—	150	150	150	150
Yvonne Greenstreet	—	900	—	—	900	—	225	225	225	225
Total	—	900	—	—	900	—	225	225	225	225

The table below shows the remaining term of the stock options held by the non-executive directors during the year ended December 31, 2021.

Name	Number of stock options	Remaining term on December 31, 2021 (rounded up)	Number of restricted stock units (1)
Peter K.M. Verhaeghe	8,741	0,5 years	
	4,854	3 years	
	5,000	3 years	
	10,000	4,5 years	
	10,000	7 years	
	10,000	8 years	
	10,000	9 years	
	2,700	10 years	600
David L. Lacey	7,800	3 years	
	10,000	4,5 years	
	15,000	6 years	
	10,000	7 years	
	10,000	8 years	
	10,000	9 years	
	2,700	10 years	600
Werner Lanthaler	10,000	2 years	
	5,580	8 years	
	10,000	9 years	
	2,700	10 years	600
J. Donald deBethizy	10,000	4,5 years	
	10,000	7 years	
	10,000	8 years	
	10,000	9 years	
	2,700	10 years	600
Pamela Klein	2,500	3,5 years	
	10,000	4,5 years	
	10,000	7 years	
	10,000	8 years	
	10,000	9 years	
	2,700	10 years	600
A.A. Rosenberg	15,000	5 years	
	10,000	7 years	
	8,840	8 years	
	10,000	9 years	
	2,700	10 years	600
James M. Daly	5,000	6,5 years	
	10,000	7 years	
	10,000	8 years	
	10,000	9 years	
	2,700	10 years	600
Yvonne Greenstreet	4,050	10 years	900

- (1) In accordance with the equity plan, RSUs, once vested, will be settled against the issuance of ordinary shares in argenx SE. Such shares have no expiry date and may be held by the participant without limitation.

The table below shows the stock options exercised by our non-executive directors during the year ended December 31, 2021 and the exercise price of those stock options. Per exercised option, one share was issued.

Name	Number of stock options	Exercise price
David Lacey	5,000	\$ 8.12
Don deBethizy	7,500	\$ 12.96
Tony Rosenberg	1,160	\$ 153.75
Pam Klein	7,500	\$ 12.96
Werner Lanthaler	4,420	\$ 153.75
Total	25,580	

Equity Incentive Plan

Our current equity incentive plan providing for the granting of a mix of stock options and restricted stock units was approved by our Board of Directors on March 15, 2021 and subsequently amended on December 15, 2021 (the **Equity Incentive Plan**). The aim of the Equity Incentive Plan is to encourage our senior management, directors and key outside consultants and advisors to acquire an economic and beneficial ownership interest in the growth and performance of argenx, to increase their incentive to contribute to our value and to attract and retain individuals who are key to the Company.

In connection with the Equity Incentive Plan, our Board of Directors has also established an equity incentive allocation scheme. The equity incentive allocation scheme contains (i) the date on which stock options and restricted stock units are granted each year, which shall be the same date each year and (ii) the number of stock options and restricted stock units granted to each person or to each group of persons, which shall be based on objective criteria only. Starting January 1, 2023, the regular annual grant of equity incentives to existing employees will be once a year in July for all participants of the Equity Incentive Plan.

Our Board of Directors, in each case subject to the approval of the majority of the non-executive directors, may grant stock options and restricted stock units to our senior management, directors or key outside consultants or advisors and in accordance with the equity incentive allocation scheme. Our Board of Directors may also grant stock options and restricted stock units at its discretion outside of the equity incentive allocation scheme, but only in a period when no inside information (as specified in our insider trading policy) is available. Persons to whom equity incentives are granted cannot refuse to accept such equity incentives.

The aggregate number of shares that may be available for the issuance of stock options and restricted stock units is based between the 50th and the 75th percentile of our reference group.

Stock options granted pursuant to the Equity Incentive 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 stock option fully vesting upon the third anniversary of the date of grant, subject, in each case, to the optionee's continued status. Stock options are exercisable when vested, and in any case not after the stock option expiration date included in each individual stock option grant, which is (at the election of the optionee) either five years or ten years from the date of grant.

Each stock 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 five year period as this may limit their personal tax obligations in respect of the option in respect to the jurisdiction where options are taxed at grant, compared to a ten year option.

Restricted stock units granted under the Equity Incentive Plan shall vest over a period of four years with respect to one fourth of the shares upon each anniversary of the date of grant. At the time of vesting, the holder of such restricted stock unit receives argenx shares for free in the number equal to the number of restricted stock units

vested minus a certain number of shares required to cover employee taxes payable by argenx on behalf of the holder of restricted stock units, if applicable.

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 argenx's assets or (iii) dissolution and/or liquidation of argenx, then 100% of any unvested equity incentives shall vest.

Our Board of Directors, upon approval of a majority of the non-executive directors may amend or terminate the Equity Incentive Plan or may amend the terms of any outstanding stock options or restricted stock units, provided that no amendment or termination may negatively affect any existing rights without the consent of the affected optionees.

The table below sets forth the details of all options under the Equity Incentive Plan in force as of December 31, 2021, including the offer date, exercise price, expiry date, number of options exercised, number of options voided and number of options outstanding. Aside from the stock options set forth in the below table, there are currently no other stock options, options to purchase securities, convertible securities or other rights to subscribe for or purchase outstanding securities.

Plan	Offer date	Exercise price (\$)	Number of options granted	Options Number of options exercised	Number of options voided	Number of options still outstanding	Exercisable from	Expiry date
SOP A	5/11/2010	4.47	103,370	102,150	1,220	—	5/11/2013	5/11/2020
SOP A	11/30/2010	4.47	62,460	62,460	—	—	11/30/2013	11/30/2020
SOP A	2/1/2011	4.47	3,800	3,800	—	—	2/1/2014	2/1/2021
SOP B	6/29/2012	2.76	590,307	464,968	—	125,339	5/23/2016	6/29/2022
Reshuffling A	9/30/2014	4.47	55,746	49,633	—	6,113	9/30/2017	9/30/2024
Reshuffling B1	9/30/2014	2.76	174,362	82,246	—	92,116	9/30/2017	9/30/2024
Reshuffling B2	9/30/2014	2.76	19,719	17,747	—	1,972	9/30/2017	9/30/2024
SOP 2014.12.18	12/18/2014	8.12	585,250	261,000	47,750	276,500	12/18/2017	12/18/2024
SOP 2015.06.18	6/18/2015	12.96	56,500	34,500	17,500	4,500	6/18/2018	6/18/2025
SOP 2015.09.03	9/3/2015	11.71	3,000	3,000	—	—	9/3/2018	9/3/2025
SOP 2015.12.15	12/15/2015	10.72	243,400	129,493	8,050	105,857	12/15/2018	12/15/2025
SOP 2016.05.25	5/25/2016	12.99	288,950	178,463	7,647	102,840	5/25/2019	5/25/2026
SOP 2016.06.18	6/18/2016	12.88	60,000	19,000	—	41,000	6/18/2019	6/18/2026
SOP 2016.12.13	12/13/2016	16.01	363,226	231,460	14,185	117,581	12/13/2019	12/13/2026
SOP 2017.06.26	6/26/2017	20.85	120,536	66,933	460	53,143	6/26/2020	6/26/2027
SOP 2017.12.14	12/14/2017	23.98	653,825	259,588	32,887	361,350	12/14/2020	12/14/2027
SOP 2018.06.28	6/28/2018	91.54	89,600	—	4,520	85,080	6/28/2021	6/28/2023
SOP 2018.06.28	6/28/2018	91.54	89,300	42,605	7,180	39,515	6/28/2021	6/28/2028
SOP 2018.12.21	12/21/2018	97.77	369,760	9,740	38,547	321,473	12/21/2021	12/21/2023
SOP 2018.12.21	12/21/2018	97.77	491,815	71,239	69,945	350,631	12/21/2021	12/21/2028
SOP 2019.06.28	6/28/2019	128.54	89,529	—	516	89,013	6/28/2022	6/28/2024
SOP 2019.06.28	6/28/2019	128.54	252,733	65,686	44,646	142,401	6/28/2022	6/28/2029
SOP 2019.06.28	6/28/2019	153.75	54,800	15,757	9,385	29,658	6/28/2022	6/28/2029
SOP 2019.06.28	6/28/2019	128.54	22,161	—	—	22,161	6/28/2019	6/28/2024
SOP 2019.06.28	6/28/2019	128.54	4,364	—	—	4,364	6/28/2019	6/28/2029
SOP 2019.12.20	12/20/2019	153.75	185,781	3,330	10,563	171,888	12/20/2022	12/20/2024
SOP 2019.12.20	12/20/2019	153.75	1,802	—	—	1,802	12/20/2023	12/20/2024
SOP 2019.12.20	12/20/2019	153.75	687,320	48,384	73,088	565,848	12/20/2022	12/20/2029
SOP 2019.12.20	12/20/2019	153.75	1,400	—	1,400	—	12/20/2023	12/20/2029
SOP 2019.12.20	12/20/2019	153.75	29,968	—	—	29,968	12/20/2019	12/20/2024
SOP 2019.12.20	12/20/2019	153.75	15,616	—	—	15,616	12/20/2019	12/20/2029
SOP 2020.04.14	4/14/2020	135.38	9,285	—	1,029	8,256	4/14/2023	4/14/2025
SOP 2020.04.14	4/14/2020	135.38	9,283	—	1,259	8,024	4/14/2024	4/14/2025
SOP 2020.04.14	4/14/2020	135.38	432	—	—	432	4/14/2020	4/14/2025
SOP 2020.04.14	4/14/2020	135.38	61,635	12,284	750	48,601	4/14/2023	4/14/2030
SOP 2020.04.14	4/14/2020	135.38	61,634	8,858	750	52,026	4/14/2024	4/14/2030
SOP 2020.04.14	4/14/2020	135.38	1,931	—	—	1,931	4/14/2020	4/14/2030
SOP 2020.06.25	6/25/2020	222.16	82,903	—	969	81,934	6/25/2023	6/25/2025
SOP 2020.06.25	6/25/2020	222.16	16,355	—	1,090	15,265	6/25/2024	6/25/2025
SOP 2020.06.25	6/25/2020	222.16	32,512	—	—	32,512	6/25/2020	6/25/2025
SOP 2020.06.25	6/25/2020	222.16	276,724	18,937	58,000	199,788	6/25/2023	6/25/2030
SOP 2020.06.25	6/25/2020	226.77	21,000	1,573	—	19,427	6/25/2023	6/25/2030
SOP 2020.06.25	6/25/2020	222.16	91,161	4,614	15,020	71,528	6/25/2024	6/25/2030
SOP 2020.06.25	6/25/2020	226.77	21,000	1,573	—	19,427	6/25/2024	6/25/2030
SOP 2020.06.25	6/25/2020	222.16	8,435	—	—	8,435	6/25/2020	6/25/2030
SOP 2020.10.01	10/1/2020	226.77	14,376	—	—	14,376	10/1/2023	10/1/2025
SOP 2020.10.01	10/1/2020	226.77	7,887	—	—	7,887	10/1/2020	10/1/2025
SOP 2020.10.01	10/1/2020	226.77	9,837	—	—	9,837	10/1/2023	10/1/2025
SOP 2020.10.01	10/1/2020	226.77	64,266	3,235	13,130	47,902	10/1/2024	10/1/2030
SOP 2020.10.01	10/1/2020	280.43	17,400	167	—	17,234	10/1/2024	10/1/2030
SOP 2020.10.01	10/1/2020	222.16	2,900	175	—	2,725	10/1/2024	10/1/2030
SOP 2020.10.01	10/1/2020	226.77	62,358	3,060	13,129	46,170	10/1/2024	10/1/2030
SOP 2020.10.01	10/1/2020	280.43	13,800	167	—	13,634	10/1/2024	10/1/2030
SOP 2020.10.01	10/1/2020	226.77	3,676	—	—	3,676	10/1/2020	10/1/2030
SOP 2020.12.21	12/21/2020	280.43	180,136	—	5,472	174,664	12/21/2023	12/21/2025
SOP 2020.12.21	12/21/2020	280.43	10,386	—	2,359	8,027	12/21/2024	12/21/2025

SOP 2020.12.21	12/21/2020	280.43	20,523	—	—	20,523	12/21/2020	12/21/2025
SOP 2020.12.21	12/21/2020	280.43	570,300	5,446	20,250	544,605	12/21/2023	12/21/2030
SOP 2020.12.21	12/21/2020	280.43	116,375	2,825	7,450	106,101	12/21/2024	12/21/2030
SOP 2020.12.21	12/21/2020	280.43	10,642	—	—	10,642	12/21/2020	12/21/2030
SOP 2021.04.01	4/1/2021	265.48	19,240	—	—	19,240	4/1/2024	4/1/2026
SOP 2021.04.01	4/1/2021	265.48	5,126	—	—	5,126	4/1/2021	4/1/2026
SOP 2021.04.01	4/1/2021	265.48	39,839	—	1,185	38,654	4/1/2024	4/1/2031
SOP 2021.04.01	4/1/2021	265.48	3,628	—	—	3,628	4/1/2021	4/1/2031
SOP 2021.07.01	7/1/2021	288.93	44,703	—	—	44,703	7/1/2024	7/1/2026
SOP 2021.07.01	7/1/2021	288.93	16,802	—	—	16,802	7/1/2021	7/1/2026
SOP 2021.07.01	7/1/2021	288.93	216,073	—	11,370	204,703	7/1/2024	7/1/2031
SOP 2021.07.01	7/1/2021	288.93	2,761	—	—	2,761	7/1/2021	7/1/2031
SOP 2021.10.01	10/1/2021	293.91	44,311	—	—	44,311	7/1/2024	10/1/2026
SOP 2021.10.01	10/1/2021	293.91	3,827	—	—	3,827	7/1/2021	10/1/2026
SOP 2021.10.01	10/1/2021	293.91	96,417	—	4,230	92,187	7/1/2024	10/1/2031
SOP 2021.10.01	10/1/2021	293.91	269	—	—	269	7/1/2021	10/1/2031
SOP 2021.12.24 (1)	12/24/2021	350.20	389,588	—	—	389,588	12/24/2021	12/24/2031
Total			8,452,136	2,286,092	546,931	5,619,113		

(1) On December 24, 2021, the company 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, 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 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 Annual Report, 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 Annual Report (or in any period before), none of the members of our Board of Directors and senior management has or has had a family relationship with any other member of our Board of Directors or senior management.

Diversity

We value diversity as a way of recognizing and valuing the differences between individuals to come to the most efficient and effective way to achieve our strategic objectives. For our board of directors, this means that when making recommendations to the general meeting for the (re-)appointment of directors, the board will aim for a diverse composition in terms of such factors as gender and age, in accordance with our diversity policy as may be in force from time to time. Under Dutch law reporting rules, we will be required to address diversity of our Board of Directors

in our Annual Report or in the report of the Board of Directors (*bestuursverslag*): (i) composition of the Board of Directors by gender; (ii) objectives of the diversity policy; (iii) description of how the diversity policy is being implemented and the results thereof and (iv) if there is no diversity policy, this should be explained.

On January 01, 2022, new legislation entered into force, requiring “large Dutch companies” to set an ‘appropriate and ambitious’ target for their management board, supervisory board and senior executives (the latter as determined by the company). If a company has adopted a one-tier board structure, the appropriate and ambitious target applies to both the executive and non-executive directors. The legislation is based on a “comply or explain” principle. Accordingly, we will be required to disclose in our report of the Board of Directors whether or not we are in compliance with the self-imposed target. In addition, within ten months of the end of the financial year, we will need to report to the *Sociaal-Economische Raad* (SER) whether or not we have complied with the self-imposed target.

