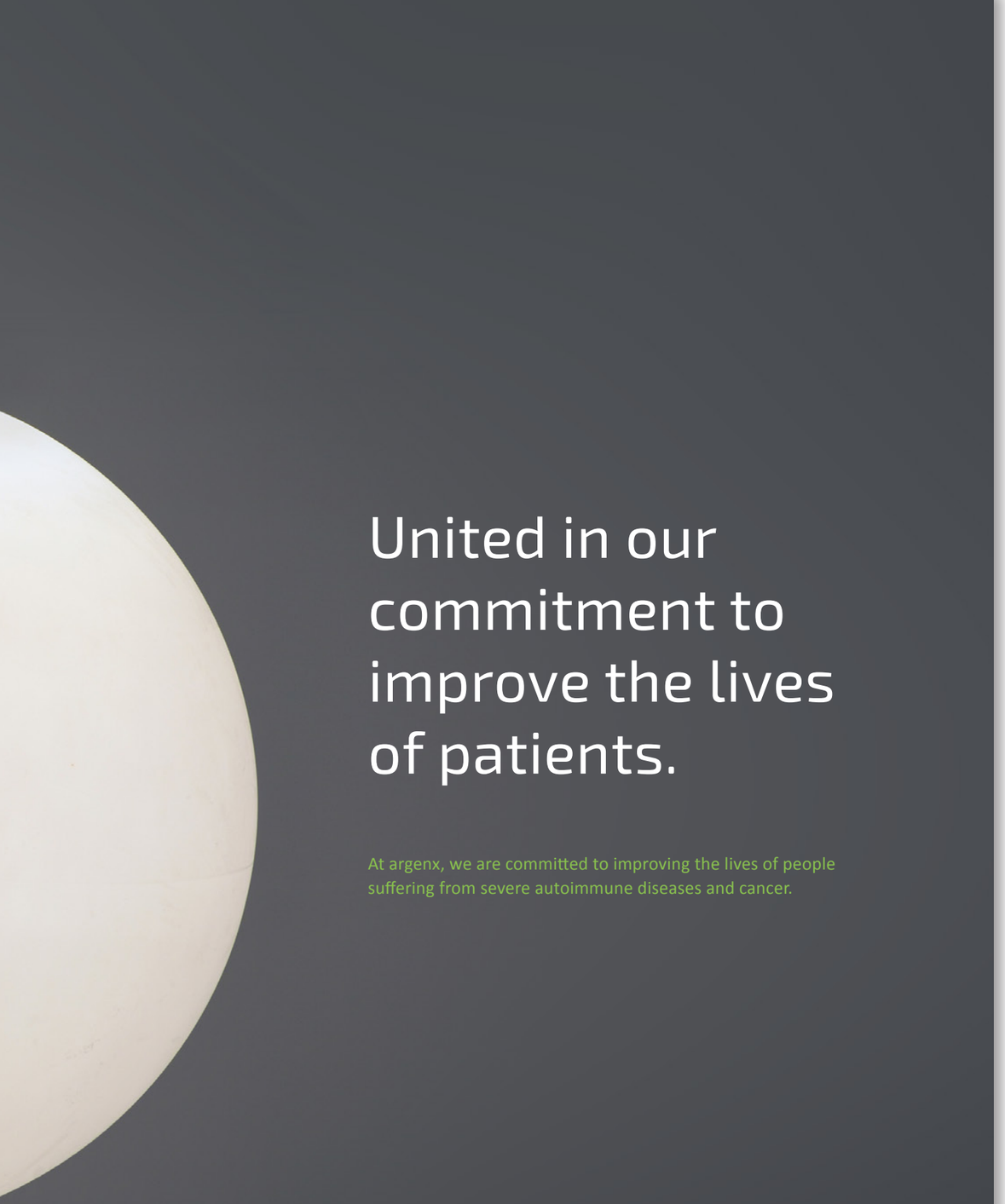
argenx

Annual Report 2020



United in our commitment to improve the lives of patients.

At argenx, we are committed to improving the lives of people suffering from severe autoimmune diseases and cancer.

argenx

Annual Report 2020

We See You,
We Hear You,
We Are Here With You

Each day at argenx, we are motivated to pursue a better tomorrow alongside patients.

As your ally, we pioneer innovations to advance the understanding of rare diseases; we want to deliver immunology treatments to patients worldwide. We listen to patients, supporters and advocacy communities; we hear your stories and share your determination.

Registration Document, dated March 30, 2021

argenx SE (hereinafter **argenx**) is a European public company (Societas Europaea) incorporated under the laws of the Netherlands with its statutory seat in Rotterdam, the Netherlands, which is listed in Belgium and the United States of America. This document constitutes a universal registration document (the ***Registration Document***) within the meaning of article 9 of Regulation 2017/1129 of the European Parliament and of the Council of the European Union (the ***Prospectus Regulation***) and has been prepared by argenx SE (argenx and hereinafter jointly with its subsidiaries also the ***Company***) in accordance with the Prospectus Regulation, annex 1 and 2 of Commission Delegated Regulation (EU) 2019/980. This Registration Document contains the information referred to in article 4 of Directive 2004/109/EG and as such pursuant to article 9, clause 12 of the Prospectus Regulation shall also satisfy the Company's obligations to publish an annual report within the meaning of the aforementioned regulation.

The Company is subject to the risks and uncertainties described in the chapter "Risk Factors" of this Registration Document. In accordance with the Prospectus Regulation and accompanying delegated regulations, guidelines and recommendations, the risks set out in this chapter "Risk Factors" have been limited to those risks which are (i) known to the Company, (ii) which the Company considers specific to the Company and (iii) which the Company considers material to its business, its financial condition and/or results of operations. As a result, and by definition the risk factors described in chapter 1 "Risk Factors" do not provide an exhaustive list of material risks the Company faces or may face. The disclosure of risks in this Registration Document may not meet the requirements of risk disclosure applicable in other jurisdictions.

This Registration Document, particularly in chapter 2 "To our Shareholders", chapter 3 "Business" and in chapter 4 "Management's discussion and analysis of financial condition and results of operations", contains forward-looking statements. All statements other than present and historical facts and conditions contained in this Registration Document, 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 Registration Document, 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. We refer to chapter 1 "Risk factors" for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Registration Document 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, these statements should not be regarded 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. This Registration Document and the documents that we reference in this Registration Document should be read 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.

Only the information included in this Registration Document or in the documents specified in chapter 7 "Information Incorporated by Reference" should be deemed part of this Registration Document.

Patient Stories

We integrate our patients aspirations into how we innovate, how we conduct research and design trials, and how we can support you in the daily struggles you face living with a rare disease.

There is a common purpose across argenx that is driven by your resilience and we welcome this opportunity to be with you on this journey.

Together we discover,
Team argenx

Patients living with MG

30 Kait Masters

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Together
We Discover

The science of co-creation drives our quest to engineer innovative immunology solutions – but it is the resilient spirit of patients that fuels our urgency to deliver them.

Our goal is to treat the person, not the disease, across all of our programs. We believe that through collaboration with patients and their supporters, we can create medicines that aim to address the real-life burden faced by rare disease communities.

1

Risk Factors

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1 Risk Factors

The occurrence of any of the events or circumstances described in these risk factors, individually or together with other circumstances, could have a material adverse effect on the business, results of operations, financial condition and prospects of the Company. These are not the only risks the Company faces. Additional risks and uncertainties not presently known to the Company or that it currently considers immaterial or not specific may also impair its business, results of operation and financial condition.

1.1 Risk Factors Related to Our Financial Position and Need for Additional Capital

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

We are a clinical-stage biopharmaceutical company with a limited operating history. We do not currently have any approved products and have never generated any revenue from product sales. Since our inception, we have incurred significant operating losses, totaling €758.5 million of cumulative losses over the financial years 2018, 2019 and 2020. Our losses resulted principally from costs incurred in research and development, preclinical testing, clinical development of our product candidates as well as costs incurred for research programs, pre-commercial activities and from general and administrative costs associated with our operations. In addition, we expect to continue to incur significant costs associated with our listings in the United States and in Europe. In the future, we intend to continue to conduct research and development, preclinical testing, clinical trials and regulatory compliance activities and we intend to continue our efforts to establish a sales, marketing and distribution infrastructure. These expenses, together with anticipated general and administrative expenses, will result in incurring further significant losses for at least the next several years. We anticipate that our expenses will increase substantially if and as we execute our business plan as further set out in chapter 3 “Business” on page 70 and further and as we experience delays or encounter issues relating thereto, including failed studies, ambiguous trial results, safety issues or other regulatory challenges. If our losses become greater than expected, we may require additional financing than anticipated and such financing may not be available to us on acceptable terms or at all.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, discovering and developing additional product candidates, obtaining regulatory approval for any product candidates that successfully complete clinical trials, establishing manufacturing and marketing capabilities and ultimately selling any products for which we may obtain regulatory approval. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability. For instance, even if we receive approval of and commercialize efgartigimod for the treatment of MG in the United States, we can provide no assurances that we will be able to achieve profitability based on sales in that indication alone or that we will be able to receive approval of and commercialize efgartigimod in other indications or in other countries.

Even if we do generate product royalties or product sales, we may never achieve or sustain profitability on a quarterly or annual basis. Our failure to achieve or sustain profitability could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations and as such could have a material adverse impact on our business, financial condition and results of operations.

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

Notwithstanding our significant position of cash and cash equivalents and current financial assets as of December 31, 2020, we expect to require additional funding in the future to sufficiently finance our operations, to advance development of our product candidates and to continue our business activities relating to research and development and the commercialization of our products. Our future capital requirements for efgartigimod or our preclinical programs will depend on many factors, including those set out in the paragraph 4.1.3 “Liquidity and Capital Resources” on page 153 and further.

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

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

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

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

1.2 Risk Factors Related to the Development and Clinical Testing of Our Product Candidates

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

For our clinical trials to succeed and in order to obtain the requisite regulatory approvals to market and sell any of our product candidates, we or our collaborators for such candidates must successfully demonstrate through extensive preclinical studies and clinical trials that our products are safe, pure and potent or effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process and our future clinical trial results may not be successful. There is a high failure rate for drugs and biologics proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies, and any such setbacks in our clinical development could have a material adverse effect on our business, operating results and financial condition.

We may experience delays in our ongoing clinical trials, including as a result of COVID-19, and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed, suspended, or terminated for a large variety of reasons outside our control, including delays of approval from regulatory authorities, institutional review boards or ethics committees, delays or failure to recruit or retain patients, failures of third parties to comply with regulatory or contractual requirements or issues relating to the quantity, quality or stability of the product candidate.

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

Clinical trials must be conducted in accordance with the EMA, FDA, PMDA and other applicable regulatory authorities' legal requirements and regulations and are subject to oversight by these governmental agencies and IRBs at the medical institutions where the clinical trials are conducted or ethics committees. In addition, clinical trials must be conducted with supplies of our product candidates produced under current good manufacturing practices, or cGMP, requirements and other regulations. Furthermore, we rely on contract research organizations or CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance. We depend on our collaborators and on medical institutions and CROs to conduct our clinical trials in compliance with Good Clinical Practice, or GCP, requirements. To the extent our collaborators or the CROs or investigators fail to enroll participants for our clinical trials, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays or both, which may harm our business. In addition, clinical trials that are conducted in countries outside the European Union and the United States may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non-European Union and non-U.S. CROs, as well as expose us to risks associated with clinical investigators who are unknown to the EMA, FDA or other regulatory authorities, and apply different standards of diagnosis, screening and medical care.

Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned Investigational New Drug applications, or INDs, in the United States or Japan, or a Clinical Trial Authorization Applications, or CTAs, in Europe, or a comparable application in other jurisdictions. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the EMA, FDA or other regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of these product candidates. Thus, we cannot be sure that we will be able to submit INDs or CTAs or comparable applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or CTAs or comparable applications will result in the EMA, FDA or other regulatory authorities allowing clinical trials to begin.

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

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

The time required to obtain approval by the FDA, the EMA and comparable foreign authorities is unpredictable but typically takes many years, if obtained at all, following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. We have limited experience in submitting and supporting the applications necessary to seek regulatory approvals and expect to rely on third-party CROs to assist us in this process. Securing regulatory approval requires the submission of extensive nonclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities.

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

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

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

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

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

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

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

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

Our product candidates are classified as biologics in the United States and, therefore, can only be sold if we obtain a BLA from the FDA and therefore cannot be sold in the United States if we do not obtain a BLA. The holder of a BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The holder of a BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process.

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

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

Undesirable side effects that may be caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the EMA, FDA or other comparable regulatory authorities. While our preclinical and clinical studies for our product candidates to date show that our product candidates have generally been well tolerated from a risk-benefit perspective, we have observed adverse events and treatment emergent adverse events in our clinical studies to date, and we may see additional adverse events and treatment emergent adverse events or TEAEs in our ongoing and future trials, which may be more serious than those observed to date, and as a result, our ongoing and future trials may be negatively impacted. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, results of operation and financial condition significantly. Further, because all of our product candidates and preclinical programs, other than efgartigimod, are based on our SIMPLE AntibodyTM platform, any adverse safety or efficacy findings related to any product candidate or preclinical program may adversely impact the viability of our other product candidates or preclinical programs.

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

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

Any of these events could prevent us, our collaborators or our potential future partners from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our products. For example, we understand that another company developing an FcRn antagonist recently initiated a voluntary pause of its ongoing clinical trials after an observed signal of elevated total cholesterol and LDL levels in one of its ongoing trials. We have evaluated efgartigimod in over 350 subjects and patients and we are not aware of any elevation of cholesterol markers related to treatment with efgartigimod. However, if we were to observe unexpected adverse events of whatever kind, our trials could be similarly paused and it could have a material adverse effect on our ability to further the advancement of our product candidates.

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

The market for pharmaceutical products is highly competitive. Our competitors include many established pharmaceutical companies, biotechnology companies, universities and other research or commercial institutions, many of which have substantially greater financial, research and development resources than we have. A detailed analysis of the intense competition we face in the autoimmune field, the field of leukemia and lymphoma and the monoclonal antibody drug discovery field is set out in paragraph 3.1.3 “Competitive Position” on page 76 and further. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing pharmaceutical products. Smaller and early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, the development of our products.

The fields in which we operate are characterized by rapid technological change and innovation. There can be no assurance that our competitors are not currently developing, or will not in the future develop, technologies and products that are equally or more effective or are more economically attractive than any of our current or future technology or product. Competing products or technology platforms may gain faster or greater market acceptance than our products or technology platforms and medical advances or rapid technological development by competitors may result in our product candidates or technology platforms becoming non-competitive or obsolete before we are able to recover our research and development and commercialization expenses. If we, our product candidates or our technology platforms do not compete effectively, it is likely to have a material adverse effect on our business, financial condition and results of operation.

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

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

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

1.2.7 We may become exposed to costly and damaging liability claims.

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

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

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

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

1.3 Risk Factors Related to Commercialization of Our Product Candidates

1.3.1 We will face significant challenges in successfully commercializing our products.

We are in the process of setting up our sales and marketing infrastructure, have no experience in the sale or marketing of pharmaceutical products and may not timely have the appropriate infrastructure in place yet (including, such as information technology, enterprise resource planning and forecasting). To achieve commercial success for any approved product, we must develop or acquire a sales and marketing organization, outsource these functions to third parties or enter into collaboration arrangements with third parties. We plan to establish our own sales and marketing capabilities and promote our product candidates if and when regulatory approval has been obtained in the major European Union countries, the United States and Japan. There are risks involved should we decide to establish our own sales and marketing capabilities or enter into arrangements with third parties to perform these services. Even if we establish sales and marketing capabilities, we may fail to launch our products effectively or to market our products effectively. Recruiting and training a sales force is expensive and costs of creating an independent sales and marketing organization and of marketing and promotion could be above those anticipated by us. In addition, recruiting and training a sales force is time consuming and could delay any product launch. In the event that any such launch (e.g. the expected launch of efgartigimod in MG in the U.S.) is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

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

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

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

When available on the market, our products may not achieve an adequate level of acceptance by physicians, patients and the medical community, and we may not become profitable. For instance, our product candidates may not achieve an adequate level of acceptance by physicians because of dosing complexity or from patients because of infusion fatigue. In addition, efforts to educate the medical community and third-party payers on the benefits of our products may require significant resources and may never be successful which would prevent us from generating significant revenues or becoming profitable. Market acceptance of our future products by physicians, patients and healthcare payers will depend on a number of factors, many of which are beyond our control, including, but not limited to:

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

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

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

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty. See also chapter 3 "Business" on page 70 and further.

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

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

In the United States, the European Union and other foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. A detailed description of the relevant legislative and regulatory initiatives and changes is contained in paragraph 3.8.7 “Healthcare Reform” on page 133 and further. If such legislative and/or regulatory initiatives and changes would lead to increased restrictions on marketing our products, or lead to limiting the funds available for healthcare in jurisdictions relevant to us which may reduce reimbursement levels and is likely to affect the prices we may set, we would be negatively impacted in our ability to successfully and profitably market our product candidates.

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

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

Although we do not currently have any products on the market, our current and future operations may be directly, or indirectly through our customers and third-party payors, subject to various U.S. federal and state, European, Japanese and Chinese healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute. Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. These laws may impact, among other things, our proposed sales, marketing and education programs and constrain our business and financial arrangements and relationships with third-party payors, healthcare professionals who participate in our clinical research program, healthcare professionals and others who recommend, purchase, or provide our approved products, and other parties through which we market, sell and distribute our products for which we obtain marketing approval. In addition, we may be subject to patient data privacy and security regulation by both the U.S. federal government and the other states and countries in which we conduct our business. Finally, our current and future operations are subject to additional healthcare-related statutory and regulatory requirements and enforcement by regulatory authorities in jurisdictions in which we conduct our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements. We have no experience in the sale or marketing of pharmaceutical products and, in light of any future approval and commercialization, we will need to continue building an internal program to ensure compliance with the different health care laws and regulations. The establishment of an internal compliance program will involve substantial costs and the program may not be successful in complying with the different reporting requirements. For an overview of some of the laws and regulations which may affect our ability to operate, please refer to the paragraph 3.8.6 “Healthcare Law and Regulation” on page 131 and further.

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

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time and resource consuming and can divert a company’s attention from the business. For further details and examples, we refer to paragraph 3.8.6 “Healthcare Law and Regulation” on page 131 and further.

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

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

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

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

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

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

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

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

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

We may from time to time seek orphan drug designation in the United States or Europe for certain indications addressed by our product candidates. For example, in September 2017, the FDA granted orphan drug designation for the use of efgartigimod for the treatment of MG, in January 2019 the FDA granted orphan drug designation for the use of efgartigimod for the treatment of Primary Immune Trombocytopenia and for the use of cusatuzumab for the treatment of acute myeloid leukemia. Even if we are able to obtain orphan designation, we may not be the first to obtain marketing approval for such indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan drug is approved, the FDA or the EMA can subsequently approve the same drug with the same active moiety for the same condition if the FDA or the EMA concludes that the later drug is safer, more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

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

Even if our product candidates are approved for marketing, sales of such product candidates will depend, in part, on the extent to which third-party payors, including government health programs in the United States (such as Medicare and Medicaid) and other countries, commercial health insurers, and managed care organizations, provide coverage and establish adequate reimbursement levels for such product candidates. Moreover, increasing efforts by governmental and third-party payors in the European Union, the United States, China and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. For instance, access to efgartigimod for the treatment of MG may be restricted by limited payer coverage due to treatment criteria, which may prevent us from realizing its full commercial potential. A detailed analysis of some of the most relevant developments and challenges regarding coverage and reimbursement is set out in the paragraph 3.8.4 "Coverage, Pricing and Reimbursement" on page 127 and further.

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.

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

Our current and future arrangements with providers, researchers, consultants, third-party payors and customers are subject to broadly applicable national, federal and state fraud and abuse, anti-kickback, false claims, transparency and patient privacy laws and regulations and other healthcare laws and regulations that may constrain our business and/or financial arrangements.