Our policy is that we will balance our Board of Directors in terms of gender, age, background and nationality as much as reasonably possible while still having our board composed of the best possible candidates overall. It has been and will remain our priority to have the best available specialists on our board of directors, irrespective of age, background, nationality and gender, who make a balanced panel of directors able to advise and guide argenx to further growth and success for all its stakeholders. This means we require a number of specialties and character traits to be present. Taking into account the aforementioned and the specialist nature of our business, we will actively seek to further improve diversity on our board if and when proposing new appointments to our board of directors, whilst acknowledging that age, gender and nationality are important, but not the only factors relevant for the ultimate decision to select a board member. We have set ourselves the target to over time achieve an equal gender balance in our Board of Directors, and we will report on our progress annually in our ESG report.

Board Diversity Matrix (as of the date of this Annual Report)

Country of Principal Executive Offices		Netherlands		
Foreign Private Issuer		Yes		
Disclosure Prohibited by Dutch Law		No		
Total Number of Directors		7		
	Female	Male	Non-Binary	Did Not Disclose Gender
Gender: Number of Directors	1*	6		
Demographic Background Categories		Number of Directors in Each Demographic Category		
Underrepresented individual in home country jurisdiction		1		
LGBTQ+				
Did not disclose demographic background		6		

* We had two female members of our board of directors as of December 31, 2021. However, on March 3, 2022, Dr. Greenstreet stepped down from her position as member of our Board of Directors due to time constraints following her appointment as Chief Executive Officer at Alnylam. As a result of such departure from our board of directors, we have one female member of our board of directors as of the date of this Annual Report.

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 of Directors in this task. While our Board of Directors oversees our risk management, our senior management is responsible for day-to-day risk management processes. Our Board of Directors expects our senior 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 (the **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. The non-executive director may subsequently be reappointed again for a period of two years, which appointment may be extended by at most two years. In the event of a reappointment after an eight-year period, reasons will be given in the report of the board of directors. The Board of Directors is required to make one or more proposals for each seat on our Board of Directors to be filled. A resolution to nominate a director by our Board of Directors (with support from the remuneration and nomination committee) may be adopted by a simple majority of the votes cast. A nomination for appointment of an executive director must state the candidate's age and the positions he or she holds, or has held, insofar as these are relevant for the performance of the duties of an executive director. The nomination must state the reasons for the nomination of the relevant person. A nomination for appointment of a non-executive director must state the candidate's age, his or her profession, the number of shares he or she holds and the employment positions he or she holds, or has held, insofar as these are relevant for the performance of the duties of a non-executive director. Furthermore, the names of the legal entities of which he or she is already a supervisory board member or a non-executive member of the board shall be indicated; if those include legal entities which belong to the same group, a reference to that group will be sufficient. The nomination must state the reasons for the nomination of the relevant person.

Our directors are appointed as either an executive director or as a non-executive director by the shareholders at the General Meeting. Our Board of Directors designates one executive director as Chief Executive Officer. In addition, the Board of Directors may grant other titles to executive directors. Our Board of Directors designates a non-executive director as chairperson of the Board of Directors and a non-executive director as vice chairperson of the board of directors. The legal relationship between an executive member of the Board of Directors and argenx 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.

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 Dutch Civil Code (*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.

On May 11, 2021, the shareholders at the General Meeting appointed Ms. Yvonne Greenstreet to our Board of Directors, and reappointed Mr. Anthony Rosenberg.

We have entered into management contracts and employment agreements with our Board members and senior management that contain certain severance provisions, see section of this Annual Report titled "Item 7.B.—Related Party Transactions—Agreements with our Senior 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;

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

Only non-executive directors qualify for membership of these 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.

In addition to the aforementioned legally required subcommittees, our Board of Directors may also opt to incorporate informal committees consisting of non-executive directors and other internal and external persons in order to facilitate discussions and act as a sounding board on specific projects, as well as on a more permanent basis. Our Board of Directors has incorporated a research and development committee and a commercial committee.

Audit and Compliance Committee

Our audit and compliance committee consists of four members: Werner Lanthaler (chairperson), Peter K. M. Verhaeghe, Anthony A. Rosenberg and James M. Daly. 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.

Our 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, our financial reporting, compliance and organization for the purpose of making appropriate recommendations to our 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 six times in the course of 2021. At these meetings, the main points of discussion were:

- key findings and risk areas of the 2021 gap analysis on compliance;
- key findings of the 2021 gap analysis on ESG;
- review of the financial statements for the year ended December 31, 2020 and related press release;
- review of the 20-F and Annual Report with respect to the year ended December 31, 2020;
- review of our Independent Registered Accounting Firm's 2020 audit report;
- discussion and review of the 2021 Independent Registered Accounting Firm's audit plan;
- review of interim consolidated financial statements and related press releases;
- review of our Independent Registered Accounting Firm's report on interim financial statements; and
- review of quarterly forecasts, updates on internal control activities, updates on corporate audit activities, updates on cash, cash equivalents and financial assets.

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 2021 since appointment	Attendance %
Peter Verhaeghe	6/6	100%
Werner Lanthaler (Chairperson)	6/6	100%
Tony Rosenberg	6/6	100%
James M. Daly (1)	3/3	100%

(1) James M. Daly joined the audit and compliance committee in May 2021.

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 four members: J. Donald deBethizy (chairperson), Peter K. M. Verhaeghe, Werner Lanthaler and Yvonne Greenstreet.

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 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 2021. The main topics of discussion were the drafts of the new remuneration policy and the new equity incentive plan, the achievements of senior management's 2021 targets and pay-out of variable pay, the proposed 2021 equity incentive grants and the proposal to move to a single annual equity grant moment for recurring equity grants.

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 2021 since appointment	Attendance %
Peter Verhaeghe	2/2	100%
Werner Lanthaler	2/2	100%
Don deBethizy (chairperson)	2/2	100%
Yvonne Greenstreet	1/1	100%

Informal subcommittees

Research and Development Committee

The research and development committee consists of members of our 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. J. Donald deBethizy and Pamela Klein are members of our Board of Directors. David L. Lacey resigned from our Board of Directors per May 11, 2021, but continues to serve as an advisor on the Research and Development Committee. Ad-hoc participants to the committee meetings furthermore include a variety of employees and/or external advisors, depending on the needs of the committee and the topics under discussion.

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 personnel, 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 typically meets at least once 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 reports to our Board of Directors on the research and development committee's discussions and strategic advice after each meeting on all matters within its duties and responsibilities.

The research and development committee has deliberated three times in the course of 2021 in which it focused mainly on the vision and strategy on science at the Company.

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

Research and Development Committee	Number of meetings attended in 2021 since appointment	Attendance %
Don deBethizy	3/3	100%
Pamela Klein	3/3	100%
David L. Lacey (chairperson) (1)	3/3	100%

(1) David L. Lacey resigned from our Board of Directors per May 11, 2021.

Commercial committee

The commercial committee consists of members of our Board of Directors and other persons, which composition may vary from time to time. As of the date of this Annual Report, the commercial committee consists of two permanent members: James M. Daly (chairperson) and A.A. 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;
- 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. In 2021, the committee held one formal meeting, in which it focused mainly on Company's readiness in the U.S., Japan and EMEA in light of the envisaged launch of efgartigimod.

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

Commercial Committee	Number of meetings attended in 2021 since appointment	Attendance %
Anthony A. Rosenberg	1/1	100%
James M. Daly (chairperson)	1/1	100%

Corporate Governance Practices

Our Board By-Laws, that describe, inter alia, 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.

Under the Board By-Laws, some specific matters require approval of the majority of the non-executive directors. These matters are set out in Schedule 1 of our Board By-Laws. Our Board By-Laws are available on our website.

In exceptional cases, if the urgent necessity and the interests of argenx require this, resolutions of our Board of Directors may also be adopted by unanimous written approval of all directors in office. A director may issue a proxy for a specific board meeting to another director in writing.

The executive director(s) are required to be asked their vision on their own remuneration in accordance with best practice provision 3.2.2 but may not participate in the adoption of resolutions (including any deliberations in respect of such resolutions) relating to their remuneration.

D. EMPLOYEES

As of December 31, 2021, we had 650 employees. At each date shown below, we had the following number of employees, broken out by department and geography:

	At December 31,		
	2021	2020	2019
Function:			
Research and development	289	193	118
Selling, general and administrative	361	143	70
Total	650	336	188
Geography:			
Zwijnaarde, Belgium	296	213	145
Boston, USA	276	108	40
Tokyo, Japan	57	13	3
Breda, the Netherlands	—	—	—
Geneva, Switzerland	9	2	—
Issy Les Moulineaux, France	3	—	—
Munich, Germany	9	—	—
Total	650	336	188

Collective bargaining agreements (**CBAs**) can be entered into in Belgium at the national, industry, or company levels. CBAs can also be entered into in France, Germany and Italy at the industry level. 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 February 28, 2022 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 senior management;
- all members of our board of directors and our senior 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 February

28, 2022. The percentage ownership information shown in the table is based upon 51,905,308 ordinary shares outstanding as of February 28, 2022.

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 February 28, 2022. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person. The information in the table below is based on information known to us or ascertained by us from public filings made by the shareholders.

Name of beneficial owner	Shares beneficially owned	
	Number	Percentage
3% or Greater Shareholders:		
T. Rowe Price Group, Inc. (1)	5,603,556	10.80 %
FMR LLC (2)	4,876,317	9.39 %
Artisan Investments GP LLC (3)	3,180,665	6.13 %
Blackrock, Inc. (4)	2,397,921	4.62 %
The Vanguard Group (5)	1,978,464	3.81 %
Federated Equity Management Company of Pennsylvania (6)	1,895,001	3.65 %
Johnson & Johnson Innovation - JJDC, Inc (7)	1,766,899	3.40 %
Directors and Senior Management:		
Tim Van Hauwermeiren (8)	324,444	*
Peter Verhaeghe (9)	50,817	*
Werner Lanthaler (10)	43,218	*
Donald deBethizy (11)	32,222	*
Pamela Klein (12)	34,722	*
A.A. Rosenberg (13)	36,062	*
James M. Daly (14)	27,222	*
Keith Woods (15)	86,111	*
Hans de Haard (16)	381,860	*
Wim Parys (17)	186,111	*
Arjen Lemmen (18)	81,212	*
Andria Wilk (19)	9,042	*
Malini Moorthy	-	-
Karl Gubitz	-	-
Yvonne Greenstreet	-	-
All directors and executive management as a group (15 persons)	1,293,043	2.43 %

* Indicates beneficial ownership of less than 1% of the total outstanding ordinary shares.

- (1) Based solely on a Schedule 13G/A filed with the SEC on February 14, 2022. Consists of 5,603,556 ADSs beneficially owned. T. Rowe Price Associates, Inc. ("Price Associates") has sole voting power with respect to 1,721,055 ADSs, sole dispositive power with respect to 5,603,556 ADSs, shared voting power with respect to none of the ADSs, and shared dispositive power with respect to none of the ADSs beneficially owned. 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 registered investment companies sponsored by Price Associates for which it also serves as investment adviser ("T. Rowe Price Funds"), only the custodian for each of such T. Rowe Price 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.

- (2) Based solely on a Schedule 13G/A filed with the SEC on February 9, 2022. Consists of 4,876,317 ordinary shares beneficially owned. FMR LLC has sole voting power with respect to 944,1184 shares and sole dispositive power with respect to all of the shares, and shared voting power and shared dispositive power with respect to none of the shares beneficially owned. 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.
- (3) Based solely on a Schedule 13G filed with the SEC on February 4, 2022. Consists of 3,180,665 ordinary shares beneficially owned. Artisan Partners Limited Partnership ("APLP"), Artisan Investments GP LLC ("Artisan Investments"), Artisan Partners Holdings LP ("Artisan Holdings"), and Artisan Partners Asset Management Inc. ("APAM") each have sole voting power and sole dispositive power with respect to none of the shares, shared voting power with respect to 2,714,431 shares, and shared dispositive power with respect to all of the shares beneficially owned. APLP is an investment adviser registered under section 203 of the Investment Advisers Act of 1940. Artisan Holdings is the sole limited partner of APLP and the sole member of Artisan Investments. Artisan Investments is the general partner of APLP. APAM is the general partner of Artisan Holdings. The address of APLP, Artisan Investments, Artisan Holdings, and APAM is 875 East Wisconsin Avenue, Suite 800, Milwaukee, WI 53202. Other information regarding this shareholder's beneficial ownership of our shares is not known to us or, to our knowledge, ascertainable from public filings.
- (4) Based solely on the most recent transparency notification filed with the AFM as of February 28, 2022. Consists of 1,718,968 ordinary shares and 678,953 depository receipts. Other information regarding this shareholder's beneficial ownership of our shares is not known to us or, to our knowledge, ascertainable from public filings. The address of BlackRock, Inc. is 55 East 52nd Street, New York, NY 10055.
- (5) Based solely on the most recent transparency notification filed with the AFM as of February 28, 2022. 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.
- (6) Based solely on (1) the most recent transparency notification filed with the AFM as of February 28, 2022 and (2) the 13G/A filed with the SEC on December 10, 2019. 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 February 28, 2022. 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.
- (8) Consists of 87,500 shares and 236,944 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of February 28, 2022.
- (9) Consists of 50,817 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of February 28, 2022.
- (10) Consists of 25,416 shares and 17,802 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of February 28, 2022.
- (11) Consists of 32,222 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of February 28, 2022.
- (12) Consists of 34,722 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of February 28, 2022.

- (13) Consists of 36,062 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of February 28, 2022.
- (14) Consists of 27,222 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of February 28, 2022.
- (15) Consists of 86,111 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of February 28, 2022.
- (16) Consists of 15,910 shares and 365,950 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of February 28, 2022.
- (17) Consists 186,111 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of February 28, 2022.
- (18) Consists of 81,212 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of February 28, 2022.
- (19) Consists of 9,042 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of February 28, 2022.
- (20) Includes 1,164,217 shares issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days of February 28, 2022 held by directors and senior management, as described in notes 8 through 19 above

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, 2019, 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 Senior 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	\$	651,986
Cash bonus	maximum 60% of base salary based on previously determined bonus targets established by the non-executive directors	
Pension contributions(1)	\$	26,894
Duration		Indefinite

(1) Amounts shown represent pension contributions paid during the year-ended December 31, 2021.

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.

Karl Gubitz, 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.

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 Beesaert, our General Counsel until December 31, 2021, 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. Mr. Beeusaert has retired per December 31, 2021 and has since been succeeded by Malini Moorthy as from February 14, 2022.

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 senior management. We have entered into such agreements with each new non-executive director or member of our senior management when they have joined us since our initial U.S. public offering. 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

From time to time, in the ordinary course of our business we may contract for services from companies in which certain of the members of our senior management or directors may serve as director or advisor. The cost of these services is negotiated on an arm's length basis and none of these arrangements are material to us.

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. 333-258251), automatically effective upon filing with the SEC on July 29, 2021, under the heading "Description of Share Capital" 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

Under the Dutch law, subject to the 1977 Sanction Act (*Sanctiewet 1977*) or otherwise by international sanctions, there are no exchange control restrictions on investments in, or payments on, Shares (except as to cash amounts). There are no special restrictions in the Articles of Association or Dutch law that limit the right of Shareholders who are not citizens or residents of the Netherlands to hold or vote Shares.