We will be required to spend substantial time and money to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations. Recent healthcare reform legislation has strengthened these federal and state healthcare laws (for more information see paragraph 3.8.6 "Healthcare Law and Regulation" on page 131 and further). 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.

1.4 Risk Factors Related to Our Business and Industry

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

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

Failure to (timely) comply with regulatory requirements could have far reaching consequences for us, including significant delay in our product development as a result of regulatory authorities recommending non-approval or restrictions on approval of a product candidate. Any failure or delay of any of our product candidates in clinical studies or to receive regulatory approval could have a material adverse effect on our business, results of operations and financial condition. If any of our product candidates fails to obtain approval on the basis of any applicable condensed regulatory approval process, this will prevent such product candidate from obtaining approval in a shortened time frame, or at all, resulting in increased expenses which would materially harm our business.

Regulations differ substantially per jurisdiction and are subject to constant change. In order to market our future products in regions such as the European Economic Area, United States of America, Asia Pacific and many other foreign jurisdictions, we must obtain separate regulatory approvals. The approval procedures vary among countries and can require additional clinical testing, and the time required to obtain approval may differ from that required to obtain approval. Moreover, clinical studies conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the EMA, the FDA or the PMDA does not ensure approval by the comparable authorities in other countries, and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other foreign countries or by the EMA, the FDA or the PMDA.

There can be no assurance that our product candidates will fulfil the criteria required to obtain necessary regulatory approval to access the market. Also, at this time, we cannot guarantee or know the exact nature, precise timing and detailed costs of the efforts that will be necessary to complete the remainder of the development of our research programs and product candidates. Each of the FDA, EMA and other comparable regulatory authorities may impose its own requirements, may discontinue an approval or revoke a license, may refuse to grant approval, or may require additional data before granting approval, notwithstanding that approval may have been granted by the FDA, EMA or one or more other comparable foreign authority. The FDA, EMA or other comparable regulatory authorities may also approve a product candidate for fewer or more limited indications or patient sub-segments than requested or may grant approval subject to the performance of post-marketing studies. The EMA's, the FDA's or other regulatory authority's approval may be delayed, limited or denied for a number of reasons, most of which are beyond our control. Such reasons could include, among others, the production process or site not meeting the applicable requirements for the manufacture of regulated products, or the products not meeting applicable requirements for safety, purity or potency, or efficacy, during the clinical development stage or after marketing.

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

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

The time required to obtain approval by the FDA, EMA and comparable regulatory authorities is unpredictable but typically takes many years, if obtained at all, following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market any of our product candidates, including efgartigimod for the treatment of gMG, which would significantly harm our business, results of operations and prospects.

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

1.4.2 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.

Kait

Setting and Readjusting Life Goals with Myasthenia Gravis

Kait Masters was an active, self-described type-A preteen when she began experiencing myasthenia gravis symptoms. It marked the beginning of a journey defined by a relentless pursuit to stay active and engaged in business, family and the MG community. The Gig Harbor, Washington, native shares the importance of setting and readjusting goals throughout your myasthenia gravis journey.

Patient Story

What was it like to be diagnosed with myasthenia gravis at a young age?

I'm a working mom, small business owner, artist—and a person living with myasthenia gravis. I was 11 years old when I was diagnosed. Before that, I was the typical type-A child. I was involved in everything, and I wanted to be the best at all of it. I played soccer, was in dance and took music lessons. When I was 10, I started having trouble seeing, so my parents got me glasses. Then I told my parents I was tired all the time, and they assumed it was a growth spurt. Those were my first symptoms. I didn't understand what was happening until I started sleeping 18 hours a day and missing a lot of school. Back then, I didn't have the emotional intelligence to communicate what I thought about being diagnosed with myasthenia gravis. But now I can tell you I was scared and confused.

Have your symptoms varied over the years?

When I was diagnosed, I had difficulty with vision, chewing and swallowing. With the help of my doctor, I was able to manage my symptoms except for fatigue, which was persistent. However, my symptoms returned when I was in college. I had a lot more difficulty breathing. Since then, my most persistent symptoms have been shortness of breath and fatigue.

You once lost a job because of your myasthenia gravis symptoms. What did you learn from that?

The biggest thing I learned was that hiding my MG diagnosis from coworkers and my boss wasn't helping me. It was difficult to request the accommodations I needed, particularly when they had no idea how sick I was. It was one of the hardest parts of navigating the perception of illness in the workplace. If I had been honest from the start, I might have received the support I needed to continue working there. I realize that not everyone is comfortable sharing their personal information. But it was very empowering to me. I learned from that experience and shared my MG diagnosis with colleagues at my next job.

1.4.3 Our employees and relevant third parties may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, consultants, vendors and collaboration partners may engage in fraudulent conduct or other illegal activities. Misconduct by these parties could include intentional, reckless and negligent conduct or unauthorized activities that violate: (i) the regulations of the FDA, EMA and other comparable regulatory authorities, including those laws that require the reporting of true, complete and accurate information to such authorities; (ii) manufacturing standards; (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and in other countries; or (iv) laws that require the reporting of true, complete and accurate financial information and data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, results of operations and financial condition, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other U.S. or international healthcare programs, individual imprisonment, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, other sanctions, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. These risks may be particularly heightened given our lack of experience with commercialization and the rapid growth of our sales and marketing function. Furthermore, due to the highly regulated environment in which we operate and our heavy reliance on approval of our products by governmental entities and healthcare providers, reputational risks related to the misconduct or other improper behavior as described above are likely to have a bigger impact on us than on most companies operating in other industries.

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

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

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

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

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

Our long-term growth strategy to develop and market additional products and product candidates is heavily dependent on precise, accurate and reliable scientific data to identify, select and develop promising pharmaceutical product candidates and products. Our business decisions may therefore be adversely influenced by improper or fraudulent scientific data sourced from third parties. Any irregularities in the scientific data used by us to determine our focus in research and development of product candidates and products could have a material adverse effect on our business, prospects, financial condition and results of operations.

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

Our product candidates are biologics and require processing steps that are more difficult than those required for most chemical pharmaceuticals. Accordingly, multiple steps are needed to control the manufacturing processes. Problems with these manufacturing processes, such as capacity issues, or even minor deviations from the normal process or from the materials used in the manufacturing process, which may not be detectable by us in a timely manner, could lead to manufacturing failures or product defects, resulting in lot failures, product recalls, product liability claims and insufficient inventory. Furthermore, our supply chain failures would create a risk of non-compliance toward partners due to shortages, for example, if argenx BV is not able to deliver its product to its partner in China.

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

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

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

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

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

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

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

1.5 Risk Factors Related to Our Dependence on Third Parties

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

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

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

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

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

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

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

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

Our dependence on collaborative partners subjects us to a number of risks, including, but not limited to termination of the collaboration agreements with all its consequences, disagreement on the interpretation of contractual terms or no adherence or uncertainties as part of the ongoing collaboration.

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

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

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

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

We and our third-party suppliers may also be subject to audits by the FDA, EMA or other comparable regulatory authorities. If any of our third-party suppliers fails to comply with cGMP or other applicable manufacturing regulations, our ability to develop and commercialize the products could suffer significant interruptions. We face risks inherent in relying on a single CMO, as any disruption, such as a fire, pandemic, natural hazards or vandalism at the CMO could significantly interrupt our manufacturing capability. Alternative production plans in place or disaster-recovery facilities available to us may not be sufficient. In case of a disruption, we may have to establish additional alternative manufacturing sources. This would require substantial investment on our part, which we may not be able to obtain on commercially acceptable terms or at all. Additionally, we may experience significant manufacturing delays as we build or locate replacement facilities and seek and obtain necessary regulatory approvals. If this occurs, we will be unable to satisfy manufacturing needs on a timely basis, if at all. Also, operating any new facilities may be more expensive than operating our current 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 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.

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

We have collaborated, and plan to continue to collaborate, with third parties on product candidates that we believe have promising utility in disease areas or patient populations that are better served by resources of larger biopharmaceutical companies. See section 3.6 "Material Contracts and Collaboration Agreements" on page 107 and further for a description of these collaborations. As part of some of these collaborations, our collaboration partners are responsible for providing us with financial information regarding specific projects, including funds spent, liabilities incurred and expected future costs, on which we rely for our own financial reporting. In the event that our collaboration partners fail to provide us with the necessary financial information within the agreed upon timeframes, or if such financial information proves partially inaccurate, this is likely to impact the accuracy of our own financial reporting. Our reliance on financial information received from our collaboration partners may impact our own internal and external financial reporting and any delay in the provision of such financial information to us or any failure by us to identify mistakes in the financial information provided to us may cause our own financial statements to be partially inaccurate. Any inaccuracy in our financial reporting could cause investors to lose confidence in our financial reporting. This in turn may lead to reputational damage and/or affect our ability to, and the terms on which we may, obtain future (equity) financing which may harm our business.

1.6 Risk Factors Related to Intellectual Property

1.6.1 We rely on patents and other intellectual property rights to protect our product candidates and platform technologies. Failure to enforce or protect these rights adequately could harm our ability to compete and impair our business.

Our commercial success depends in part on obtaining and maintaining patents and other forms of intellectual property rights for our product candidates, methods used to manufacture those products and the methods for treating patients using those products, or on licensing in such rights. Specifically, we are materially dependent on patent and other proprietary protection related to our core platform technologies, described in paragraph 3.4.2 “Platform Technologies” on page 104, and our product candidates, as described in paragraph 3.4.3 “Product Candidates: Wholly-Owned Programs” and paragraph 3.4.4 “Product Candidates: Partnered Programs”, on page 106 and further. Failure to protect or to obtain, maintain or extend adequate patent and other intellectual property rights could materially adversely affect our ability to develop and market our products and product candidates. The enforcement, defense and maintenance of such patents and other intellectual property rights may be challenging and costly.