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 within the meaning of Section 1221 of the U.S. Internal Revenue Code of 1986, as amended (the **Code**). 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, 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;
- persons subject to special tax accounting rules as a result of any item of gross income with respect to the shares being taken into account in an applicable financial statement;
- 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 USD.

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 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 (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” (**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 USDs at that time. Any foreign currency gain or loss a U.S. holder realizes on a subsequent conversion of foreign currency into USDs will be U.S. source ordinary income or loss. If dividends received in a foreign currency are converted into USDs 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 USD 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 USDs 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 USDs 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 U.S. 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 with respect to the income and assets of its subsidiaries, 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, which, assuming we are treated as a publicly traded company for these purposes, may be determined by valuing our assets 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 2022 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. We have not determined whether any of our subsidiaries are or may be lower tier PFICs for the current taxable year or future taxable years, and we do not intend to do so. We also do not intend to make available the information necessary for U.S. holders to make a QEF election with respect to any lower tier PFICs and therefore you should expect that you will not be able to make a QEF election with respect to them.

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.

This summary does not address the Dutch tax consequences for a holder of ADSs that is considered to be affiliated (*gelieerd*) to the company within the meaning of the Dutch Withholding Tax Act 2021 (*Wet bronbelasting 2021*). Generally, a holder of ADSs is considered to be affiliated to the company for these purposes if (i) it has a qualifying interest in the company, (ii) the company has a qualifying interest in such party, or (iii) a third party has a qualifying interest in both the company and such party. A party is equated with any collaborating group of parties of which it forms part. A qualifying interest is an interest that allows the holder to have a decisive influence over the other party's decisions, in such a way that it is able to determine the activities of the other party. A party is in any case considered to have a qualifying interest in another party if it (directly or indirectly) owns more than 50 per cent. of the voting rights in such other party.

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 an individual 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 income tax liability, or a full refund, of the Dutch dividend withholding tax.

A holder of the ADSs that is a legal entity 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 of the Dutch dividend withholding tax. If and to the extent such legal entity cannot credit the full amount of Dutch dividend withholding tax in a given year, the Dutch dividend withholding tax may be carried forward and credited against its corporate income tax liability in subsequent years (without time limitation).

A holder of the ADSs that is a legal entity that is resident or deemed to be resident in the Netherlands for Dutch tax purposes that is exempt from Dutch corporate income tax, is generally entitled, subject to the anti-dividend stripping rules described below, to a full refund of Dutch dividend withholding tax on dividends received.

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 2022 tax year, the deemed income derived from savings and investments will amount to 1.818% of the individual’s yield basis up to and including €50,650, 4.366% of the individual’s yield basis exceeding €50,650 up to and including €962,350 and 5.53% of the individual’s yield basis in excess of €962,350. The tax-free threshold for 2022 is €50,650. The percentages to determine the deemed income will be reassessed every year. Based on case law and depending on a holder of the ADSs’ actual income and gains from these and other passive investments, such holder may be entitled to a reduction of this tax.

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 25.8% (15% over profits up to and including €395,000) 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 €395,000), 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. The tax legislation of the investor's country of residence may have an impact on the income received from the ADSs.

This summary does not purport to address all tax consequences of investments in, 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 tax regime applicable to ADSs held by Belgian tax residents through a fixed base or a permanent establishment situated outside Belgium. 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 2022) 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. The abovementioned exempted amount is not applicable to redemption and liquidation dividends.

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 received 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.

Capital gains realized in a private (*i.e.*, non-professional) context on the transfer for consideration of shares of a Belgian company to a foreign company with its fiscal residency outside the EEA, by a private individual, who held alone or jointly with his family, directly or indirectly, more than 25% of the shares of that Belgian company, are taxable at a flat rate of 16.5%.

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 établissements de crédit, des entreprises d'investissement et des sociétés de gestion d'organismes de placement collectif/jaarrekening van de kredietinstellingen, de beleggingsondernemingen en de beheervennootschappen van instellingen voor collectieve belegging*) are subject to a different regime. The capital gains on such shares are taxable at the ordinary corporate income tax rate of 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 are obtained or received in Belgium and 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 (e.g. credit institutions, insurance companies, investment companies, and certain collective investment undertakings). 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.

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 included elsewhere 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 Company manages its exposure to market risks 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 risks relate to adequacy of equity and debt capitalization, creditworthiness of counterparties, short-term liquidity, the impact of changes in interest rates on its investments and fluctuations in foreign currency exchange rates. The Company does not believe that other risks are material, including interest rate risk on borrowings, which are inapplicable as the Company has no financial debt. We do not buy or trade financial instruments for speculative purposes. For additional information on risk factors applicable to the Company, its business, financial condition and results of operations, please see the section of this Annual Report titled "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, reflected as capital, reserves and accumulated losses as mentioned in the consolidated statements of changes in equity. The Company makes necessary adjustments from time to time in the light of changes in economic circumstances, risks associated with the different assets and the projected cash needs of the current and projected research activities of the Company. On December 31, 2021, cash and cash equivalents amounted to \$1,334.7 million and total capital amounted to \$3,469.0 million. The Company believes that its current available cash and anticipated cash generation are the most important parameters in assessing whether it has sufficient cash to satisfy its anticipated cash needs. The Company's objective is to maintain sufficient equity capital to be able to finance its anticipated activities for at least twelve months. Cash income from existing and new partnerships is taken into account and, if the Company needs additional cash and conditions in the equity or debt capital markets permit, the Company may 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 collaboration and license 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 interest income and expense resulting from short-term interest-bearing assets. 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, 2021, if applicable interest rates would increase/decrease by 25 basis points, this would have a positive/negative impact of \$0.9 million (compared to \$1.7 million for the year ended December 31, 2020 and \$2.2 million for the year ended December 31, 2019).

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 EUR, Japanese yen, British pound and Swiss franc. To limit this risk, the Company attempts to align incoming and outgoing cash flows in currencies other than USD.

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

(in thousands of \$)	At December 31,		
	2021	2020	2019
EUR	591,887	703,016	578,483
JPY	6,316	264	856
GBP	1,237	48	4
CHF	727	2	1

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 included elsewhere 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
\$0.05 (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
\$0.05 (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 USDs
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, 2021. 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, 2021, 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 consolidated 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, 2021 was effective.

The effectiveness of our internal control over financial reporting as of December 31, 2021 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 (*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 2021 and 2020. Our accountants billed the following fees to us for professional services in each of those fiscal years:

Fees	Year Ended December 31,	
	2021	2020
	in thousands of \$	
Audit Fees	\$ 1,183	\$ 923
Audit-Related Fees	267	188
Tax Fees	79	—
All other Fees	—	—
Total	\$ 1,529	\$ 1,111

“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 2021 and 2020, “Audit-Related Fees” also include fees billed for assurance and audit-related services regarding our public offerings on Nasdaq.

“Tax Fees” are the aggregate fees billed for professional services rendered by the principal accountant for permissible tax related services.

“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, 2021 and 2020.

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 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 board regulations 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).

ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable.

ITEM 16I. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 17. FINANCIAL STATEMENTS

Not applicable.

ITEM 18. FINANCIAL STATEMENTS

See pages F-1 through F-51 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	Form 20-F	001-38097	2.3	03/30/2021
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 Equity Incentive Plan 2021				
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	Form 20-F	001-38097	4.7	03/30/2021
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
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

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 21, 2022

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, 2021, 2020 and 2019

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the Board of Directors of argenx SE

Opinion on the Financial Statements

We have audited the accompanying consolidated statements of financial position of argenx SE and subsidiaries (the "Company") as of December 31, 2021, 2020 and 2019, the related consolidated statements of profit or loss, comprehensive income and loss, cash flows, and changes in equity, for each of the three years in the period ended December 31, 2021, 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, 2021, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board ("IFRS").

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, 2021, 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 21, 2022, 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 Matters

The critical audit matters communicated below are matters arising from the current-period audit of the financial statements that were communicated or required to be communicated to the audit committee and that (1) relate 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 matters below, providing a separate opinion on the critical audit matters or on the accounts or disclosures to which they relate.

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 USD 163.7 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. 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.

Determination of the research progress and the translation of the progress to the research and development cost accruals requires judgment, because such 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.

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 quarterly 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 evaluated this information to the judgements applied in recording the accruals.
- 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 with vendors related to the progress of significant projects 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.
 - Reconciled any available related statement of work, purchase order, or other supporting documentation to management's estimate (such as communications between the company and vendors).

Revenue – Determination of appropriate accounting of the license and collaboration agreement — Refer to Note 16 to the financial statements

Critical Audit Matter Description

The company recognized revenue of USD 178.4 million related to a license and collaboration agreement with Zai Lab Limited. Under the terms of the agreement, the company received USD 175 million in collaboration payments, consisting of an upfront payment and milestone payment. The upfront payment of USD 150 million is comprised of a USD 75 million upfront cash payment and a USD 75 million payment in the form of newly issued Zai Lab shares. The company has received an additional milestone payment of USD 25 million upon obtaining regulatory approval of efgartigimod by the FDA in the US. In addition, the company is eligible to receive tiered royalties based on annual net sales of efgartigimod in Greater China.

The company's license and collaboration agreement has been determined as representing two distinct performance obligations, being the transfer of the license over efgartigimod and the at arms-length supply of

clinical and commercial product to Zai Lab Limited . The upfront payment and milestone payment are allocated to the performance obligation related to the transfer of the license, whereas sales-based royalties and revenue generated from supplying Zai Lab Limited with drug product are allocated to the performance obligation related to the supply of product.

The company concluded that the license has standalone value as of the effective date of the contract. Therefore, the revenue related to the transfer of the license has been recognized at a point in time upon fulfillment of the performance obligation, being the granting of the license to Zai Lab Limited. The milestone payment was considered constrained upon the effective date of the contract and was recognized at the point in time of obtaining the FDA approval of efgartigimod. Revenue from royalties and supply of drug product to Zai Lab Limited will be recognized upon fulfillment of the performance obligation related to the supply of drug product.

Given the complexity involved in determining the appropriate accounting treatment in line with IFRS and the fact that it is the first time that the efgartigimod license is considered to have standalone value for the company, we identified the initial accounting treatment of the license and collaboration agreement with Zai Lab Limited as a critical audit matter.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures for the accounting of the collaboration and license agreement included the following, among others:

- We tested the controls over the appropriateness of the accounting of the license and collaboration agreement, including the review by management of the appropriate accounting treatment.
- We read the license and collaboration agreement and evaluated whether management's accounting position considered all relevant facts and terms included in the agreement.
- We further evaluated management's accounting position paper and evaluated management's conclusions to determine whether they had appropriately considered and applied the guidance and interpretation within IFRS 15.
- We have consulted with our financial reporting experts on the accounting treatment of the license and collaboration agreement

Deloitte Accountants B.V.

March 21, 2022

Rotterdam, the Netherlands

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, 2021, 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, 2021, 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, 2021 of the Company and our report dated March 21, 2022, 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.

Deloitte Accountants B.V.

March 21, 2022

Rotterdam, the Netherlands

ARGENX SE

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

(in thousands of \$)	Note	As of December 31,		
		2021	2020 (*)	2019 (*)
ASSETS				
Current assets				
Cash and cash equivalents	12	\$ 1,334,676	\$ 1,216,803	\$ 372,162
Research and development incentive receivables — current		—	463	293
Financial assets — current	11	1,002,052	779,649	1,128,499
Prepaid expenses		58,946	27,913	10,136
Trade and other receivables	10	38,221	6,978	31,585
Inventories	9	109,076	25,195	—
Total current assets		2,542,971	2,057,001	1,542,675
Non-current assets				
Other non-current assets	7	54,876	7,816	3,624
Research and development incentive receivables — non-current		32,707	20,626	9,624
Deferred tax asset	8	32,191	15,038	—
Property, plant and equipment	6	15,844	11,582	9,175
Intangible assets	5	171,684	167,344	45,117
Total non-current assets		307,303	222,406	67,540
TOTAL ASSETS		\$ 2,850,274	\$ 2,279,407	\$ 1,610,215

(*) The Company has adopted a change in its presentation currency from EUR to USD at January 1, 2021, as described in note 3.4.4. Accordingly, the December 31, 2020 and December 31, 2019 comparative statements of financial position and related notes have been re-presented retrospectively based on the accounting policies as outlined in note 3.4.4.

The accompanying notes form an integral part of these consolidated financial statements.

(in thousands of \$)	Note	As of December 31,		
		2021	2020 (*)	2019 (*)
EQUITY AND LIABILITIES				
Equity	13			
Equity attributable to owners of the parent				
<i>Share capital</i>		\$ 6,233	\$ 5,744	\$ 5,209
<i>Share premium</i>		3,462,775	2,339,033	1,505,641
<i>Translation differences</i>		131,684	134,732	(27,541)
<i>Accumulated losses</i>		(1,400,197)	(991,932)	(383,477)
<i>Other reserves</i>		333,729	186,474	80,577
Total equity		\$ 2,534,224	\$ 1,674,051	\$ 1,180,409
Non-current liabilities				
Provisions for employee benefits		417	156	72
Lease liabilities — non-current	22	7,956	6,181	5,101
Deferred tax liabilities	8	6,438	1,487	—
Deferred revenue — non-current	16	—	269,039	244,937
Total non-current liabilities		14,811	276,863	250,110
Current liabilities				
Lease liabilities — current	22	3,509	3,476	2,218
Trade and other payables	15	293,415	275,192	95,827
Tax liabilities		4,315	3,497	386
Deferred revenue — current	16	—	46,328	81,265
Total current liabilities		301,239	328,493	179,696
Total liabilities		\$ 316,050	\$ 605,356	\$ 429,806
TOTAL EQUITY AND LIABILITIES		\$ 2,850,274	\$ 2,279,407	\$ 1,610,215

(*) The Company has adopted a change in its presentation currency from EUR to USD at January 1, 2021, as described in note 3.4.4. Accordingly, the December 31, 2020 and December 31, 2019 comparative statements of financial position and related notes have been re-presented retrospectively based on the accounting policies as outlined in note 3.4.4.

The accompanying notes form an integral part of these consolidated financial statements.

ARGENX SE

CONSOLIDATED STATEMENTS OF PROFIT OR LOSS

(in thousands of \$ except for shares and EPS)	Note	Year Ended December 31,		
		2021	2020 (*)	2019 (*)
Revenue	16	\$ 497,277	\$ 41,243	\$ 78,462
Other operating income	17, 7	42,141	23,668	15,563
Total operating income		539,418	64,911	94,025
Research and development expenses	19	(580,520)	(370,885)	(220,771)
Selling, general and administrative expenses	20	(307,644)	(171,643)	(72,146)
Total operating expenses		(888,164)	(542,528)	(292,917)
Operating loss		\$ (348,746)	\$ (477,617)	\$ (198,892)
Financial income/(expense)	23	(944)	(1,501)	15,983
Exchange gains/(losses)	23	(50,053)	(126,234)	6,990
Loss before taxes		\$ (399,743)	\$ (605,352)	\$ (175,919)
Income tax expense	24	\$ (8,522)	\$ (3,103)	\$ (5,289)
Loss for the year		\$ (408,265)	\$ (608,455)	\$ (181,208)
Loss for the year attributable to:				
Owners of the parent		\$ (408,265)	\$ (608,455)	\$ (181,208)
Weighted average number of shares outstanding		51,075,827	45,410,442	38,619,121
Basic and diluted loss per share (in \$)	25	(7.99)	(13.40)	(4.69)

(*) The Company has adopted a change in its presentation currency from EUR to USD at January 1, 2021, as described in note 3.4.4. Accordingly, the December 31, 2020 and December 31, 2019 comparative statements of profit and loss and related notes have been re-presented retrospectively based on the accounting policies as outlined in note 3.4.4.

The accompanying notes form an integral part of these consolidated financial statements.

ARGENX SE
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME / LOSS

(in thousands of \$ except for shares)	Note	Year Ended December 31,		
		2021	2020 (*)	2019 (*)
Loss for the year		\$ (408,265)	\$ (608,455)	\$ (181,208)
Items that may be reclassified subsequently to profit or loss, net of tax				
Currency translation differences, arisen from translating foreign activities		(3,048)	—	—
Translation effect		—	162,273	(8,587)
Items that will not be reclassified subsequently to profit or loss, net of tax				
Fair value gain/(loss) on investments in equity instruments designated as at FVTOCI	7	(39,290)	—	—
Other comprehensive loss, net of income tax		(42,338)	162,273	(8,587)
Total comprehensive loss attributable to:				
Owners of the parent		\$ (450,603)	\$ (446,182)	\$ (189,795)

(*) The Company has adopted a change in its presentation currency from EUR to USD at January 1, 2021, as described in note 3.4.4. Accordingly, the December 31, 2020 and December 31, 2019 comparative statements of comprehensive income and loss and related notes have been re-presented retrospectively based on the accounting policies as outlined in note 3.4.4.

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,		
		2021	2020 (*)	2019 (*)
CASH FLOWS (USED IN) / FROM OPERATING ACTIVITIES				
Operating loss		\$ (348,746)	\$ (477,617)	\$ (198,892)
Adjustments for non-cash items				
Amortization of intangible assets	5	776	246	43
Depreciation of property, plant and equipment	6	5,091	3,671	2,382
Provisions for employee benefits		260	76	64
Expense recognized in respect of share-based payments	14	179,366	96,932	44,236
Fair value gains on non-current financial assets at fair value through profit or loss	7	(11,152)	(2,951)	(1,214)
Non-cash revenue	16	(75,000)	—	—
		\$ (249,405)	\$ (379,643)	\$ (153,381)
Movements in current assets/liabilities				
(Increase)/decrease in trade and other receivables	10	(31,632)	21,961	(25,709)
(Increase)/decrease in inventories	9	(83,880)	(23,852)	—
(Increase)/decrease in other current assets		(30,990)	(16,189)	(5,788)
Increase/(decrease) in trade and other payables	15	134,892	50,537	53,729
Increase/(decrease) in deferred revenue – current	16	(46,327)	(40,441)	69,526
Movements in non-current assets/liabilities				
(Increase)/decrease in other non-current assets		(13,975)	(10,299)	(6,224)
Increase/(decrease) in deferred revenue – non-current	16	(269,039)	2,655	224,492
Cash flows (used in)/from operating activities		(590,356)	(395,272)	156,645
Interest paid		(684)	(401)	(139)
Income taxes paid		(15,772)	(2,791)	(4,876)
NET CASH FLOWS (USED IN) / FROM OPERATING ACTIVITIES		\$ (606,812)	\$ (398,463)	\$ 151,630
Purchase of intangible assets	5	(117,811)	(4,071)	(44,939)
Purchase of property, plant and equipment	6	(3,623)	(1,068)	(1,796)
(Increase)/decrease in financial assets – current	11	(228,239)	341,869	(792,655)
Interest received		2,603	7,962	6,122
NET CASH FLOWS (USED IN) / FROM INVESTING ACTIVITIES		\$ (347,070)	\$ 344,692	\$ (833,267)
Principal elements of lease payments	22	(3,855)	(2,550)	(1,515)
Proceeds from issue of new shares	13	1,091,326	813,186	755,641
Issue costs paid	13	(528)	(613)	(25,747)
Exchange gain from currency conversion on proceeds from issue of new shares		966	68	—
Proceeds from exercise of stock options	13	33,433	22,912	5,345
NET CASH FLOWS (USED IN) / FROM FINANCING ACTIVITIES		\$ 1,121,342	\$ 833,003	\$ 733,726
NET INCREASE (DECREASE) IN CASH & CASH EQUIVALENTS		\$ 167,460	\$ 779,232	\$ 52,088
Cash and cash equivalents at the beginning of the period		\$ 1,216,803	\$ 372,162	\$ 321,791
Exchange gains/(losses) on cash & cash equivalents		\$ (49,587)	\$ 65,409	\$ (1,717)
Cash and cash equivalents at the end of the period		\$ 1,334,676	\$ 1,216,803	\$ 372,162

(*) The Company has adopted a change in its presentation currency from EUR to USD at January 1, 2021, as described in note 3.4.4. Accordingly, the December 31, 2020 and December 31, 2019 comparative statements of cash flows and related notes have been re-presented retrospectively based on the accounting policies as outlined in note 3.4.4.

The accompanying notes form an integral part of these consolidated financial statements.

ARGENX SE

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

(in thousands of \$)	Attributable to owners of the parent (*)						Total equity attributable to owners of the parent	Total equity
	Share capital	Share premium	Accumulated losses	Translation differences	Other reserves			
Balance at January 1, 2019	\$ 4,451	\$ 796,894	\$ (202,270)	\$ (18,954)	\$ 36,341		\$ 616,462	\$ 616,462
Loss for the year			(181,208)				(181,208)	(181,208)
Other comprehensive income / (loss)				(8,587)			(8,587)	(8,587)
Total comprehensive loss of the period			(181,208)	(8,587)			(189,795)	(189,795)
Share-based payment					44,236		44,236	44,236
Issue of share capital	710	756,472					757,182	757,182
Transaction costs for equity issue		(25,476)					(25,476)	(25,476)
Accounting treatment of the share subscription agreement		(27,635)					(27,635)	(27,635)
Exercise of stock options	48	5,386					5,434	5,434
Balance year ended December 31, 2019	\$ 5,209	\$ 1,505,641	\$ (383,477)	\$ (27,541)	\$ 80,577		\$ 1,180,409	\$ 1,180,409
Loss for the year			(608,455)				(608,455)	(608,455)
Other comprehensive income / (loss)				162,273			162,273	162,273
Total comprehensive loss of the period			(608,455)	162,273			(446,182)	(446,182)
Income tax benefit from excess tax deductions related to share-based payments					8,965		8,965	8,965
Share-based payment					96,932		96,932	96,932
Issue of new shares	468	812,718					813,186	813,186
Transaction costs for equity issue		(613)					(613)	(613)
Exercise of stock options	67	21,287					21,354	21,354
Balance year ended December 31, 2020	\$ 5,744	\$ 2,339,033	\$ (991,932)	\$ 134,732	\$ 186,474		\$ 1,674,051	\$ 1,674,051
Loss for the year			(408,265)				(408,265)	(408,265)
Other comprehensive income / (loss)				(3,048)	(39,290)		(42,338)	(42,338)
Total comprehensive loss of the period			(408,265)	(3,048)	(39,290)		(450,603)	(450,603)
Income tax benefit from excess tax deductions related to share-based payments					7,179		7,179	7,179
Share-based payment					179,366		179,366	179,366
Issue of new shares	430	1,090,896					1,091,326	1,091,326
Transaction costs for equity issue		(528)					(528)	(528)
Exercise of stock options	59	33,374					33,433	33,433
Balance year ended December 31, 2021	\$ 6,233	\$ 3,462,775	\$ (1,400,197)	\$ 131,684	\$ 333,729		\$ 2,534,224	\$ 2,534,224

(*) The Company has adopted a change in its presentation currency from EUR to USD at January 1, 2021, as described in note 3.4.4. Accordingly, the December 31, 2020 and December 31, 2019 comparative statements of changes in equity and related notes have been re-presented retrospectively based on the accounting policies as outlined in note 3.4.4.

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 dollar, 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 18, 2022.

3.2 Adoption of new and revised standards

New standards and interpretations applicable for the annual period beginning on January 1, 2021

New standards and interpretations for the annual period beginning on January 1, 2021 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, 2021

We have not early adopted any other standard, interpretation, or amendment that has been issued but is not yet effective. Of the standards that are not yet effective, we expect no standard to have a material impact on our financial statements in the period of initial application.

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 or loss and consolidated statements of 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. As of January 1, 2021, the consolidated financial statements are presented in USD (\$), 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 or loss and the consolidated statements of 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 USD:

- assets and liabilities for each balance sheet presented are translated at the closing rate at the date of the balance sheet.
- income and expenses for each statement presenting profit or loss and statements of statements of 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 the statements other comprehensive income.

3.4.4 Change in functional and presentation currency as of January 1, 2021

As of January 1, 2021, the Company changed its functional and presentation currency from EUR to USD. The change in functional currency was made to reflect that USD has become the predominant currency in the Company, representing a significant part of the Company's cash flows and financing. The change has been implemented with prospective effect.

The change in presentation currency, effective January 1, 2021, from EUR to USD is retroactively applied on comparative figures according to IAS 8 and IAS 21, as if USD had always been the presentation currency of the consolidated financial statements. The change was made to better reflect the economic footprint of the Company's business going forward. The Company believes that the presentation currency change will give investors and other stakeholders a clearer understanding of the Company's performance over time.

Comparison figures in the consolidated statements of financial position, the consolidated statements of profit or loss and the consolidated statements of other comprehensive income, the consolidated statements of changes in equity, consolidated statements of cash flows, and all disclosures have been re-presented, unless otherwise stated, using the procedures outlined below:

- Assets and liabilities are translated into USD at the closing rates applicable at the end of each reporting period.
- Income and expenses are translated at exchange rates at the dates of the respective transaction or average rates where these are a suitable proxy.
- Differences resulting from the re-presentation have been presented as translation difference, a component within shareholders' equity.
- Share capital, share premium, and other reserves are translated at historic rates prevailing at the date of transaction.

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 or loss and the consolidated statements of 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.

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 or loss and the consolidated statements of 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 the consolidated statements of 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 pre-approval access program. 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 production facilities not yet approved, 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

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 the statement of 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, 2021.

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 or OCI (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 or OCI

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 the consolidated statements of 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 the consolidated statements of other comprehensive income.

3.10.1.1 Non-current financial assets at fair value through profit or loss or OCI

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 or financial assets at fair value through OCI. The fair value of listed investments is based upon the closing price of such securities at each reporting date. If there is no active market for an equity instrument, the Company establishes the fair value by using valuation techniques.

Based on IFRS 9, the Company irrevocably elected to designate specific investments as a financial asset at fair value through OCI as the participation is not held for trading purposes nor contingent consideration recognised by an acquirer in a business combination.

3.10.1.2 Current financial assets at fair value through profit or loss

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 the consolidated statements of 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 “Other non-current assets”.

3.10.1.7 Current financial assets measured at amortized costs

Current financial assets include financial assets measured at amortized costs and comprise of term accounts that have an initial maturity equal or less than 12 months, but exceeding 3 months.

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, 2021, no profits were available for distribution.

3.12 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.

3.13 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 the consolidated statements of other comprehensive income such that the cumulative expense reflects the revised estimate, with a corresponding adjustment to the equity-settled share-based payment reserve.

3.14 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.

3.15 Income taxes

Income tax in the consolidated statements of profit or loss and the consolidated statements of other comprehensive income represents the total 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 statement of 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.

3.16 Revenue and other operating income recognition

3.16.1 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 products/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.

For our material ongoing collaboration and license agreement (i.e. the Zai Lab Agreement), the Company has assessed that there is more than one distinct performance obligation, being the transfer of a license and supply of clinical and commercial product.

This is because the Company considers the performance obligations is distinct in the context of the contract as the license has stand-alone value without the Company being further involved in the research and development collaboration and that there is no interdependence between the license and the clinical and commercial supply to be provided.

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

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 distinct from the other promises to transfer goods and/or services. The Company utilizes judgement to assess the nature of the performance obligation to determine whether the 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 collaboration and license agreement (i.e. the Zai Lab Agreement) contains more than one performance obligation, the Company assess to allocate the transaction price to all performance obligations identified.

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 collaboration and license agreement (i.e. the Zai Lab Agreement) contains more than one performance obligation, the Company recognized revenue at point in time for transfer of license and the Company recognizes revenue over time for supply of clinical and commercial products as customer simultaneously receive the benefits provided by the Company's performance, satisfied over time.

Other ongoing collaboration and license agreements only contain one single performance obligation which is, as the customer simultaneously receive the benefits provided by the Company's performance, satisfied over time. As such, 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.

3.16.2 Grants, research and development incentives, payroll tax rebates and changes in fair value on non-current financial assets

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 or loss and the consolidated statements of 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. Fair value gains resulting from the change in the fair value of non-current financial assets are credited to the consolidated statements of profit or loss and the consolidated statements of other comprehensive income, under the line “Other operating income”.

3.17 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 \$163.7 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.

5. Intangible assets

(in thousands of \$)	Acquired In-Process R&D	Software & databases	Other Intangibles	Total
Cost				
On January 1, 2019	\$ —	\$ 182	\$ —	\$ 182
Additions	45,000	293	—	45,293
Translation differences	(198)	(2)	—	(200)
On December 31, 2019	44,802	473	—	45,275
Additions	16,182	2,814	98,000	116,996
Translation differences	4,196	256	1,058	5,510
On December 31, 2020	65,180	3,543	99,058	167,781
Additions	5,000	—	—	5,000
Disposals	—	(190)	—	(190)
On December 31, 2021	\$ 70,180	\$ 3,353	\$ 99,058	\$ 172,591
Amortization and impairment				
On January 1, 2019	\$ —	\$ (118)	\$ —	\$ (118)
Amortization	—	(43)	—	(43)
Translation differences	—	4	—	4
On December 31, 2019	—	(158)	—	(158)
Amortization	—	(246)	—	(246)
Translation differences	—	(33)	—	(33)
On December 31, 2020	—	(437)	—	(437)
Amortization	—	(470)	—	(470)
On December 31, 2021	\$ —	\$ (907)	\$ —	\$ (907)
Carrying Amount				
On December 31, 2019	\$ 44,802	\$ 315	\$ —	\$ 45,117
On December 31, 2020	65,180	3,106	99,058	167,344
On December 31, 2021	\$ 70,180	\$ 2,446	\$ 99,058	\$ 171,684

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, 2021, 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, 2019	\$ 3,105	—	—	—	290	\$ 3,395
Adoption of IFRS 16	—	2,677	517	—	—	3,194
Additions	856	5,097	588	905	32	7,478
Translation differences	(55)	(33)	(7)	3	(5)	(97)
On December 31, 2019	3,906	7,741	1,098	908	317	13,970
Additions	733	3,335	1,074	432	—	5,574
Disposals	(110)	—	—	—	—	(110)
Translation differences	360	645	101	84	29	1,219
On December 31, 2020	4,889	11,721	2,273	1,424	346	20,653
Additions	3,163	4,923	802	543	—	9,430
Disposals	(217)	—	—	—	—	(217)
Currency translation adjustment	104	(182)	—	14	—	(64)
On December 31, 2021	\$ 7,938	\$ 16,462	\$ 3,075	\$ 1,981	\$ 346	\$ 29,802
Depreciation and impairment						
On January 1, 2019	\$ (2,439)	\$ —	\$ —	\$ —	\$ (13)	\$ (2,452)
Depreciation	(515)	(1,472)	(261)	(103)	(31)	(2,382)
Translation differences	45	(5)	(1)	—	—	39
On December 31, 2019	(2,909)	(1,477)	(262)	(103)	(44)	(4,795)
Depreciation	(535)	(2,262)	(441)	(401)	(32)	(3,671)
Disposals	103	—	—	—	—	103
Translation differences	(301)	(305)	(57)	(39)	(6)	(708)
On December 31, 2020	(3,642)	(4,044)	(760)	(543)	(82)	(9,071)
Depreciation	(1,118)	(2,714)	(651)	(539)	(34)	(5,055)
Disposals	158	—	—	—	—	158
Currency translation adjustment	37	(15)	—	(11)	—	10
On December 31, 2021	\$ (4,565)	\$ (6,774)	\$ (1,411)	\$ (1,093)	\$ (116)	\$ (13,958)
Carrying Amount						
On December 31, 2019	\$ 997	\$ 6,264	\$ 836	\$ 805	\$ 273	9,175
On December 31, 2020	1,247	7,677	1,513	881	264	11,582
On December 31, 2021	\$ 3,373	\$ 9,688	\$ 1,664	\$ 888	\$ 230	\$ 15,844

(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 or through OCI.