We cannot be certain that patents will be issued or granted with respect to applications that are currently pending. As a biopharmaceutical company our patent position is uncertain because it involves complex legal and factual considerations. The standards applied by the European Patent Office, the United States Patent and Trademark Office, or USPTO, and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biopharmaceutical patents. Consequently, patents may not issue from our pending patent applications. As such, we do not know the degree of future protection that we will have on our proprietary products and technology. The scope of patent protection that the European Patent Office and the USPTO will grant with respect to the antibodies in our antibodies product pipeline is uncertain. It is possible that the European Patent Office and the USPTO will not allow broad antibody claims that cover antibodies closely related to our product candidates as well as the specific antibody. As a result, upon receipt of EMA or FDA approval, competitors may be free to market antibodies almost identical to ours, including biosimilar antibodies, thereby decreasing our market potential. However, a competitor cannot submit to the FDA an application for a biosimilar product based on one of our products until four years following the date of approval of our “reference product,” and the FDA may not approve such a biosimilar product until 12 years from the date on which the reference product was approved. See paragraph 3.8.2 “Licensure and Regulation of Biologics in the United States” on page 113 and further for more details regarding biosimilar regulatory exclusivities.

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

Because patent applications are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our licensors were the first to file any patent application related to a product candidate. Furthermore, as to the United States, if third parties have filed such patent applications on or before March 15, 2013, an interference proceeding can be initiated by such third parties to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. If third parties have filed such applications after March 15, 2013, a derivation proceeding can be initiated by such third parties to determine whether our invention was derived from theirs. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing our invention where the other party can show that they used the invention in commerce before our filing date, or if the other party is able to obtain a compulsory license. Any of the aforementioned situations could cause harm to our ability to protect our intellectual property, which in turn would allow competitors to market comparable products which could materially adversely affect our competitive position and as such our business, financial condition and results of operation.

1.6.2 Issued patents could be found invalid or unenforceable if challenged in court.

To protect our competitive position, we may from time to time need to resort to litigation in order to enforce or defend any patents or other intellectual property rights owned by or licensed to us, or to determine or challenge the scope or validity of patents or other intellectual property rights of third parties. Enforcement of intellectual property rights is difficult, unpredictable and expensive, and many of our or our licensors’ or collaboration partners’ adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors or collaboration partners can. Accordingly, despite our or our licensors’ or collaboration partners’ efforts, we or our licensors or collaboration partners may not prevent third parties from infringing upon or misappropriating intellectual property rights we own or control, particularly in countries where the laws may not protect those rights as fully as in the European Union and the United States. We may fail in enforcing our rights—in which case our competitors may be permitted to use our technology without being required to pay us any license fees. In addition, however, litigation involving our patents carries the risk that one or more of our patents will be held invalid (in whole or in part, on a claim-by-claim basis) or held unenforceable. Such an adverse court ruling could allow third parties to commercialize our products or use our SIMPLE AntibodyTM, NHance® and ABDEG™ platform technologies, and then compete directly with us, without payment to us.

If we were to initiate legal proceedings against a third party to enforce a patent covering one of our products, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States or in Europe, defendant counterclaims alleging invalidity or unenforceability are commonplace. A claim for a validity challenge may be based on failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. A claim for unenforceability could involve an allegation that someone connected with prosecution of the patent withheld relevant information from the European Patent Office or the USPTO or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our products or certain aspects of our SIMPLE AntibodyTM, 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.

1.6.3 Intellectual property rights of third parties could adversely affect our ability to commercialize our product candidates and may harm our competitive position.

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

It is also possible that we failed to identify relevant patents or applications. For example, certain U.S. applications filed after November 29, 2000 that will not be filed outside the United States may remain confidential until patents issue. In general, patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing from which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our products or platform technology could have been filed by others without our knowledge. Furthermore, we operate in a highly competitive field, and given our limited resources, it is unreasonable to monitor all patent applications purporting to gain broad coverage in the areas in which we are active. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies, our products or the use of our products.

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

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

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

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

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

Our involvement in litigation, and in, e.g., any interference, derivation, reexamination, inter partes review, opposition or post-grant proceedings or other intellectual property proceedings inside and outside of the European Union or the United States may divert management time from focusing on business operations, could cause us to spend significant amounts of money and may have no guarantee of success. Potential intellectual property litigation could also, amongst other things, force us to stop selling, incorporating, manufacturing or using certain of our products, to obtain a license to sell or use certain technology from a third party asserting its intellectual property rights, to redesign certain products or processes that use any allegedly infringing or misappropriated technology or pay damages, including the possibility of treble damages in a patent case if a court finds us to have willfully infringed certain intellectual property rights, which may result in significant cost and/or delay to us. Moreover, certain licenses may not be available on reasonable terms, or at all, or may be non-exclusive thereby giving our competitors access to the same technologies licensed to us and redesigning certain products or processes could be technically infeasible.

1.6.5 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.

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

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

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

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

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

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

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

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

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

1.6.8 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.

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

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

Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act and similar legislation in the European Union. The Hatch-Waxman Act permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. The

patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent applicable to an approved drug may be extended. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner than we expect. As a result, our revenue from applicable products could be reduced, possibly materially.

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

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

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

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

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

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

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

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

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

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

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

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

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

1.7 Risk Factors Related to Our Organization and Operations

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

Our success depends upon the continued contributions of our key management, scientific and technical personnel, many of whom have been instrumental for us and have substantial experience with our therapies and related technologies. These key management individuals include the members of our board of directors and executive management, as described in detail in section 6.3 “Our Executive Management“ on page 187 and further.

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.

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

We have grown significantly in number of employees and scope of operations over the recent years and expect to experience significant growth in the number of our employees and the scope of our operations also in the near future, particularly in the areas of drug research, drug development, regulatory affairs and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources and may dilute our corporate culture, which in turn may make it more difficult to attract and retain employees. Any inability to manage growth could delay the execution of our business plans or disrupt our operations, which in turn could materially harm our business and prospects.

1.7.3 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.

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

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

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

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

Due to the international scope of our operations and the significant position of cash we need to have available to continue our business activities, our assets, earnings and cash flows are influenced by movements in exchange rates of several currencies. Our net sales and costs will be affected by fluctuations in the rate of exchange particularly between the U.S. dollar, our new functional currency as per January 1, 2021, and the euro, Swiss francs, Japanese Yen and British pounds, which are our main financing and potential revenue currencies beyond the U.S. dollar. The majority of our operating expenses are paid in euros, but we also receive payments and we regularly acquire services, consumables and materials in euros, Swiss francs and British pounds. As a result, our business may be affected by fluctuations in foreign exchange rates between the U.S. dollar and other currencies, which may also have a significant impact on our reported results of operations and cash flows from period to period. Currently, we do not have any exchange rate hedging arrangements in place.

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

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

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

Our effective tax rates could be adversely affected by changes in tax laws, treaties and regulations, both internationally and domestically, or the interpretation thereof by the relevant tax authorities, including changes to the patent income deduction, possible changes to the corporate income tax base, wage withholding tax incentive for qualified research and development personnel in Belgium and other tax incentives and the implementation of new tax incentives such as the innovation deduction. For example, whether the tax authorities in Belgium will agree with argenx BV's qualifications and proposed application of patent box tax advantages will have a significant taxation impact on argenx BV. An increase of the effective tax rates could have an adverse effect on our business, financial position, results of operations and cash flows.

In addition, we may not be able to use, or changes in tax regulations may affect the use of, certain unrecognized tax assets or credits that we have built over the years. For instance, as of December 31, 2020, we had €567.8 million of consolidated tax loss carry forwards. In general, some of these tax losses carry forwards may be forfeited in whole, or in part, as a result of various transactions, or their utilization may be restricted by statutory law in the relevant jurisdiction. Any corporate reorganization by us or any transaction relating to our shareholding structure may result in partial or complete forfeiture of tax loss carry forwards. For instance, under Belgian law, argenx BV may lose its tax loss carry forwards and other tax incentives in case of a change of control, through an acquisition or otherwise, not meeting legitimate financial or economic needs as well as in case of a tax neutral reorganization, such as a merger or a demerger, involving argenx BV. The tax burden would increase if profits, if any, could not be offset against tax loss carry forwards.

2 To Our Shareholders

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Tim Van Hauwermeiren

Peter Verhaeghe

"As much as we are rooted in science, our focus is on the patients"

To Our Shareholders

Message from the CEO and the chairman of our Board of Directors

Dear Shareowners,

2020 was a transformational year for argenx. In the face of a global pandemic, we are proud to have delivered on all of our business objectives as we transition to an integrated, global immunology company. We completed the year with the submission of a Biologics License Application (BLA) for efgartigimod in generalized myasthenia gravis (gMG) supported by our Phase 3 data. We also initiated an impressive number of new clinical trials and will soon have seven global trials underway for efgartigimod across six indications with both IV and SC formulations.

We believe efgartigimod is the type of asset which has the potential to build a great company. We are working every day to advance our broad, late-stage efgartigimod pipeline with the goal of unveiling potential new indications as quickly as possible.

argenx was founded around an antibody engineering discovery and we will always be rooted in scientific innovation. To that end, we continue to invest in the expansion of our pipeline of differentiated potential first-in-class antibody assets. We progressed ARGX-117, a C2-inhibitor, into clinical development and now have a second potential pipeline-in-a-product opportunity within our neuromuscular franchise. We are moving forward with the early development work of ARGX-118 targeting Galectin-10 and ARGX-119, the latest pipeline compound out of our Immunology Innovation Program. We believe we are building a pipeline that is as broad as it is deep and that MG is just the beginning of our journey to be an integrated, immunology company.

As much as we are rooted in science, our focus is on the patients. Our teams have done an incredible job connecting with the patient communities we aim to serve. We have listened to their needs and learned from their experiences in an effort to truly work alongside rare disease patients and their supporters. In partnership with the MG community, we launched MG United, a digital lifestyle resource that offers clear and credible information to people affected by MG. We were thrilled to premiere A Mystery to Me, a first-of-its-kind documentary series that depicts the experience of living with this rare, chronic autoimmune disease.

Entering 2021, we are ready to scale our organization with confidence and with the goal of reaching patients globally for the first time. We are very grateful to our fellow Argonauts in Boston, Ghent and Tokyo for their steadfast dedication to our bold mission of transforming the field of immunology. We remain focused and driven by the resilient spirit of the patients who we know are waiting for us.

Thank you,

Tim Van Hauwermeiren & Peter Verhaeghe

2020 In Brief

Operational Highlights

Despite the challenges of the COVID-19 pandemic, argenx remained focused to execute its plan to become a fully integrated immunology company through its "argenx 2021" vision, including building two commercial franchises in neuromuscular indications and hematology/oncology, with the potential to expand to include a third commercial franchise.

Neuromuscular Franchise

Efgartigimod ARGX-113

- Announced positive topline data from the Phase 3 ADAPT trial of efgartigimod in May 2020.
- Presented additional data consistent with positive topline results from Phase 3 ADAPT trial of efgartigimod at the Myasthenia Gravis Foundation of America (MGFA) 2020 Virtual Scientific Session and American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) 2020 Virtual Annual Meeting.
- Filed a Biologics License Application (BLA) by year-end 2020 with the U.S. Food and Drug Administration (FDA) for efgartigimod in generalized myasthenia gravis (gMG) with an expected commercial launch in 2021.
- Phase 2 ADHERE trial evaluating efficacy and safety of SC ENHANZE®-efgartigimod in approximately 130 patients with active chronic inflammatory demyelinating polyneuropathy (CIDP) ongoing.
- Initiated bridging study for SC ENHANZE® efgartigimod in gMG based on association between total IgG reduction and clinical benefit. The study is a registrational, non-inferiority trial comparing the pharmacodynamic effect of 1000mg SC ENHANZE® efgartigimod with 10mg/kg IV efgartigimod and is expected to enroll approximately 50 patients.
- Engaged the U.S. Food and Drug Administration (FDA) on the potential bridging strategy for 1,000mg subcutaneous SC ENHANZE® efgartigimod in gMG, and received feedback from the FDA.
- ADHERE trial ongoing evaluating SC ENHANZE® efgartigimod in chronic inflammatory demyelinating polyneuropathy (CIDP), and completed enrollment of first 30 patients. The "GO" decision was announced on 1 February 2021 based on evaluation of interim safety as well as efficacy assessments that surpassed pre-defined "GO" threshold. 130 patients targeted for enrollment to support registrational program in CIDP.

ARGX-117

- Initiated Phase 1 healthy volunteer trial of IV and SC ARGX-117, a first-in-class C2 antibody, to evaluate safety and tolerability and establish dosing regimen.

Hematology Franchise

Efgartigimod ARGX-113

- ADVANCE (IV) and ADVANCE SC Phase 3 trials ongoing evaluating IV and SC ENHANZE® efgartigimod in patients with primary immune thrombocytopenia (ITP). The global program is expected to support registration of both formulations.

Cusatuzumab ARGX-110

- Initiated Phase 1b ELEVATE trial, which is evaluating cusatuzumab in combination with venetoclax and azacitidine in newly-diagnosed, elderly patients with AML who are ineligible for intensive chemotherapy.
- Enrollments of Phase 2 CULMINATE trial and Phase 1b platform trial evaluating cusatuzumab in combination with venetoclax and azacytidine. Topline data from CULMINATE trial presented early 2021. A pre-planned interim analysis was conducted of the 52 patients receiving 20mg/kg cusatuzumab plus azacitidine treatment. In a cohort where patients received at least two treatment cycles 42% (14/33) achieved CR and 64% (21/33) achieved CRc. Cusatuzumab was observed to be well-tolerated.
- Part 1 dose escalation of Phase 1 study of cusatuzumab in combination with azacytidine in newly diagnosed, elderly patients with AML who are ineligible for intensive chemotherapy published in Nature Medicine.

Potential Expansion Franchise

Efgartigimod ARGX-113

- Detailed proof-of-concept data from adaptive Phase 2 trial evaluating the efficacy of 10mg/kg IV or 25mg/kg IV efgartigimod in patients with pemphigus vulgaris (PV) presented at the 2020 Society for Investigative Dermatology (SID).
- Phase 3 registrational trial following proof-of-concept data from adaptive Phase 2 trial started in fourth quarter 2020.

Preclinical Program

ARGX-118

ARGX-118, an immunology breakthrough in airway inflammation, is undergoing lead optimization work as a potential treatment for airway inflammation.

Collaborations

Entered into a non-exclusive license agreement with the Clayton Foundation for Research under which we have been granted access to the proprietary DHS mutations of Clayton Foundation for Research to extend the serum half-life of therapeutic antibodies through the use of a non-exclusive research technology license.

Entered into a non-exclusive research license and option agreement with Chugai Pharmaceutical Co., Ltd. under which we have been granted access to two of Chugai's antibody engineering technologies, being SMART-Ig® (Recycling Antibody and part of Sweeping Antibody technology) and ACT-Ig® (Antibody half-life extending technology).

In October 2020, we have expanded our collaboration with Halozyme for ENHANZE® drug delivery technology to include three additional exclusive targets upon nomination bringing the total to six potential targets under the collaboration. To date, two targets have been nominated including the human neonatal Fc receptor FcRn and complement component C2.

Entered into an exclusive license agreement with Zai Lab Limited for the development and commercialization of efgartigimod in Greater China, including mainland China, Hong Kong, Taiwan and Macau.

Corporate Achievements

Priority Review Voucher

Acquired a U.S. FDA Priority Review Voucher from Bayer Healthcare Pharmaceuticals.

Andria Wilk

Appointed Andria Wilk, as Global Head of Quality. Prior to joining argenx, Mrs. Wilk served as Senior Director, Head of Medical, Regulatory & Clinical QA (MRC QA) at Lundbeck.

Marc Schorpion

Appointed Marc Schorpion as Global Head of Human Resources. Prior to joining argenx, Mr. Schorpion served as Vice President, Human Resources at Johnson & Johnson.

IIP BV & Switserland SA

Incorporated argenx IIP BV and argenx Switzerland SA as new subsidiaries.

Significantly strengthened our commercial organization to prepare the launch of our first FcRn antagonist with efgartigimod in gMG, expected in 2021.

436 Employees

Company expanded to 436 employees (per December 31, 2020) and consultants in support of the growth of the business.

Anant Murthy

Appointed Anant Murthy, Ph.D., as General Manager of argenx Europe. In this role, Dr. Murthy will establish the commercial infrastructure for a European launch and lead market development activities in advance of a potential European Medicines Agency (EMA) approval of efgartigimod. Dr. Murthy brings around 20 years of international experience to argenx, most recently as Head of Market Access for EMEA and Canada and the General Manager of multiple European countries for Alnylam Pharmaceuticals.

Opened Geneva office to support commercial infrastructure ahead of expected EU launch of efgartigimod.

Financial Highlights

€ 1,627 million

Cash

Cash position of €1,627 million (cash, cash-equivalents and current financial assets) allowing the Company to pursue development of its pipeline as planned (December 31, 2019: €1,335.8 million).

€ 54.5 million

Operating Income

Total operating income of €54.5 million (December 31, 2019: €82.6 million).

€ 529.0 million

Loss

Loss for the year and total comprehensive loss of €529.0 million (December 31, 2019: €163.0 million).

€ 784.7 million

Raised

Raised €784.7 million in gross proceeds in a global offering from offering of 4,207,292 ordinary shares (including in the form of American Depositary Shares (ADSs)), which included the full exercise of the underwriters' option to purchase 548,777 additional ADSs. The global offering consisted of (i) a public offering of 3,132,915 ADSs in the U.S. and certain other countries outside the European Economic Area (EEA) at a price of $205.00 per ADS; and (ii) a concurrent private placement of 1,074,377 of ordinary shares in the EEA at an offering price of €186.52 per share.

argenx Share 2020

argenx (ticker ARGX) has been listed on **Euronext Brussels** since June 2014 and on the **NASDAQ Global Select Market** since May 2017. argenx forms part of the Bel20 index on Euronext Brussels and the NASDAQ Biotechnology Index on NASDAQ in New York.

The evolution of the argenx share (Euronext) in 2020 is displayed below (amounts along the vertical axis are denominated in euros):

The evolution of the argenx share (NASDAQ) in 2020 is displayed below (amounts along the vertical axis are denominated in dollars):

Investor relations activities

We attracted additional sell-side analyst coverage by U.S. banks and presented at a number of virtual conferences in 2020, meeting with institutional US and EU investors and retail investors in Belgium. We presented Full Year, Half Year and Q1 and Q3 2020 results.

2021 Outlook

We continue to execute our “argenx 2021” business plan to become a fully integrated immunology company by executing on three corporate priorities in 2021, including the preparation for the potential FDA approval and U.S. commercial launch of efgartigimod for the treatment of patients with gMG, the progression of its clinical-stage autoimmune pipeline and the continued growth of its broad and differentiated pipeline through our Immunology Innovation Program.

With efgartigimod, we continue to build our leadership position in FcRn and expect to run up to seven global trials across IV and subcutaneous formulations in four targeted indications (gMG, ITP, CIDP and PV), and to further evaluate its unique potential with the expansion into a fifth and sixth indication. In addition, we continue our global development for cusatuzumab for the treatment of AML as part of our global collaboration with Cilag GmbH International, an affiliate of Janssen.

Furthermore, we continue to invest in a broad and differentiated pipeline through our Immunology Innovation Program, by identifying potential value-creation opportunities through collaboration with leading disease biologists. In 2021, we anticipate the following late-stage pipeline milestones:

Neuromuscular Franchise

Efgartigimod ARGX-113

ARGX-117

- First commercial launch of efgartigimod in gMG.
- Japanese Marketing Authorization Application (J-MAA) expected to be filed with the Pharmaceuticals and Medical Devices Agency (PMDA) in the first half of 2021 with an anticipated Japan commercial launch in 2022 File a Marketing Authorisation Application (MAA) with European Medicines Agency (EMA) in second half of 2021.
- Zai Lab Limited to discuss potential accelerated regulatory pathway for approval in China with National Medical Products Administration (NMPA).
- Continue the bridging study for SC ENHANZE® efgartigimod in gMG. Trial expected to enroll approximately 50 patients.
- Commercial preparation activities are underway and on track for potential 2021 launch, including continued engagement with key stakeholders, commercial inventory build, milestonebased hiring of field force around potential BLA acceptance and FDA approval, and development of a patient services program.
- Report data Phase 1 healthy volunteer study of IV and SC ARGX-117. Data expected in mid-2021, after which argenx plans to launch Phase 2 proof-of-concept trials in severe autoimmune diseases, including multifocal motor neuropathy (MMN).
- Enrollment ongoing in registrational trial evaluating SC efgartigimod for treatment of CIDP following interim analysis of safety data as well as efficacy assessments that surpassed pre-defined “GO” threshold, trial expected to enroll approximately 130 patients.