(in thousands of \$)	At December 31,		
	2021	2020	2019
Restricted Cash - non-current	\$ 1,707	\$ 1,509	\$ 708
Non-current financial assets held at fair value through profit or loss	17,459	6,307	2,916
Non-current financial assets held at fair value through OCI	35,710	—	—
Total other non-current assets	\$ 54,876	\$ 7,816	\$ 3,624

Non-current restricted cash on December 31, 2021 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 Immunology Innovative Program. In exchange for granting this license, the Company received a profit share in AgomAb Therapeutics NV.

In March 2021, AgomAb Therapeutics NV secured \$74 million in Series B financing by issuing 286,705 of Preferred B Shares. The Company used the post-money valuation of Series B financing round and the number of outstanding shares in determining the fair value of the profit-sharing instrument, which results in a change in fair value of non-current financial assets of \$11.2 million recorded through profit or loss.

Fair value changes on non-current financial assets with fair value through profit or loss are recognized in the consolidated statements of profit or loss in line "Other operating income".

As part of the license agreement for the development and commercialization for efgartigimod in Greater China (see note 16 for further information), the Company obtained, amongst others, 568,182 newly issued Zai Lab shares calculated at a price of \$132 per share. The fair value of the equity instrument at reporting date is determined by reference to the closing price of such securities at each reporting date (classified as level 1 in the fair value hierarchy), resulting in a change in fair value. The Company made the irrevocable election to recognize subsequent changes in fair value through OCI in line "Fair value gain/(loss) on investments in equity instruments designated as at FVTOCI".

The table below illustrates these non-current financial assets at fair value through profit or loss or OCI as of December 31, 2021, 2020 and 2019.

(in thousands of \$)	At December 31,		
	2021	2020	2019
Cost at January 1	\$ 1,659	\$ 1,659	\$ —
Additions of the year	75,000	—	1,659
Cost at December 31	\$ 76,659	\$ 1,659	\$ 1,659
Fair value adjustments at January 1	\$ 4,648	\$ 1,257	\$ —
Fair value adjustment of the year through profit or loss	11,152	2,951	1,214
Fair value adjustment of the year through OCI	(39,290)	—	—
Translation difference	—	440	43
Fair value adjustment at December 31	\$ (23,490)	\$ 4,648	\$ 1,257
Net book value at December 31	\$ 53,169	\$ 6,307	\$ 2,916

8. Deferred Taxes

The amount of deferred tax assets and liability by type of temporary difference can be detailed as follows:

(in thousands of \$)	At December 31, 2021		
	Assets	Liabilities	Net
Deferred tax assets / (liabilities)			
Accruals and allowances	\$ 2,858	\$ —	\$ 2,858
Income tax benefit from excess tax deductions related to share-based payments	26,026	—	26,026
Profit in inventory	3,305	—	3,305
Property, plant and equipment	532	(740)	(208)
Intangible assets	—	(2,714)	(2,714)
Non-current fixed assets	—	(3,725)	(3,725)
Other	210	—	210
Netting by taxable entity	(740)	740	—
Net deferred tax assets / (liabilities)	\$ 32,191	\$ (6,438)	\$ 25,753

(in thousands of \$)	At December 31, 2020		
	Assets	Liabilities	Net
Deferred tax assets / (liabilities)			
Accruals and allowances	\$ 2,147	\$ —	\$ 2,147
Income tax benefit from excess tax deductions related to share-based payments	13,362	—	13,362
Profit in inventory	—	—	—
Property, plant and equipment	—	(167)	(167)
Intangible assets	—	(1,792)	(1,792)
Non-current fixed assets	—	—	—
Other	—	—	—
Netting by taxable entity	(471)	471	—
Net deferred tax assets / (liabilities)	\$ 15,038	\$ (1,487)	\$ 13,551

The change in net deferred taxes recorded in the consolidated statements of financial position can be detailed as follows:

(in thousands of \$)	Deferred tax	
	assets	liabilities
Balance at January 1, 2021	\$ 15,038	\$ (1,487)
Recognized in profit or loss	11,385	(5,082)
Recognized in equity	5,494	—
Effects of change in foreign exchange rate	274	131
Balance at December 31, 2021	\$ 32,191	\$ (6,438)

(in thousands of \$)	Deferred tax	
	assets	liabilities
Balance at January 1, 2020	\$ —	\$ —
Recognized in profit or loss	8,351	(1,384)
Recognized in equity	6,225	—
Effects of change in foreign exchange rate	462	(103)
Balance at December 31, 2020	\$ 15,038	\$ (1,487)

9. Inventories

(in thousands of \$)	At December 31,		
	2021	2020	2019
Raw materials and consumables	\$ 70,134	\$ 18,608	\$ —
Inventories in process	37,705	6,587	—
Finished goods	1,237	—	—
Total inventories	\$ 109,076	\$ 25,195	\$ —

On December 31, 2021, inventories amounted to \$109.1 million related to efgartigimod. Of the total inventory, \$48.8 million relates to inventory which is currently awaiting facility approval. As of December 31, 2021, no inventory write-downs were recorded.

Included in inventory are products which could, besides commercial activities, be used for in-house preclinical and clinical programs, non-reimbursed pre-approval programs and clinical programs carried out by Zai Lab.

10. Trade and other receivables

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

(in thousands of \$)	At December 31,		
	2021	2020	2019
Trade receivable	\$ 28,058	\$ 287	\$ 25,367
Interest receivable	1,325	993	2,338
Other receivable	8,838	5,698	3,880
Total trade and other receivables	\$ 38,221	\$ 6,978	\$ 31,585

The carrying amounts of trade and other receivables approximate their respective fair values. On December 31, 2021, we did not have any provision for expected credit losses.

Please also refer to note 26 for more information on the financial risk management.

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.

(in thousands of \$)	At December 31,		
	2021	2020	2019
Money market funds	\$ 73,052	\$ 130,290	\$ 804,099
Term accounts	929,000	649,359	324,400
Total current financial assets	\$ 1,002,052	\$ 779,649	\$ 1,128,499

On December 31, 2021, the current financial assets included €60.7 million held in EUR, which could generate a foreign currency exchange gain or loss in our financial results in accordance with the fluctuations of the USD/EUR exchange rate as the Company's functional currency is USD.

Please also refer to note 26 for more information on the financial risk management.

12. Cash and cash equivalents

(in thousands of \$)	At December 31,		
	2021	2020	2019
Money market funds	\$ 997,092	\$ 858,291	\$ —
Term accounts	95,090	61,356	255,631
Cash and bank balances	242,494	297,156	116,531
Total cash and cash equivalents	\$ 1,334,676	\$ 1,216,803	\$ 372,162

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, 2021, the cash and cash equivalents included €462.0 million held in EUR, which could generate a foreign currency exchange gain or loss in our financial results in accordance with the fluctuations of the USD/EUR exchange rate as the Company's functional currency is USD.

Please also refer to note 26 for more information on the financial risk management.

13. Share capital and share premium

On December 31, 2021, the Company's share capital was represented by 51,668,315 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, 2019	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
Exercise of stock options	503,282
Global public offering in Euronext and Nasdaq on February 2, 2021	3,125,000
Over-allotment option exercised by underwriters on February 4, 2021	468,750
Number of shares outstanding on December 31, 2021	51,668,315

On February 2, 2021, argenx SE offered 3,125,000 of its ordinary shares through a global offering which consisted of 1,608,000 ADSs in the U.S. at a price of \$320.0 per ADS, before underwriting discounts and commissions and offering expenses; and 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, argenx SE received \$1,146.7 million in gross proceeds from this offering, decreased by \$56.6 million of underwriter discounts and commissions, and offering expenses, of which \$56.0 million has been deducted from equity. The total net cash proceeds from the offering amounted to \$1,090.1 million.

On May 11, 2021 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.

On December 31, 2021, an amount of €410,857.7, represented by 4,108,577 shares, still remained available under the authorized capital.

14. Share-based payments

Stock Option Plans

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. As of January 1, 2021, the Company decided to change the vesting period of its sign-on stock options from 4 years to 3 years to make the vesting consistent for all the options granted.

The stock options granted (regular and sign-on) vest, in principle, as follows:

- 1/3rd of the total stock options granted will vest on the first anniversary of the granting of the stock options, and
- 1/36th of the total grant on the first day of each month following the first anniversary of the date of grant of the stock options.

Upon leave of the employee, consultant or director, stock options must be exercised before the later of (i) 90 days after the last working day at argenx, or (ii) March 31 of the 4th year following the date of grant of those stock options, and in any case no later than the expiration date of the option.

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, 2021, the economic benefits of 190,560 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 \$) (1)	Outstanding stock options on December 31,		
		2021	2020	2019
2020	\$ 4.47	—	—	7,210
2022	2.76	125,339	—	—
2023	2.76	—	165,693	211,769
2024	2.76	94,088	100,086	102,696
2024	4.47	6,113	6,238	6,238
2024	8.12	276,500	294,167	335,067
2025	12.96	4,500	21,500	39,000
2025	11.71	—	950	3,000
2025	10.73	105,857	114,232	185,832
2026	12.89	41,000	45,000	45,000
2026	12.99	102,840	127,252	219,791
2026	16.00	117,581	176,426	258,746
2027	20.85	53,143	102,479	108,613
2027	23.98	361,350	460,701	565,798
2023	91.54	85,080	85,077	94,100
2028	91.54	39,515	49,532	73,100
2023	97.77	321,473	325,661	366,260
2028	97.77	350,631	381,317	402,714
2024	128.54	111,174	111,174	111,690
2029	128.54	146,765	163,410	299,560
2024	153.75	203,658	195,452	204,430
2029	153.75	611,122	692,914	717,455
2025	135.38	16,712	19,000	—
2030	135.38	102,558	123,700	—
2025	222.16	129,711	131,770	—
2030	222.16	282,475	325,150	—
2025	226.77	32,100	32,100	—
2030	226.77	136,601	175,200	—
2030	280.43	692,214	728,517	—
2025	280.43	203,214	211,045	—
2026	265.48	24,366	—	—
2026	288.93	61,505	—	—
2026	293.91	48,138	—	—
2031	265.48	42,282	—	—
2031	288.93	207,464	—	—
2031	293.91	92,456	—	—
2026/2031 (2)	\$ 350.20	389,588	—	—
		5,619,113	5,365,743	4,358,069

(1) Amounts have been converted to USD at the closing rate as of December 31, 2021.

(2) As of December 2021, the Company granted options for which the beneficiaries had a 60-day period to choose between a contractual term of five or ten years

	2021		2020		2019	
	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	5,365,743	\$ 142.87	4,358,069	\$ 78.23	3,536,651	\$ 37.54
Granted	882,584	314.99	1,797,652	266.71	1,365,172	144.38
Exercised	(503,282)	64.72	(602,463)	38.86	(419,317)	12.75
Forfeited	(125,932)	234.98	(187,515)	170.98	(124,437)	99.89
Outstanding at December 31	5,619,113	164.33	5,365,743	142.87	4,358,069	71.62
Exercisable at December 31	3,613,371	\$ 106.53	2,833,680	\$ 65.24	2,203,476	\$ 25.38

(*) amounts have been converted to USD at the closing rate of the respective period.

The weighted average share price at the date of exercise of options exercised during the year ended December 31, 2021 was \$305.9, compared to \$254.54 during the year ended December 31, 2020 and \$124.69 during the year ended December 31, 2019. The weighted average remaining contractual life of the stock options outstanding amounted to 6.3 years on December 31, 2021 compared to 7.08 years on December 31, 2020 and 7.27 years on December 31, 2019. The table below shows the weighted average remaining contractual life for each range of exercise price:

Exercise price (in \$)	Outstanding on December 31, 2021	Weighted average remaining contractual life (in years)
2.76 - 4.47	225,540	1.50
8.12 - 10.73	382,357	3.24
11.71 - 16.00	265,921	4.64
20.85 - 23.98	414,493	5.90
91.54 - 97.77	796,699	4.35
128.54 - 153.75	1,191,989	6.50
222.16 - 280.43	1,542,963	7.56
288.93 - 350.20	799,151	9.10

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 2021:

Stock options granted in	April 2021	July 2021	Oct 2021	Dec 2021 (1)
Number of options granted	67,833	280,339	144,824	389,588
Average Fair value of options (in \$) (*)	\$ 98.96 - 154.88	\$ 131.65 - 159.13	\$ 101.53 - 131.80	\$ 145.35 - 149.09
Share price (in \$) (*)	\$ 248.9 - 283.67	\$ 300.78 - 340.95	\$ 286.52 - 304.5	\$ 351.73
Exercise price (in \$) (*)	\$ 275.33	\$ 303.16	\$ 301.02	\$ 349.92
Expected volatility	54.24 - 60.08 %	45.58 - 47.96 %	46.01 - 48.46 %	43.57 - 43.58 %
Average Expected option life (in years)	4 - 6.50	4 - 6.50	4 - 6.50	6.15 - 6.50 (1)
Risk-free interest rate	(0.41) - (0.08) %	(0.41) - (0.17) %	(0.18) - (0.05) %	0.03 - 0.05 %
Expected dividends	— %	— %	— %	— %

(1) In December 2021, the Company granted a total of 389,588 stock options. The beneficiary can choose between a contractual term of five or ten years. The expected option life ranges between 6.15 and 6.50 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 \$45.0 million (100% of the stock options with a contractual term of five years) to \$57.1 million (100% of the stock options with a contractual term of ten years).

(*) amounts have been converted to USD at the applicable rate prevailing at the grant date.

Below is an overview of the parameters used in relation to the determination of the fair value of 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
Average Fair value of options (in \$) (*)	\$ 76.46 - 148.03	\$ 83.46 - 129.64	\$ 91.10 - 156.68	\$ 101.23 - 229.20
Share price (in \$) (*)	\$ 155.23 - 252.29	\$ 224.80 - 281.25	\$ 256.46 - 293.52	\$ 273.15 - 383.10
Exercise price (in \$) (*)	\$ 146.68	\$ 240.70	\$ 245.69	\$ 303.83
Expected volatility	44.44 - 64.77 %	43.46 - 52.19 %	44.17 - 52.71 %	46.80 - 59.94 %
Average Expected option life (in years)	4 - 6.68	4 - 6.68	4 - 6.68	4 - 6.68
Risk-free interest rate	(0.32) - (0.18) %	(0.43) - (0.28) %	(0.51) - (0.34) %	(0.51) - (0.28) %
Expected dividends	— %	— %	— %	— %

(*) amounts have been converted to USD at the closing rate of the respective period.