Hematology/Oncology Franchise

Continue the ongoing global program which is expected to support registration of ADVANCE (IV) and ADVANCE SC trials evaluating IV and SC ENHANZE® efgartigimod in patients with primary immune thrombocytopenia (ITP). Trials expected to each enroll approximately 156 patients.
Continue the ongoing Phase 1b ELEVATE trial which is evaluating cusatuzumab in combination with venetoclax and azacitidine in newly-diagnosed, elderly patients with AML who are ineligible for intensive chemotherapy. The decision to initiate additional studies in the development of cusatuzumab, under the collaboration with Cilag GmbH International (please see paragraph 3.6.1 “Our Strategic Partnership with Janssen (for cusatuzumab)” on page 107 and further for more information), will be determined following review of all available data including ongoing Phase 1b ELEVATE trial.

Potential Expansion Franchise

- Continue the global Phase 3 registrational trial in pemphigus patients (vulgaris and foliaceus); trial expected to enroll approximately 150 patients.

In addition, at the core of our ambitious growth strategy remains our commitment to expand our early-stage pipeline with immunology breakthroughs and expect the following milestones in 2021:

- Announce fifth and sixth indication for efgartigimod
- Continue lead optimization work on ARGX-118 for airway inflammation.
- Announce new product candidate, ARGX-119 and ARGX-120.
- Commitment to expand pipeline at cadence of one new candidate per year from Immunology Innovation Program.

For a detailed description of our business activities and our strategies for creating value in the long term, we refer to chapter 3 “Business” on page 70 and further

Business

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Our Values

Our values guide our business relationships and collaborations both within and beyond our walls.

We thrive on curiosity and trust in the power of the team to help us identify immunology breakthroughs. We are inspired by patients to translate these breakthroughs into medicines. The resilience and hope of patients gives us purpose, empowering us to work with urgency because we know they are waiting.

Co-Creation
We create through collaboration.

Humillity
We listen to patients and their communities.

Excellence
We live by our reputation for data-driven decision-making.

Empowerment
We build our people based on strengths to benefit the broader team.

Innovation
We live to innovate and do so at every step.

3 Business

3.1 Presentation of the Company

3.1.1 Overview and Recent Developments

General

We are a clinical-stage biotechnology company developing a deep pipeline of differentiated therapies for the treatment of severe autoimmune diseases and cancer. We have a particular focus on neuromuscular and hematology indications within our franchises. Our suite of antibody technologies and our Immunology Innovation Program, or IIP, exploring novel disease biology enables us to focus on developing product candidates with the potential to be either first-in-class against novel targets or best-in-class against known, but complex, targets in order to treat diseases with a significant unmet medical need. Through our "argenx 2021" vision, we are on track to becoming a global, fully integrated company with the potential launch of our first product, efgartigimod, in the United States in 2021, if approved.

Our suite of technologies

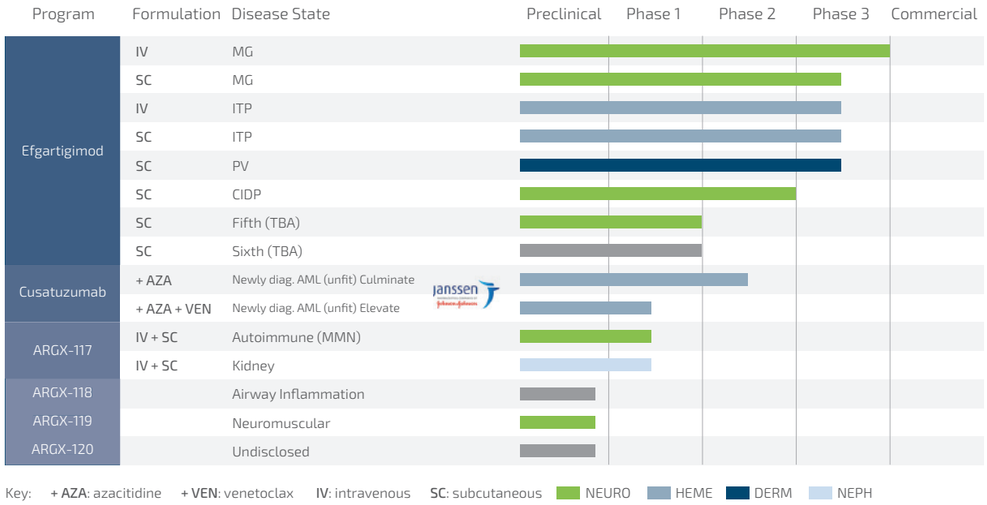
Our product candidates are focused on indications for which there is a solid biological rationale and for which we believe there is an advantage to utilizing our suite of proprietary and licensed technologies. Together with our antibody discovery and development expertise, this suite of technologies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

- Our proprietary SIMPLE Antibody™ Platform—Our SIMPLE Antibody™ Platform, based on the powerful llama immune system, together with the IIP allows us to exploit novel and complex targets, and our antibody engineering technologies are designed to enable us to expand the therapeutic index of our product candidates. The platform sources antibody V-regions from the immune system of outbred llamas, each of which has a different genetic background. The V-region is responsible for targeting a specific antibody towards an antigen, which is a substance that induces an immune response, and is specific for every antibody. The llama produces highly diverse panels of antibodies with a high human homology, or similarity, in their V-regions when immunized with targets of human disease. By contrast, most antibody screening platforms use antibodies generated in inbred mice or synthetic antibody library systems, approaches that we believe are limited by insufficient antibody repertoires and limited diversity, respectively. Our SIMPLE Antibody™ Platform allows us to access and explore a broad target universe, including novel and complex targets, while potentially minimizing the long timelines associated with generating antibody candidates using traditional methods.

- Our proprietary engineering technologies—ENHANZE®, ABDEG™, POTELLIGENT®, and DHS mutations—focus on engineering the Fc region of antibodies in order to augment their intrinsic therapeutic properties. In addition, we obtained a non-exclusive research license and option for the SMART-Ig® and ACT-Ig® technologies. These technologies are designed to enable us to expand the therapeutic index of our product candidates, which is the ratio between toxic and therapeutic dose, by potentially modifying their half-life, tissue penetration, rate of disease target clearance and potency.

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

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



Our programs

Efgartigimod

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

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

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

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

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

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

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

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

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

Cusatuzumab

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

In July 2020, we announced that the development strategy for clinical trials of cusatuzumab initiated under the global cusatuzumab collaboration and licensing agreement with Cilag has been aligned with the evolving treatment landscape and anticipated global adoption of venetoclax in acute myeloid leukemia, or AML, clinical practice.

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

ARGX-117, ARGX-118 and Immunology Innovation Program

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

Partnerships

We have a disciplined strategy to maximize the value of our pipeline whereby we plan to retain development and commercialization rights to those product candidates that we believe we can ultimately commercialize successfully on our own, if they are approved. We plan to collaborate on product candidates that we believe have promising potential and benefits in disease areas or patient populations that are better served by the resources of larger biopharmaceutical companies. As such, we have entered into collaborations with a number of biopharmaceutical companies, including our collaborations with Zai Lab and Cilag.

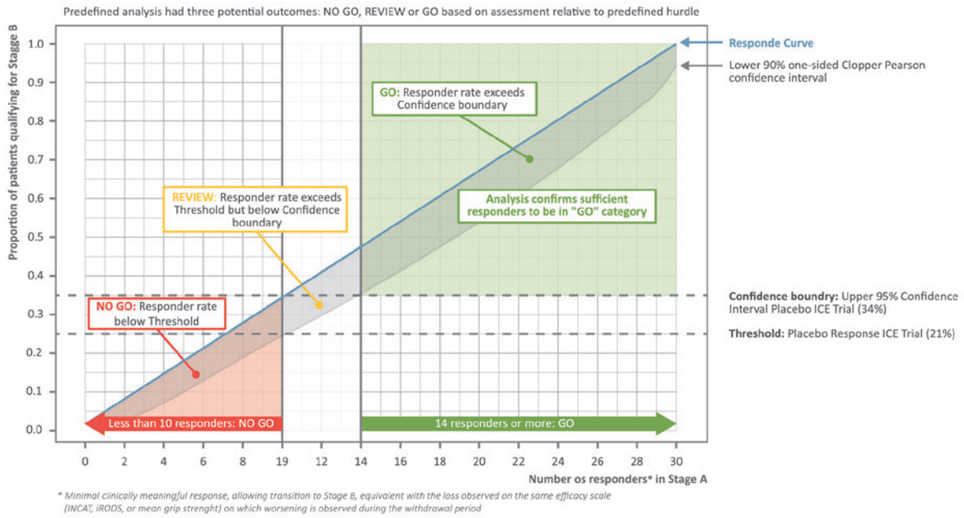
In January 2021, we entered into an exclusive license agreement with Zai Lab Limited, or Zai Lab, for the development and commercialization of efgartigimod in China, Taiwan, Hong Kong and Macau and the acceleration of efgartigimod development through Phase 2 proof-of-concept trials in new autoimmune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

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

Recent developments

Interim analysis from ADHERE trial

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



Interim results from the Cusatuzumab CULMINATE Phase 2 trial

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

Priority Review Voucher

In November 2020, we announced the agreement to acquire an FDA Priority Review Voucher, or PRV, from Bayer Healthcare Pharmaceuticals, Inc. for $98 million. A PRV entitles the holder to FDA priority review of a single New Drug Application or BLA, which reduces the target review time and may potentially lead to an expedited approval. We expect to redeem the PRV for a future marketing application for efgartigimod. We will not use the PRV for the BLA submission of IV efgartigimod in gMG.