Below is an overview of the parameter 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 \$) (*)	\$ 71.28	\$ 64.81	\$ 46.51 - 74.58
Share price (in \$) (*)	\$ 138.40	\$ 142.00	\$ 146.15-169.30
Exercise price (in \$) (*)	\$ 127.49	\$ 127.49	\$ 152.50
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	— %	— %	— %

(*) amounts have been converted to USD at the closing rate of the respective period.

The total share-based payment expense recognized in the consolidated statements of comprehensive income totaled \$179.4 million for the year ended December 31, 2021, compared to \$96.9 million for the year ended December 31, 2020 and \$44.2 million for the year ended December 31, 2019.

15. Trade and other payables

(in thousands of \$)	At December 31,		
	2021	2020	2019
Trade payables	\$ 208,850	\$ 206,325	\$ 65,639
Short-term employee benefits	83,737	68,867	30,188
Other	828	—	—
Total trade and other payables	\$ 293,415	\$ 275,192	\$ 95,827

Trade payables correspond primarily to clinical and manufacturing activities and include accrued expenses related to these activities.

As of December 31, 2021 and December 31, 2020, the trade payables include accruals amounting to \$163.7 million and \$64.5 million, respectively, 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, 2021, 2020 and 2019 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,		
	2021	2020	2019
Zai Lab	\$ 151,903	—	—
Janssen	292,279	33,759	22,386
AbbVie	121	565	855
Agomab	—	—	1,684
Other	—	38	50
Upfront payments	444,303	34,362	24,975
Zai Lab	25,634	—	—
Janssen	22,865	2,641	1,738
AbbVie	102	762	30,077
Other	1,214	19	25
Milestone payments	49,815	3,422	31,840
Janssen	2,028	3,175	21,236
Other	298	284	411
Research and development service fees	2,326	3,459	21,647
Zai Lab	833	—	—
Other revenues	833	—	—
Total revenue	\$ 497,277	\$ 41,243	\$ 78,462

For the years ended December 31, 2021, 2020 and 2019, the majority of the revenue was generated under the agreements with Zai Lab, 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, 2021, 2020 and 2019.

(in thousands of \$)	Janssen	AbbVie	Other	Total
On January 1, 2019	\$ —	\$ 2,342	\$ 133	\$ 2,475
Received				
Upfront	328,327	—	—	328,327
Milestone	25,000	30,000	—	55,000
Revenue recognition				
Upfront	(22,386)	(855)	(50)	(23,291)
Milestone	(1,738)	(30,077)	(25)	(31,840)
Translation difference	(4,575)	107	(2)	(4,470)
On December 31, 2019	324,629	1,517	56	326,202
Received				
Milestone	—	—	—	—
Revenue recognition				
Upfront	(33,759)	(565)	(38)	(34,362)
Milestone	(2,641)	(762)	(19)	(3,422)
Translation difference	26,915	33	1	26,949
On December 31, 2020	315,144	223	—	315,367
Received				
Upfront	—	—	—	—
Milestone				
Revenue recognition				
Upfront	(292,279)	(121)	—	(292,400)
Milestone	(22,865)	(102)	—	(22,967)
On December 31, 2021	\$ —	\$ —	\$ —	\$ —

Below are summaries of the key collaborations.

Zai Lab

On January 6, 2021, argenx and Zai Lab announced the License agreement for the development and commercialization of efgartigimod in Greater China, granting Zai Lab the exclusive rights to develop and commercialize efgartigimod in Greater China.

Under the terms of the agreement, the Company received \$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, received in the first quarter of 2021, and an additional \$25 million milestone payment upon regulatory approval of efgartigimod by FDA 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.

With regard to this collaboration with Zai Lab:

- The Company concluded there are two performance obligations under IFRS 15, being the transfer of a license and the at arms-length supply of clinical and commercial product. The Company concluded that these performance obligations are distinct in the context of the contract.
- The Company concluded that the Subscription Shares granted by Zai Lab, as included in the Share Issuance Agreement, entered into on January 6, 2021, was obtained because of the existing obligations

under the terms of the Collaboration and License 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 payment of \$75 million in the form of newly issued Zai Lab shares, and a \$75 million guaranteed, non-creditable, non-refundable payment and \$25 million milestone upon approval of efgartigimod in the U.S. and the consideration received in return for the supply of clinical and commercial product. 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 associated with the contingent consideration is subsequently resolved. We estimate the amount to be included in the transaction price upon achievement of the milestone event or the supply of clinical and commercial product. Sales-based milestones and sales-based royalties are a part of the Company's arrangements but are not yet included in its revenue.
- The fixed part of the transaction price, as well as the \$25 million milestone upon approval of efgartigimod in the U.S. has been allocated to the transfer of a license performance obligation.
- The Company concludes that the license as of the effective date of the contract has standalone value. As such, the Company concluded that the promise in granting the license to Zai is to provide a right to use the entity's intellectual property as it exists at the point in time at which the license is granted and therefore, revenue accrued has been recognised at a point in time. This conclusion was reached, taking into account following aspects:
 - there are no material restrictions included in the contract which would prevent Zai Lab to direct the use of, and obtain substantially all of the remaining benefits, within Greater China and considering the sales-based royalties which become due to the Company upon successful commercialization.
 - the current phase of efgartigimod, successfully completed the Phase III trials.
- Under the collaboration agreement, the Company provides clinical and commercial supply to Zai Lab. Company concludes to recognize such sales as revenue given that the Company acts as principal in the transaction as the risk related to inventory is born by the Company until the inventory is transferred to Zai. The revenue related to clinical and commercial supply is recorded under line item "Other revenues" within the revenue footnote.

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, non-refundable, non-creditable payment of \$40 million 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.

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 collaboration and license agreements.

Janssen

On June 4, 2021, the Company received a termination notification from Cilag GmbH International, an affiliate of Janssen, which results in the termination of the Collaboration Agreement to jointly develop and commercialize cusatuzumab. As a result, the Company regains the worldwide rights to its anti-CD70 antibody cusatuzumab.

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. 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 was 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 was therefore considered to be part of the overall consideration received.

- The transaction price of these two agreements 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.
- The transaction price was allocated to the single performance obligation and revenue was previously 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.

Following the termination, the Company concluded that it has substantially satisfied the performance obligation, and as a consequence, recorded \$315.1 million for the 12 months ending December 31, 2021.

17. Other operating income

(in thousands of \$)	Year Ended December 31,		
	2021	2020	2019
Grants	\$ 4,398	\$ 1,365	\$ 2,563
Research and development incentives	13,970	10,257	5,373
Payroll tax rebates	12,621	9,095	6,413
Change in fair value on non-current financial assets	11,152	2,951	1,214
Total other operating income	\$ 42,141	\$ 23,668	\$ 15,563

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 \$14.0 million in the year ended December 31, 2021, compared to \$10.3 and \$5.4 million in the year ended December 31, 2020 and December 31, 2019, 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 \$12.6 million payroll tax rebates in the year ended December 31, 2021, compared to \$9.1 and \$6.4 million in the year ended December 31, 2020 and December 31, 2019, 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, Japan, Switzerland, Germany and France. Revenues are generated by external customers with their main registered office geographically located as shown in the table below.

(in thousands of \$)	Revenue from external customers		
	Year ended December 31,		
	2021	2020	2019 (*)
Denmark	\$ 1,389	\$ 342	\$ 488
Belgium	—	—	1,684
United States	317,396	40,901	76,290
China	178,370	—	—
Other	123	—	—
Total	\$ 497,277	\$ 41,243	\$ 78,462

(*) In prior periods this has been presented based on the geographical location of the contracting entity.

The non-current assets of the Company, with the exception of the deferred tax assets, are geographically located as shown in the table below:

(in thousands of \$)	Non-current assets		
	At December 31,		
	2021	2020	2019 (*)
Netherlands	\$ —	\$ 1	\$ 1
Belgium	268,733	200,125	63,785
United States	3,138	4,751	3,435
Japan	3,232	2,491	319
Switzerland	8	—	—
Total	\$ 275,111	\$ 207,368	\$ 67,540

(*) In prior periods this has been presented based on the geographical location of the contracting entity.

19. Research and development expenses

(in thousands of \$)	Year Ended December 31,		
	2021	2020	2019
Personnel expenses	\$ 160,464	\$ 86,036	\$ 51,172
External research and development expenses	382,902	259,943	152,889
Materials and consumables	2,735	3,562	2,267
Depreciation and amortization	3,742	2,835	1,840
Other expenses	30,677	18,509	12,603
Total research and development expenses	\$ 580,520	\$ 370,885	\$ 220,771

20. Selling, general and administrative expenses

(in thousands of \$)	Year Ended December 31,		
	2021	2020	2019
Personnel expenses	\$ 164,646	\$ 108,507	\$ 44,774
Professional fees	102,674	48,681	18,181
Supervisory board	12,958	4,838	3,127
Other Expenses	27,366	9,617	6,064
Total Selling, general and administrative expenses	\$ 307,644	\$ 171,643	\$ 72,146

21. Personnel expenses

The personnel expenses mentioned in note 19 and 20 above are as follows:

(in thousands of \$)	Year Ended December 31,		
	2021	2020	2019
Short-term employee benefits—Salaries	\$ 135,676	\$ 75,437	\$ 36,747
Short-term employee benefits—Social Security	12,785	9,087	3,996
Post-employment benefits	2,864	1,242	837
Termination benefits	818	1,005	722
Share-based payment	167,965	92,558	41,612
Employer social security contributions stock options	5,002	15,214	12,032
Total personnel expenses	\$ 325,110	\$ 194,543	\$ 95,946

The post-employment benefits relate to the pension plans the Company has in place for its employees.

The average number of full-time equivalents (FTE) employees by department is presented below:

Average Number of FTE	Year Ended December 31,		
	2021	2020	2019
Research and development	349.7	213.0	121.6
Selling, general and administrative	264.4	119.5	56.3
	614.1	332.5	177.9

22. Leases

The statement of financial position shows the following amounts relating to leases:

In thousands of \$	December 31,	Year Ended December 31,	
	2021	2020	2019
Right-of-use assets			
Buildings	\$ 9,688	\$ 7,677	\$ 6,264
Vehicles	1,664	1,513	836
Equipment	230	264	273
	\$ 11,583	\$ 9,454	\$ 7,373
Lease liabilities			
Current	\$ 3,509	\$ 3,476	\$ 2,218
Non-current	7,956	6,181	5,101
	\$ 11,465	\$ 9,657	\$ 7,319

Additions to the right-of-use assets amounted to \$5.7 million for the year ended December 31, 2021.

The table below shows a maturity analysis of the lease liabilities as on December 31, 2021:

(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	\$ 3,509	\$ 6,331	\$ 2,164	\$ —	\$ 12,004	\$ 11,465

The consolidated statements of profit or loss and the consolidated statements of other comprehensive income shows the following amounts relating to leases:

In thousands of \$	Year Ended December 31,		
	2021	2020	2019
Depreciation charges			
Buildings	\$ 2,714	\$ 2,262	\$ 1,472
Vehicles	651	441	261
Equipment	34	32	31
	<u>\$ 3,399</u>	<u>\$ 2,735</u>	<u>\$ 1,764</u>
Interest expense (included in finance cost)	\$ 412	\$ 201	\$ 117
Expense relating to short-term leases	212	264	137
Expense relating to leases of low-value assets that are not shown above as short-term leases	7	6	6

The total cash outflow for leases in 2021 and 2020 was \$4.5 million and \$3.0 million respectively.

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,		
	2021	2020	2019
Interest income	\$ 3,489	\$ 5,119	\$ 8,805
Net gain on current financial assets held at fair value through profit or loss and cash equivalents	144	1,340	7,317
Financial income	<u>\$ 3,633</u>	<u>\$ 6,459</u>	<u>\$ 16,122</u>
Net loss on current financial assets held at fair value through profit or loss and cash equivalents	\$ (3,482)	\$ (7,559)	\$ —
Other financial expense	(1,096)	(401)	(139)
Financial expense	<u>\$ (4,578)</u>	<u>\$ (7,960)</u>	<u>\$ (139)</u>
Realized exchange gains/(losses)	\$ 15	\$ (443)	\$ (385)
Unrealized exchange gains/(losses)	(50,068)	(125,791)	7,375
Exchange gains/(losses)	<u>\$ (50,053)</u>	<u>\$ (126,234)</u>	<u>\$ 6,990</u>

The exchange losses of \$50.1 million for the year ended December 31, 2021 were primarily attributable to unrealized exchange rate losses on our cash and cash equivalents and current financial assets position in EUR due to the unfavorable fluctuation of the EUR 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,		
	2021	2020	2019
Loss before taxes	\$ 399,743	\$ 605,352	\$ 175,919
Income tax calculated at 25%	99,936	151,338	43,980
Effect of expenses and gains that are not deductible in determining taxable results	(34,366)	(12,813)	(8,625)
Effect of stock issue expenses that are not deductible in determining taxable results	14,119	14,139	6,363
Effect of concessions	13,413	7,900	635
Effect of tax losses carried forward not recognized	(44,232)	(116,711)	(12,952)
Effect of different tax rates in jurisdictions in which the company operates	(2,084)	(195)	(58)
Deferred tax asset other than loss carryforwards not recognized	(50,389)	(45,601)	(30,336)
Withholding tax paid	(5,076)	—	—
(Underprovided)/overprovided in prior years	398	(1,014)	(4,310)
Other	(241)	(146)	15
Income tax expense recognized in the consolidated statements of profit or loss	\$ (8,522)	\$ (3,103)	\$ (5,289)

The tax rate used for the 2021, 2020 and 2019 reconciliations above is the corporate income tax rate of 25% payable by corporate entities in the Netherlands.

The unrecognized deferred tax asset on unused tax losses amounts to \$203.8 million on December 31, 2021, compared to \$174.2 million on December 31, 2020. 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 \$815.3 million on December 31, 2021, compared to \$696.7 million on December 31, 2020. 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 future, the Company did not recognize any deferred tax assets, with the exception of those further detailed in note 8.

As a company active in research and development in Belgium, we expect to benefit from the innovation income deduction, or IID, in Belgium. The innovation income deduction regime allows net profits attributable to revenue from among others patented products to be taxed at a lower effective tax rate than other revenues. At the end of 2021 and 2020, we had \$161.5 million and \$52.1 million of carry-forward IID in Belgium.

Income taxes were directly recognized in the income statement can be detailed as follows:

(in thousands of \$)	Year Ended December 31,		
	2021	2020	2019
Current year	\$ 15,224	\$ 7,847	\$ 5,289
Income tax prior years	(398)	1,732	—
Current tax expense	14,826	9,579	5,289
Originating and reversal of temporary differences	(6,304)	(6,476)	—
Deferred tax expense / (income)	(6,304)	(6,476)	—
Total tax expense	\$ 8,522	\$ 3,103	\$ 5,289

25. Loss per share

(in thousands of \$)	Year Ended December 31,		
	2021	2020	2019
Loss of the year	\$ (408,265)	\$ (608,455)	\$ (181,208)
Weighted average number of shares outstanding	51,075,827	45,410,442	38,619,121
Basic and diluted loss per share (in \$)	\$ (7.99)	\$ (13.40)	\$ (4.69)

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 2021, 2020 and 2019, 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		
		At December 31,		
		2021	2020 (*)	2019 (*)
Financial assets — non-current	FVTPL	\$ 17,459	\$ 6,307	\$ 2,916
Financial assets — non-current	FVTOCI	35,710	—	—
Research and development incentive receivables — non-current	Amortised cost	32,707	20,626	9,624
Restricted cash — non-current	Amortised cost	1,707	1,509	708
Trade and other receivables	Amortised cost	38,221	6,978	31,585
Financial assets—current	FVTPL	73,052	130,290	804,099
Financial assets—current	Amortised cost	929,000	649,359	324,400
Research and development incentive receivables — current	Amortised cost	—	463	293
Cash and bank balances	Amortised cost	242,494	297,156	116,531
Cash equivalents	FVTPL	997,092	858,291	—
Cash equivalents	Amortised cost	95,090	61,356	255,631
Trade and other payables	Amortised cost	293,415	275,192	95,827

(*) The historical consolidated financial information for 2020 and 2019 presented in this disclosure note has been adjusted to present the breakdown of current financial assets that are measured at FVTPL and amortized cost.