3.1.2 Strategy and Objectives

Strategy

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

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

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

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

- **Focus our discovery and development efforts on novel and complex targets to generate new first-in-class and best-in-class product candidates for autoimmune diseases and hematology/cancer.** Our SIMPLE Antibody™ Platform together with the IIP allows us to explore novel disease biology and pathways, allows us to access and explore a broad target universe, including novel and complex targets, while minimizing the long timelines associated with generating antibody candidates using traditional methods. By exploring a broad target universe, we are able to develop a breadth of antibodies to test many different epitopes. Being able to test many different epitopes with our antibodies enables us to search for an optimized combination of safety, potency and species cross-reactivity. We believe our Fc engineering and drug delivery technologies will allow us to augment our antibodies for maximum therapeutic effect.

- **Selectively leverage our suite of technologies to seek strategic collaborations and maximize the value of our pipeline.** Our suite of technologies and productive discovery capabilities have yielded several potential product candidates for which we seek to capture value, while maintaining our focus and discipline. We plan to collaborate on product candidates that we believe have promising utility in disease areas or patient populations that are better served by the resources of larger biopharmaceutical companies. In addition to collaborating on our product candidates, we may also elect to enter into collaborations for third-party product candidates for which we believe that our technologies and expertise may be valuable.

- **Implement our "argenx 2021" vision to become a global, fully integrated, novel immunology company and independently commercialize our product candidates in indications and geographies where we believe we can extract maximum value.** We plan to independently develop and commercialize those product candidates that we believe have a clear clinical and regulatory approval pathway and that we believe we can commercialize successfully ourselves, if approved. Our commercialization strategy for any product candidates that are approved will focus on key academic centers, specialist physicians and advocacy groups, as well as on providing patients with support programs and maximizing product access and reimbursement. As part of this strategy, we are building two commercial franchises in neuromuscular and hematology/oncology disorders, with the potential to expand into a third franchise in skin and kidney diseases. In 2021, we expect to launch efgartigimod in the U.S. in its first indication of generalized MG, or gMG, if approved. Through the building of commercial franchises, we plan to leverage capabilities and an organizational footprint for subsequent potential launches across our broad immunology pipeline.

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

3.1.3 Competitive Position

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

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

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

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

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

3.1.4 Our Competitive Strengths

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

- **Efgartigimod: Phase 3 product candidate with clinical proof-of-concept in MG, ITP and PV; pipeline-in-a-product opportunity in seven global clinical trials and two additional indications are selected.** We launched a Phase 3 clinical trial in MG for our lead product candidate, efgartigimod, in September 2018 and announced topline data of the Phase 3 in May 2020. In addition, the bridging study with SC ENHANZE® efgartigimod was launched by the end of 2020. We also announced full data from the Phase 2 clinical trial in ITP in December 2018 and launched a Phase 3 clinical trial, ADVANCE and ADVANCE SC in this indication at the end of 2019 and 2020 respectively. Also, at the end of 2019 we initiated a Phase 2 clinical trial, ADHERE, of SC ENHANZE® efgartigimod in CIDP, and we reported interim data of the Phase 2 clinical trial of efgartigimod in PV in May 2020. MG, ITP, PV and CIDP are rare, severe autoimmune diseases with high unmet medical need. Each indication is characterized by high levels of pathogenic or IgG antibodies, and we specifically designed efgartigimod to reduce IgG antibody levels. In a Phase 1 clinical trial of efgartigimod with healthy volunteers, we observed a reduction of circulating IgG antibody levels of 50% to 85%. We believe that a reduction of pathogenic IgG antibody levels, which are a subset of circulating IgG antibodies in people with autoimmune disease, of at least 30% would be clinically meaningful. In addition, all patients in the treatment arm of our Phase 3 clinical trial in MG showed a rapid and deep reduction of their total IgG levels and disease improvement was found to correlate with reduction in pathogenic IgG levels. The treated ITP patients in the Phase 2 clinical trial showed a correlation between IgG reduction, platelet counts increase and reduction of bleeding events. In addition, interim data from the treated PV patients showed a rapid disease control in 28 out of 31 patients and complete clinical remission was observed in 7 out of 10 patients receiving the optimized dosing regimen. Based on these data, we believe efgartigimod is a pipeline-in-a-product opportunity in these, and potentially other, indications.

- **Productive discovery capabilities through our IIP that fuel a deep pipeline of clinical and preclinical product candidates.** We are advancing a deep pipeline of both clinical- and preclinical-stage product candidates for the treatment of severe autoimmune diseases, hematological disorders and cancer. Leveraging our technology suite and clinical expertise, we have advanced six product candidates into late-stage clinical development —efgartigimod, cusatuzumab, ARGX-111, ARGX-109, LP0145 (formerly ARGX-112) and ARGX-115 (ABBV-151); three into the preclinical stage — STT-5058 (formerly ARGX-116), ARGX-117 and ARGX-118; and we currently have multiple programs in the discovery stage. We believe this level of productivity affords us a breadth of options with regard to independently advancing or partnering our pipeline assets.

- **The ability to exploit novel and complex targets for maximum therapeutic effect.** Our SIMPLE Antibody™ Platform, which is based on outbred llamas, combined with our IIP allows us to explore novel disease biology,and to access and explore a broad target universe. We believe the benefit of our platform is that it provides a broader set of human-like V-regions as compared to other sources such as mice or synthetic antibody libraries. With this breadth of antibodies, we are able to test many different epitopes, which are binding sites on antigens capable of eliciting an immune response. Being able to test many different epitopes with our antibodies enables us to search for an optimized combination of safety, potency and species cross-reactivity with the potential for maximum therapeutic effect on disease.

- **The ability to use our proprietary Fc engineering technologies to modulate immune response.** We employ technologies—NHance®, ABDEG™ and POTELLIGENT®—that focus on engineering the Fc region of antibodies in order to augment their intrinsic therapeutic properties. These technologies are designed to expand the therapeutic index of our product candidates by modifying their half-life, tissue penetration, rate of disease target clearance and potency.

- **Validating strategic collaborations to maximize pipeline value or access complementary technology.** Our productive discovery capabilities and deep pipeline have provided us with multiple product candidates for which we seek to capture the greatest value. We have partnered, and expect to continue to partner, product candidates that we believe have promising utility in disease areas or patient populations that are better served by the resources of larger biopharmaceutical companies. As a result, we have entered into collaborations with a number of biopharmaceutical companies, including our collaboration with Janssen for cusatuzumab, our product candidate targeting CD70 for rare and aggressive hematological cancers and with AbbVie for ARGX-115 (ABBV-151), a cancer immunotherapy-focused product candidate against the novel target GARP. In addition, we seek partnerships with companies that have complementary technologies. For instance, under the global collaboration and license agreement we have with Halozyme for their ENHANCE® subcutaneous drug delivery technology for which we have access for up to six targets, including exclusive rights to develop therapeutic products targeting human neonatal Fc receptor FcRn. Under the terms of the agreement, we paid an upfront payment of $30 million to Halozyme with potential future payments up to $160 million per selected target subject to achievement of specified development, regulatory and sales based milestones.

3.2 Our Product Candidates

3.2.1 Our Suite of Technologies

Harnessing the Therapeutic Potential of Antibodies

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

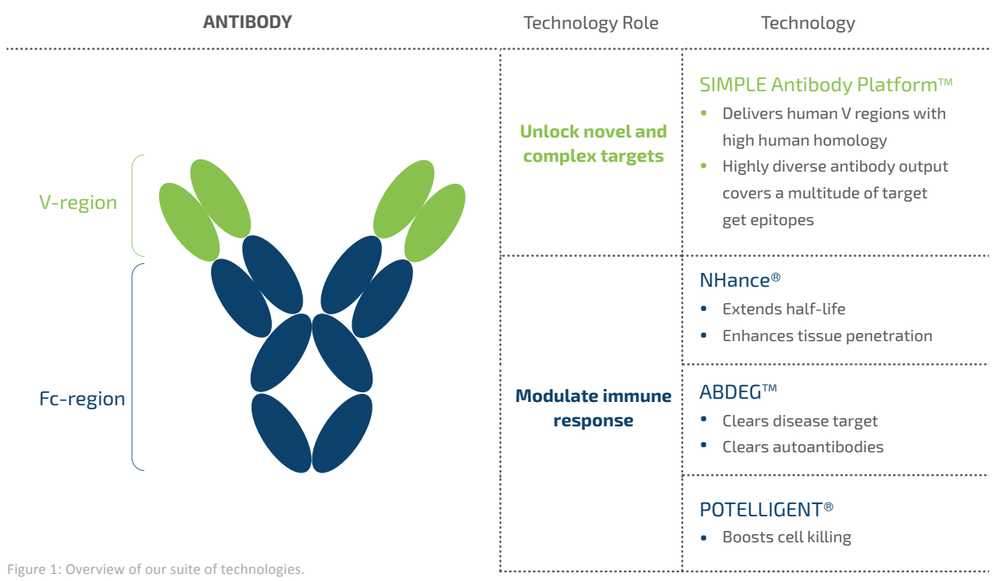


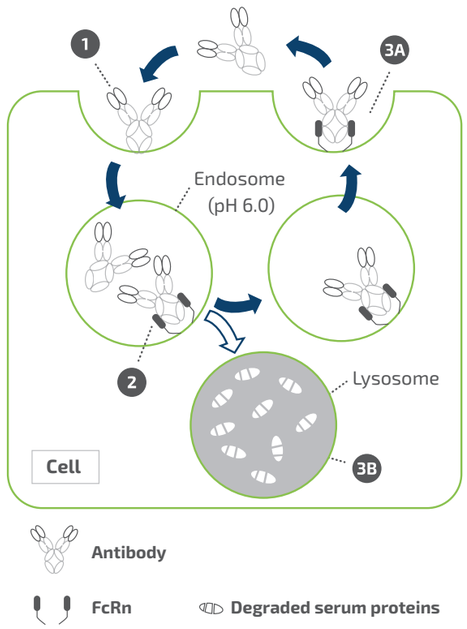
Figure 1: Overview of our suite of technologies.