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 or OCI

Financial assets held at fair value through profit or loss or OCI 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 or OCI 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 weighted average maturity 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, 2021, 2020 and 2019 respectively:

(in thousands of \$)	At December 31, 2021		
	Level 1	Level 2	Level 3
Non-current financial assets	\$ 35,710	\$ —	\$ 17,459
Current financial assets	73,052	—	—
Cash Equivalents	997,092	—	—
Assets carried at fair value	\$ 1,105,854	\$ —	\$ 17,459

(in thousands of \$)	At December 31, 2020 (*)		
	Level 1	Level 2	Level 3
Non-current financial assets	\$ —	\$ —	\$ 6,307
Current financial assets	130,290	—	—
Cash Equivalents	858,291	—	—
Assets carried at fair value	\$ 988,581	\$ —	\$ 6,307

(*) The historical consolidated financial information for 2020 presented in this disclosure note has been adjusted to correct for the amounts of current financial assets that are measured at fair value.

(in thousands of \$)	At December 31, 2019 (*)		
	Level 1	Level 2	Level 3
Non-current financial assets	\$ —	\$ —	\$ 2,916
Current financial assets	804,099	—	—
Assets carried at fair value	\$ 804,099	\$ —	\$ 2,916

(*) The historical consolidated financial information for 2019 presented in this disclosure note has been adjusted to correct for the amounts of current financial assets that are measured at fair value.

During the disclosed calendar year, no transfers occurred between the applicable categories.

Non-current financial assets – Level 3

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 Immunology Innovative Program. In exchange for granting this license, the Company received a profit share in AgomAb Therapeutics NV.

In March 2021, AgomAb Therapeutics NV secured \$74 million in Series B financing by issuing 286,705 of Preferred B Shares. The Company used the post-money valuation of Series B financing round and the number of outstanding shares in determining the fair value of the profit-sharing instrument, which results in a change in fair value of non-current financial assets of \$11.2 million recorded through profit or loss. Since AgomAb Therapeutics NV is a private company, the valuation of the profit share is based on level 3 assumptions.

Non-current financial assets – Level 1

As part of the license agreement for the development and commercialization for efgartigimod in Greater China (see note 16 for further information), the Company obtained, amongst others, 568,182 newly issued Zai Lab shares calculated at a price of \$132 per share. The fair value of the equity instrument at period-end is determined by reference to the closing price of such securities at each reporting date (classified as level 1 in the fair value hierarchy), resulting in a change in fair value. The Company made the irrevocable election to recognize subsequent changes in fair value through OCI.

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, 2021, cash and cash equivalents amounted to \$1,334.7 million and total capital amounted to \$3,469 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 collaboration and license 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 company has adopted a policy whereby money market funds must have an average rating of "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 assets. 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 assets.

For the year ended December 31, 2021, if applicable interest rates would increase/decrease by 25 basis points, this would have a positive/negative impact of \$0.9 million (compared to \$1.7 million for the year ended December 31, 2020 and \$2.2 million for the year ended December 31, 2019).

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 Euro, Japanese yen, British pound and Swiss franc. To limit this risk, the Company attempts to align incoming and outgoing cash flows in currencies other than USD.

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

(in thousands of \$)	At December 31,		
	2021	2020	2019
EUR	591,887	703,016	578,483
JPY	6,316	264	856
GBP	1,237	48	4
CHF	727	2	1

On December 31, 2021, if the EUR/USD exchange rate would have increased/decreased by 10%, this would have had a negative/positive impact of \$53.81 million, compared to \$63.91 million and \$52.6 million on December 31, 2020 and December 31, 2019, respectively. On December 31, 2021, 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, 2021, the senior management consisted of 8 members: Chief Executive Officer, Chief Operating Officer, Chief Financial Officer, Chief Scientific Officer, General Counsel, Chief Medical Officer, Vice President Corporate Development and Strategy and Global Head of Quality Assurance. They provide their services on a full-time basis.

On December 31, 2021, the board of directors consisted of 8 members: Peter Verhaeghe, Don deBethizy, Pamela M. Klein, Werner Lanthaler, A.A. Rosenberg, James M. Daly, Yvonne Greenstreet and Tim Van Hauwermeiren.

Only the Chief Executive Officer is a member of both the senior management team and the board of directors. The Chief Executive Officer does not receive any remuneration for his board membership, as this is part of his total remuneration package in his capacity as member of the senior management team.

The remuneration package of the members of key management personnel comprises:

(in thousands of \$, except for the number of stock options & RSUs)	Year Ended December 31,		
	2021	2020	2019
Remuneration of key management personnel			
<i>Short-term benefits for senior management members as a group</i>			
Gross salary	\$ 3,465	\$ 3,246	\$ 2,829
Variable pay	2,020	1,510	1,091
Employer social security	789	753	910
Other short term benefits	274	156	137
Termination Benefits	382	385	526
<i>Post-employment benefits for senior management members as a group</i>	150	161	161
<i>Cost of stock options granted in the year for senior management members as a group</i>	15,060	42,824	24,457
<i>Cost of restricted stock units granted in the year for senior management members as a group</i>	8,025	—	—
<i>Employer social security cost related to stock options</i>	4,172	11,206	10,255
Total benefits for key management personnel	34,337	60,241	40,366
<i>Numbers of stock options granted in the year</i>			
Senior Management as a group	101,446	334,900	405,000
<i>Numbers of restricted stock units granted in the year</i>			
Senior Management as a group	22,888	—	—
Remuneration of non-executive directors			
<i>Board fees and other short-term benefits for non-executive directors</i>	435	405	423
<i>Cost of stock options granted in the year for non-executive directors</i>	3,263	9,576	4,847
<i>Cost of restricted stock units granted in the year for non-executive directors</i>	1,731	—	—
Total benefits for non-executive board members	\$ 5,429	\$ 9,981	\$ 5,270
<i>Numbers of stock options granted in the year</i>			
Non-executive directors	22,950	70,000	70,000
<i>Numbers of restricted stock units granted in the year</i>			
Non-executive directors	5,100	—	—

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	\$ —	\$ —	\$ 1,437	\$ 17,718	\$ 19,155

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). In 2021, the Company initiated a Phase 1 clinical trial using Halozyme's proprietary ENHANZE® drug delivery technology (triggering a \$5.0 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 \$312.4 million.

30. Audit fees

The following auditors' fees were expensed in the income statement:

Fees	Year Ended December 31,		
	2021	2020	2019
	in thousands of \$		
Audit Fees (1)	\$ 1,183	\$ 923	\$ 817
Audit-related Fees	267	188	178
Tax Fees (2)	79	—	—
All other Fees	—	—	—
Total	\$ 1,529	\$ 1,111	\$ 995

- (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 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 five subsidiary, argenx US, Inc., based in the United States of America, argenx Japan KK, based in Japan, argenx Switzerland SA, based in Switzerland, argenx France SAS based in France and argenx Germany GmbH based in Germany. 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
argenx France SAS	90065093800013	France	100.00 %	Pharmaceuticals and pharmacy supplies merchant wholesalers
argenx Germany GmbH	HRB 268437	Germany	100.00 %	Pharmaceuticals and pharmacy supplies merchant wholesalers

32. Events after the balance sheet date

No events have occurred after the Balance Sheet date that could have a material impact on the consolidated financial statements.

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EQUITY INCENTIVE PLAN 2021

as approved by the board of directors of argenx SE on
15 December 2021

1. INTRODUCTION

1.1. PURPOSE

Our mission is to transform patients' lives by providing them with life-changing medicines which build on scientific breakthroughs in immunology. Our future success is largely dependent on our ability to attract and retain highly qualified individuals such as you, and to motivate and incentivize you to contribute to our long-term success.

At argenx, we have a *pay-for-performance* culture, of which long term equity incentive grants are a key component. This plan is designed to maximally align your interests as a key person with those of our (other) stakeholders, and serves to:

- (i) make you a *co-owner* of our business, allowing you to share in sustainable future success of argenx;
- (ii) incentivize you to *favor long term value creation* over short term success;
- (iii) *reward you based on your contributions* to our mission, by making new grants subject to your performance; and
- (iv) *promote your long-term commitment* to argenx by making the vesting of incentive grants subject to long-term commitment to and involvement with argenx.

1.2. TYPES OF INSTRUMENTS

This plan allows for the granting of two distinct types of equity incentives, being **stock options** and **RSUs**:

Stock options are a right to purchase a given number of argenx shares in the future against the *fair market value* of those shares at the date of grant, allowing you to benefit from the value increase (if any) on argenx shares after the grant date of your stock options. The *fair market value* exercise price of stock options is equal to the closing price of argenx shares on the Euronext Brussels stock exchange on the last trading day prior to the date of grant.

Restricted Stock Units (or **RSUs**) are a right for you to receive argenx shares for free at a predefined moment in the future.

2. GRANTING EQUITY INCENTIVES

2.1. ELIGIBILITY TO PARTICIPATE IN THIS PLAN

You are eligible to participate in this plan because you are an employee, key consultant, board member, senior manager or key outside advisor of argenx (referred to in this plan as a **key person**). You will not receive equity incentives prior to your first or after your last workday with argenx.

2.2. ANNUAL GRANTS, SIGN-ON GRANTS

Subject to your continued status as key person, you may receive grants of equity incentives under this plan. Our board of directors will establish an equity incentive grant allocation scheme determining the criteria for determining the number of equity incentives granted to you and/or any additional equity incentives granted to you as a *sign-on* grant, if any, based on your position and your performance. The equity incentive grant allocation scheme will furthermore define the dates throughout the year on which equity incentive grants may be made to new key persons and/or existing key persons.

2.3. NO ENTITLEMENT TO GRANTS

The granting of equity incentives to you hereunder is in each case subject to a resolution of our board of directors, and our board of directors requires an authorization from our general meeting of shareholders to be able to grant equity incentives to you. If at any time our board of directors does not have such authorization from our general meeting or otherwise decides it is not in the best interest of argenx to grant equity incentives to you hereunder, our board of directors can decide not to grant any further equity incentives, or to grant fewer or different equity incentives to you, each time as it deems fit and in the best interest of argenx.

3. VESTING MECHANISM

3.1. GENERAL

To promote your long term commitment to argenx, equity incentives granted to you are subject to a vesting scheme, meaning they are earned and become exercisable (in the



EQUITY INCENTIVE PLAN 2021

case of stock options) or will be settled (in case of RSUs) over the course of your multi-year commitment to argenx. Unvested stock options cannot be exercised and unvested RSUs cannot be settled.

3.2. VESTING SCHEME

3.2.1. Stock options vest over a period of 3 years, as follows:

- (i) 1/3rd of the total grant on the first anniversary of the date of grant; and
- (ii) 1/36th of the total grant on the first day of each month following the first anniversary of the date of grant.

3.2.2. RSUs vest over a period of 4 years with 1/4th of the total grant vesting at each anniversary of the date of grant.

3.2.3. The number of equity incentives to vest on each vesting date is rounded to the nearest whole number, and if rounded down the difference is added to the next vesting moment, if rounded up the difference is deducted from the next vesting moment. Any remaining equity incentives vest on the last day of the applicable vesting period for such grant (meaning 3 years for stock options and 4 years for RSUs).

3.3. ACCELERATED VESTING

All of your unvested stock options will become immediately vested and exercisable and all of your unvested RSUs will become immediately vested and will be settled if:

- (i) argenx SE is dissolved or put into liquidation;
- (ii) argenx SE sells or otherwise disposes of all or substantially all of its assets; or
- (iii) a change of control over argenx SE occurs (as further defined in section 8.1).

3.4. LEAVING ARGENX

3.4.1. If you leave argenx, the date on which you will be deemed to have left argenx is the last calendar day of your contract term with argenx. If you are dismissed by argenx, the date per which you are deemed to have left argenx is the date of dismissal set out in the written notice of termination or dismissal sent to you by argenx.

3.4.2. Per the date you are deemed to have left argenx, all your then remaining unvested stock options and RSUs will terminate without compensation, unless:

- (i) you are leaving argenx due to your death or permanent disability; or
- (ii) the board of directors decides that (part of) your options and RSUs will fully vest,

in which case your unvested options and RSUs (or a part thereof pursuant to (ii)) will vest on the last day prior to you having left argenx.

4. EXERCISING AND SETTLEMENT OF EQUITY INCENTIVES

4.1. TRANSACTIONS IN EQUITY SECURITIES - GENERAL

4.1.1. This equity incentive plan should be read in conjunction with, and is fully subject to, the argenx insider trading policy, including the restrictions on exercising stock options and buying or selling argenx equity as set out therein.

4.1.2. In any case, you may not buy argenx securities (through the exercise of stock options or otherwise) or sell argenx securities (whether those shares originate from the settlement of RSUs or otherwise) if the company is in a closed period or if you possess inside information. Violation of the insider trading policy and/or of applicable securities law may lead to dismissal and even criminal prosecution, and may harm the reputation of argenx.

4.1.3. We use an online equity portal to manage equity incentives granted by argenx, to document the grant and acceptance of new equity incentives and for further communication pertaining to equity incentives. Access to any online equity portal will be provided to you through our HR team and may be subjected to the acceptance of specific terms and conditions for using such portal.

We may at any time decide to stop using an online equity portal, to switch to a different provider or to use a different mechanism for managing equity incentives. Your access to any such online or other system may be subject to you accepting the terms and conditions of third party service provider(s).

4.1.4. Please note that there is no guarantee that there will be a buyer for your shares at your asking price or at all and if there is a market for the shares it may not be possible to execute the full sale order on the same day.

4.2. EXERCISING STOCK OPTIONS

4.2.1. You can enter orders to exercise vested stock options in the online equity portal. The intermediary designated by argenx SE will then create shares in argenx SE equal to the number of stock options exercised, and either (i) transfer the shares to you, against payment by you of the full amount of the exercise price (plus taxes, see section 5 below) to argenx, or (ii) sell the shares on the Euronext stock exchange, using the proceeds to pay the exercise price of the shares to argenx SE,



EQUITY INCENTIVE PLAN 2021

and the remainder (after taxes, see section 5 below) to your bank account.

4.2.2. The term of stock options is 10 years and stock options will lapse and are no longer exercisable after the lapse of 10 years from the date of grant.

4.2.3. If you leave argenx (or are dismissed) and are no longer a key person, you must exercise any vested options before the later of (i) 90 days after your last working day at argenx or (ii) 31 March of the 4th year following the date of grant of those options, and in any case no later than the expiration date of the option.

4.3. SETTLEMENT OF VESTED RSUS

4.3.1. If you hold vested RSUs on the first business day following the second Monday of January, April, July and October of any year, argenx SE will issue shares to your securities account set up through the equity portal. The number of shares delivered to you will be the number of vested RSUs held by you, minus a number of shares required to cover employee taxes payable by argenx on your behalf in relation to such RSUs. Further details regarding this mechanism as well as a calculation example is provided in schedule A to this plan. The equity portal may also offer you the opportunity to manage your equity stake in argenx SE and may allow you to give sell orders regarding shares held by you.

4.3.2. If you do not have a securities account you will not be able to receive shares, and if you do not receive the shares ultimately within the first 2.5 months following the year in which the RSUs vested, you will forfeit those shares without compensation.

4.3.3. RSUs do not give you any shareholder rights. Shares issuable in relation to vested RSUs do not give you shareholder rights or the ability to transfer such shares, *unless and until* they are issued and transferred by us to your securities account.

4.3.4. If our board of directors so decides in relation to a change of control (or any party acquiring control over argenx SE through a change of control so decides), RSUs may at all times be settled in cash, in which case the holder of such RSU shall receive an amount equal to the amount per share payable in relation to such change of control, minus the amount of income or employee social security tax payable thereon, if any.

5. TAXATION – JURISDICTION SPECIFIC RULES

5.1. GENERAL – TAX LIABILITY

5.1.1. You are fully liable and responsible for any income and/or employee social security taxes due in relation to the equity incentives granted hereunder, including the receipt and

exercise of stock options, the receipt and settlement of RSUs and the sale of any shares underlying stock options or RSUs, as may be the case.

5.1.2. If you fail to pay your taxes in full and/or on time and any tax and/or social security authority subsequently raises a claim in relation thereto against argenx, we will be entitled to reclaim from you any amounts payable by argenx, including through set-off against any amounts payable by argenx to you (if any). argenx will furthermore be entitled to withhold any income, employee social security and/or any other taxes due in relation to the receipt or exercise of stock options, the vesting of the RSUs, the sale and/or the delivery of the shares from any proceeds from the exercise of stock options, the sale and/or the delivery of the shares.

5.2. SPECIFIC TAX JURISDICTIONS

We have the right to deviate from this plan and to implement additional or different terms for stock options and/or RSUs granted to key persons under any specific local tax regime, if we deem this necessary or beneficial to argenx or the key person. Such deviations, to the extent they apply to all key persons subject to a certain tax jurisdiction, are set out schedules to this plan. We may amend the jurisdiction specific tax schedules from time to time be at our discretion.

5.3. TAXES DUE UPON SETTLEMENT OF RSUS

5.3.1. If any income or employee social security tax is payable by argenx on your behalf in relation to shares deliverable to you upon the vesting of RSUs, argenx may reduce the number of shares issuable to you with a number of shares required to cover such income and social security tax payments on your behalf. In doing so:

- (i) the value of shares shall be deemed to be the closing price of the shares on Euronext Brussels on the last trading day preceding the date on which the shares are issued to you;
- (ii) the number of shares deliverable to you shall be rounded down to the nearest whole number of shares; and
- (iii) argenx accepts no liability in case the calculation of taxes by argenx on your behalf was incorrect and/or any additional tax (of any kind) is payable by you on the shares received, under local tax rules applicable to you.

5.3.2. argenx may also decide, at its sole discretion, to opt for another way to recover/finance the tax due on your behalf,



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such as withholding such taxes from other payments due by argenx to you.

6. DEVIATIONS FROM THE PLAN, AMENDMENTS TO GRANTS AND TO THE PLAN

6.1. DEVIATIONS FROM THE PLAN

Our board of directors may decide from time to time at its discretion, to deviate from the terms of this plan for any particular grant or set of grants of equity incentives to key persons, including with regard to the number of equity incentives to be granted (if any) and the vesting period.

6.2. AMENDMENTS TO THE PLAN

Our board of directors may amend this plan from time to time and may decide that the terms of an amended or new plan prevail over the terms of this plan, also for stock options and/or RSUs granted prior to the date of such new or amended plan.

6.3. AMENDMENTS TO INDIVIDUAL GRANTS

argenx is entitled to amend the terms of any grant of stock options and/or RSUs granted hereunder if we deem this beneficial to you or to argenx, for reasons of tax compliance or otherwise, but we will compensate you for any direct negative financial impact such amendment would have on you (if any).

6.4. STOCK OPTIONS GRANTED UNDER A PRIOR STOCK OPTION PLAN

Stock options which were granted to you under a previous stock option plan of argenx shall continue to vest in accordance with the vesting scheme then applicable. The terms of the previous option plan(s) are otherwise aligned with (albeit more detailed in) this plan, but this plan shall in any case not change the terms of equity incentives granted to you under previous equity incentive plans administrated by argenx.

7. STATUTORY DIRECTORS AND SENIOR MANAGERS

7.1. GENERAL

7.1.1. Members of our board of directors are not allowed to exercise stock options within the first 3 years following the date of grant of such stock options.

7.1.2. Members of our board of directors and senior managers who qualify as Person Discharging Managerial Responsibilities

(PDMR) under the European Market Abuse Regulation (C-level and other key argenx executives reporting directly to our Chief Executive Officer) have a personal obligation by law to notify the Dutch Financial Markets Authority (*Autoriteit Financiële Markten*) of any transactions in equity instruments in argenx SE, including the grant or exercise of stock options or RSUs and the purchase or sale of any shares in argenx SE.

7.1.3. Specific arrangements (if any) regarding the accelerated vesting of options set out in your employment or engagement contract with argenx will apply also to RSUs granted hereunder.

7.2. NON-EXECUTIVE DIRECTORS

7.2.1. In deviation from section 3.2.1, stock options granted to non-executive directors vest on the third anniversary of the date of grant.

7.2.2. In deviation from section 3.4, unvested stock options and RSUs granted to non-executive directors shall terminate without compensation if, and per the date on which, the non-executive director (i) is dismissed as non-executive director by the company's general meeting, (ii) unilaterally terminates his/her relationship with argenx by resigning as non-executive director prior to the end of such fixed appointment term other than at the written request of the board of directors or (iii) resigns following a written request thereto from the board of directors on the basis of such non-executive director's functioning. If a non-executive director serves up to the end of his/her fixed appointment term and the situations set out in (i) through (iii) above do not apply, then the RSUs and stock options granted to such non-executive director over the course of such fixed appointment term shall continue to vest in accordance with their vesting scheme. In case of ceasing services due to death or permanent disability of the non-executive director, the unvested options and RSUs will vest on the last day prior to ceasing services for argenx.

8. OTHER PROVISIONS

8.1. DEFINITIONS

As used in this plan, the following terms have the following meanings:

board of directors means the statutory board of directors of argenx SE;

business day means a day other than a Saturday, a Sunday or any day on which banks in Amsterdam, the Netherlands are closed due to a public holiday in the Netherlands;



EQUITY INCENTIVE PLAN 2021

argenx means the argenx group consisting of argenx SE and each of its direct and indirect 100% subsidiaries;

argenx SE means argenx SE, a European public company (*societas europaea*) incorporated and registered in the Netherlands and registered with the Dutch chamber of commerce under number 24435214;

change of control means any transaction or series of transactions in which a third party (together, if applicable, with persons acting in concert with any such third party) acquires a controlling interest in argenx SE which it does not have prior to such transaction or series of transactions;

controlling interest means (i) the ownership or control (directly or indirectly) of more than 50% of the voting share capital of argenx SE (ii) the ability to direct the casting of more than 50% of the votes exercisable at general meetings of argenx SE on all, or substantially all, matters, or (iii) the right to appoint or remove directors of argenx SE;

date of grant means the date on which your equity incentives are deemed granted, which shall be determined by the board of directors in accordance with the equity allocation scheme and shall be communicated to you through the online equity portal or otherwise in a manner decided by argenx; and

equity incentives means stock options and RSUs granted under this plan.

Where reference is made to 'argenx' in the context of a specific right or obligation for argenx, this shall be construed with respect to you, as a reference to the argenx legal entity with which you have entered into an employment agreement, consultancy agreement or other (service) agreement making you a key person of argenx.

8.2. NON-TRANSFERABILITY

Equity incentives, whether vested or not, are strictly personal and are not transferable other than upon your death, by operation of the laws of inheritance applicable to you in your jurisdiction. Shares obtained by you through the exercise or settlement of equity incentives, are transferable unless specific restrictions apply to you pursuant to this plan and/or to the operation of local tax laws applicable to you or otherwise.

8.3. STEADY COURSE OF ACTION

The board of directors follows a steady course of action in the granting of stock options and RSUs under this plan. In relation to this:

- (i) the number of equity incentives to be granted to any key person shall be within the limits of the equity incentive allocation scheme in force from time to time;
- (ii) a person granted equity incentives hereunder shall be deemed to have automatically accepted such equity incentives on the date of grant and may not refuse such grant.

8.4. APPLICABLE LAW

The validity, construction, and effect of this plan shall be determined in accordance with the laws of the Netherlands.



EQUITY INCENTIVE PLAN 2021

SPECIAL RULES FOR KEY PERSONS TAXED IN BELGIUM

BELGIAN TAXED KEY PERSONS

In deviation from the plan, the following rules shall apply to equity incentives granted to you under this plan for which you are obligated to pay income taxes in Belgium.

ACCEPTANCE OF STOCK OPTIONS

In deviation from section 8.3(ii), from the date of grant of stock options, you will need to accept such stock options within 60 days following the date of grant. If you do not accept the stock options within this timeframe, you will lose the stock options without any compensation from argenx. Acceptance of stock options is done through the argenx equity portal, unless argenx has specified another method of acceptance to you in writing.

EXERCISABILITY OF STOCK OPTIONS

Stock options are not exercisable before the 1st of January of the 3rd year following the year during which the date of grant of such stock options occurred.

Illustration: If a stock option is granted in 2020, it may not be exercised before 1 January 2024.

OPTION TERM

Upon accepting a grant of stock options, you have the choice to elect either a 5-year term or a 10-year term for the stock options. If you opt for a 5 year term, your stock options will – in deviation from section 4.1.1 of the plan – lapse and be no longer exercisable after the 5th anniversary of the date of grant.

MIRROR OPTIONS

If you are liable to pay taxes upon the date of grant of your stock options, and you choose to finance the tax burden through the use of a third party financing option using *mirror options*, then (i) the number of stock options corresponding to the number of mirror options granted by you to such third party necessary to finance the full amount of such taxation (but no more) at grant, shall become immediately and irrevocably vested and (ii) section 4.2.3 shall not apply to such immediately and irrevocably vested stock options. The total number of unvested stock options remaining shall vest in accordance with the vesting scheme of section 3.2.1, calculated as if the total amount of unvested stock options remaining represented the full option grant.

UNRECOVERABLE PRE-FINANCED TAXES

If (i) you have paid income taxes at the moment options were granted to you without using a third-party mirror option financing structure; and (ii) you are subsequently not able to recover these income taxes because during the exercise window for your options (i.e. from the moment they are exercisable up to the end of their validity term) the price of argenx shares did not exceed the exercise price by an amount sufficient for you to recover the amount of taxes you pre-financed; and (iii) your option term lapsed and you did not exercise any stock options that were part of the specific grant to which (i) and (ii) apply, then argenx will reimburse you for taxes you have pre-financed following the lapse of your vested options (at the end of their term).

HOLDING PERIOD

Upon receiving shares in relation to the settlement of RSUs, we may offer you the opportunity to opt for a holding period of 2 years during which you cannot sell (or enter into other transactions, including hedging transactions regarding) those shares, to enable applicability of a lower taxation rate for your benefit.



EQUITY INCENTIVE PLAN 2021

SPECIAL RULES FOR KEY PERSONS TAXED IN THE UNITED STATES OF AMERICA

US TAXED KEY PERSONS

In deviation from the plan, the following rules shall apply to equity incentives granted to you under this plan for which you are obligated to pay income taxes in the United States.

409A STATUS

It is intended that the equity incentives (as defined in section 8.1) granted under the plan shall be exempt from Section 409A of Internal Revenue Code of 1986 (as amended, supplemented and/or updated from time to time) (the "**Code**") and this plan shall be interpreted in a manner consistent with such exemption. In the event the equity incentives are not exempt, the plan is intended to satisfy the requirements of section 409A of the Code and shall be interpreted in a manner consistent with such status.

LIMITATIONS ON DEVIATIONS

Deviations from the terms of the plan for equity incentive grants thereunder will be limited to deviations that would be permitted under section 409A of the Code.

For any "specified employee" within the meaning of Section 409A of the Code, no payments in respect of any equity incentives that are subject to Section 409A of the Code and which would otherwise be payable upon "separation from service" (as defined in Section 409A of the Code) shall be made prior to the date that is six months after the date of such specified employee's "separation from service" or, if earlier, the date of the specified employee's death. Following any applicable six month delay, all such delayed payments will be paid in a single lump sum on the earliest date permitted under Section 409A of the Code that is also a business day. Notwithstanding any other provision of the plan, argenx makes no guarantee that the equity incentives comply with or are exempt from Section 409A of the Code and argenx shall have no liability for the failure of the terms of this plan or any equity incentives to comply with or be exempt from the provisions of Section 409A of the Code.

SPECIAL RULES FOR KEY PERSONS TAXED IN CANADA

CANADA TAXED KEY PERSONS

In deviation from the plan, the following rules shall apply to equity incentives granted to you under this plan for which you are obligated to pay income taxes in Canada.

NO CASH SETTLED RSUS

In deviation from section 4.3.4, RSUs may not be settled in cash.

SPECIAL RULES FOR KEY PERSONS TAXED IN SWITZERLAND

SWITZERLAND TAXED KEY PERSONS

In deviation from the plan, the following rules shall apply to equity incentives granted to you under this plan for which you are obligated to pay income taxes in Switzerland.

HOLDING PERIOD

argenx may decide to put a mandatory holding period of 2 years during which you cannot sell (or enter into other transactions, including hedging transactions regarding) shares received from settling RSUs, to enable applicability of a lower taxation rate for your benefit.

SPECIAL RULES FOR KEY PERSONS TAXED IN THE NETHERLANDS

NETHERLANDS TAXED KEY PERSONS

In deviation from the plan, the following rules shall apply to equity incentives granted to you under this plan for which you are obligated to pay income taxes in the Netherlands.

HOLDING PERIOD

Upon receiving shares in relation to the settlement of RSUs, we may offer you the opportunity to opt for a holding period of 2 years during which you cannot sell (or enter into other transactions, including hedging transactions regarding) those shares, to enable applicability of a lower taxation rate for your benefit.

SUBSIDIARIES

<u>Subsidiary</u>	<u>Jurisdiction of Incorporation</u>
argenx BV	Belgium
argenx IIP BV	Belgium
argenx US, Inc.	United States
argenx Japan KK	Japan
argenx Switzerland SA	Switzerland

**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 21, 2022

/s/ Tim Van Hauwermeiren

Name: Tim Van Hauwermeiren

Title: Chief Executive Officer

(Principal Executive Officer)

**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, Karl Gubitz, 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 21, 2022

/s/ Karl Gubitz

Name: Karl Gubitz

Title: Chief Financial Officer

(Principal Financial Officer)

**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, 2021 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 21, 2022

/s/ Tim Van Hauwermeiren

Name: Tim Van Hauwermeiren

Title: Chief Executive Officer

(Principal Executive Officer)

**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, 2021 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 21, 2022

/s/ Karl Gubitz

Name: Karl Gubitz

Title: Chief Financial Officer

(Principal Financial Officer)

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in Registration Statements No. 333-258253 and 333-225375 on Form S-8 and Registration Statement No. 333-258251 on Form F-3 of our reports dated March 21, 2022, 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, 2021.

Deloitte Accountants B.V.

Rotterdam

March 21, 2022