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

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.

Figure 2: The FcRn-mediated recycling mechanism.



Our proprietary Fc Engineering Technologies

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

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

An illustration of the FcRn-mediated antibody recycling mechanism is shown in Figure 2. (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.

NHance®

NHance® refers to two mutations that we introduce into the Fc region of an IgG antibody. NHance® is designed to extend antibody serum half-life and increase tissue penetration. In certain cases, it is advantageous to engineer antibodies that remain in the circulation longer, allowing them to potentially exert a greater therapeutic effect or be dosed less frequently. As shown in Figure 3, 1 NHance® antibodies bind to FcRn with higher affinity, specifically under acidic pH conditions. 2 Due to these tighter bonds, NHance® FcRn-mediated antibody recycling is strongly favored over lysosomal degradation, although some degradation does occur. 3 NHance® allows a greater proportion of antibodies to return to the circulation potentially resulting in increased bioavailability and reduced dosing frequency. ARGX-111, ARGX-109, ARGX-117 and a number of our discovery-stage programs utilize NHance®.

ABDEG™

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

As shown in Figure 4, our ABDEG™ technology can also be used with our pH-dependent SIMPLE Antibodies in a mechanism referred to as sweeping. Certain SIMPLE Antibodies bind to their target in a pH-dependent manner. These antibodies 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 3: NHance® mutations favor the FcRn-mediated recycling of IgG antibodies.

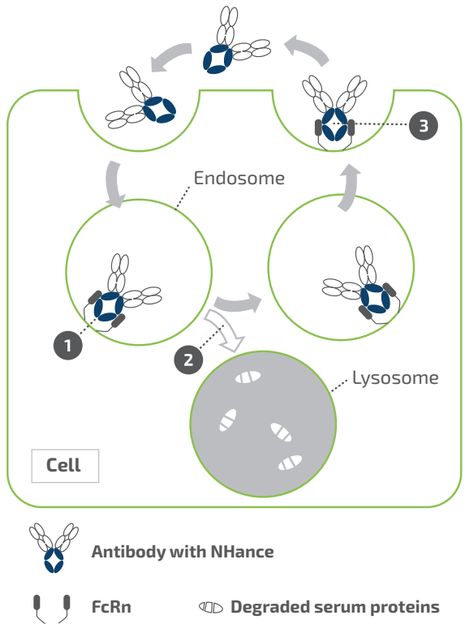
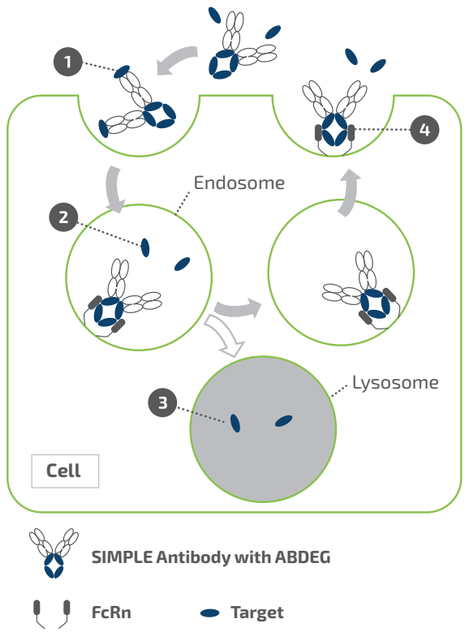


Figure 4: SIMPLE Antibody™ and ABDEG™ technologies work in concert to sweep disease targets.



POTELLIGENT®: Modulation of Fc Interaction with NK Cells

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

3.2.2 Our Wholly-Owned Programs

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

Efgartigimod (formerly referred to as ARGX-113)

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

Efgartigimod utilizes our ABDEG™ engineering technology and is designed to block the recycling of IgG antibodies, which results in their removal from circulation. We believe that our approach presents potential benefits relative to the current standard of care for MG, ITP and PV: corticosteroids and immunosuppressants in the early stages, followed by intravenous IgG, or IVIg, and plasma exchange, or plasmapheresis, as the disease progresses. The current standard of care for CIDP is IVIg. We believe efgartigimod's potential benefits include improved time of onset, increased magnitude and duration of therapeutic benefit, a more favorable safety and tolerability profile and a reduced cost burden to the healthcare system. Data reported to-date have shown that efgartigimod is well-tolerated, with reductions in pathogenic autoantibodies correlating with improvements in clinical scores.

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

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

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

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

Efgartigimod in PV

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

Efgartigimod in CIDP

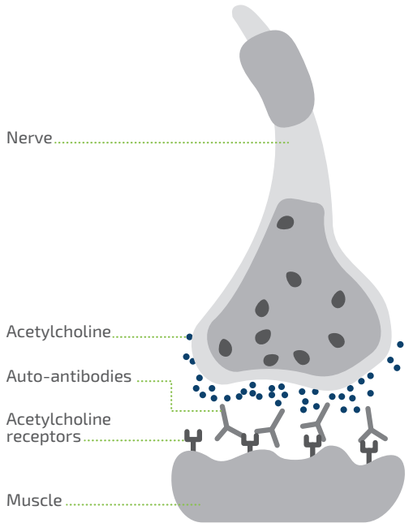
At the end of 2019, we initiated the Phase 2 ADHERE trial of SC ENHANZE® efgartigimod in patients with CIDP. We have

completed the enrollment of the first 30 patients. The potential decision to expand the trial up to 130-140 patients is now expected in first quarter 2021.

Formulation Options for Efgartigimod

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

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



Overview of Myasthenia Gravis

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

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

The U.S. prevalence of MG is estimated at approximately 20 cases per 100,000 (source: Philips et al, Ann NY Acad Sci. 2003; www.myasthenia.org/LinkClick.aspx?fileticket=EjpV6nDv8pU=&tabid=84). Currently, there are an estimated 64,000 MG patients in the United States, of which an estimated 55,000 patients are suffering from generalized MG. We believe that the prevalence in Europe is at a similar level. Our initial focus is on generalized MG patients whose disease is not well-controlled with corticosteroids and immunosuppressants, which we believe represents a majority of generalized MG patients.

Limitations of Current MG Treatments

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

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

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

Both of these approaches place a heavy cost burden on the healthcare system. In addition to the costs of the IVIg or plasmapheresis treatment itself, hospitalization of patients receiving these treatments further adds to this cost burden. According to a 2011 study, the average short-term cost for utilizing IVIg or plasmapheresis for MG crisis was $78,814 and $101,140 per patient, respectively (source: J Clin Neuromuscul Dis. 2011 Dec; 13(2):85–94. doi: 10.1097/CND.0b013e31822c34dd). In addition to patients experiencing an MG crisis, we believe a substantial number of MG patients receive chronic IVIg or plasmapheresis for which they require frequent hospitalization.

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

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

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

Overview of Primary Immune Thrombocytopenia

ITP is a bleeding disease caused by an autoimmune reaction in which a patient develops antibodies that attack and destroy their own platelets, which are blood cells that help blood to clot, or their own platelet-forming cells. ITP, which develops for no known reason, is differentiated from secondary immune thrombocytopenia, which is associated with other illnesses, such as infections or autoimmune diseases, or which occurs after transfusion or taking other drugs, such as cancer drugs. Platelet deficiency, or thrombocytopenia, can cause bleeding in tissues, bruising and slow blood clotting after injury. ITP affects approximately 72,000 patients in the United States (sources: Current Medical Research and Opinion, 25:12, 2961-2969; Am J Hematol. 2012 Sep; 87(9): 848–852; Pediatr Blood Cancer. 2012 Feb; 58(2): 216–220).

Limitations of Current ITP Treatments

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

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

The production of platelets in patients refractory to other treatments can be stimulated by drugs such as romiplostim (Nplate) or eltrombopag (Promacta) that mimic thrombopoietin. While these therapies lead to increases in blood platelet counts, they do not address the underlying cause of the disease, which is the destruction of platelets by the immune system. Romiplostim (Nplate),Eltrombopag (Promacta) and Fostamatinib (Rigel) are approved as last-line therapy for ITP and have generated global revenues of $584 million and $635 million in 2016, respectively (source: Amgen Inc. Annual Report on Form 10-K for Fiscal Year Ended December 31, 2016 (page 126)).

Overview of Pemphigus Vulgaris

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

Currently, there are an estimated 17,400 pemphigus patients in the United States, of which an estimated 13,100 patients are suffering from PV. We believe that the prevalence in Europe is at a similar level. Our initial focus is on mild-to-moderate PV patients who are either newly diagnosed or not well-controlled with corticosteroids and immunosuppressants. Several disease activity measurements exist for the clinical evaluation of PV patients, including the pemphigus disease area index, or PDAI; autoimmune bullous skin disorder intensity score, or ABSIS; and the PV activity score, or PVAS. The PDAI is reported to have the highest validity and is recommended for use in clinical trials of PV.

Limitations of Current PV Treatments

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

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

Overview of Chronic Inflammatory Demyelinating Polyneuropathy

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

Limitations of Current CIDP Treatments

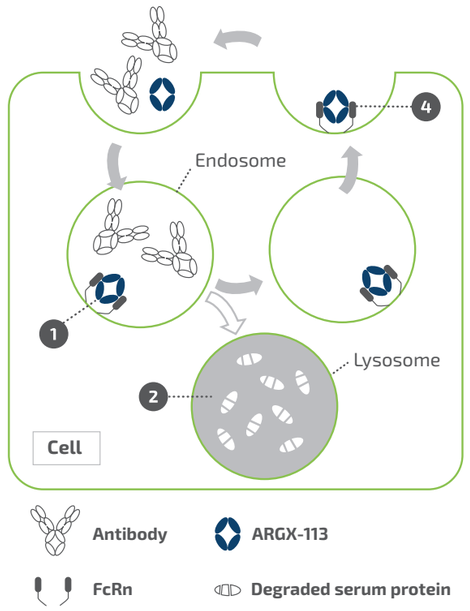
Most CIDP patients require treatment and intravenous immunoglobulin, or IVIg, which is the preferred first-line therapy. Glucocorticoids and plasma exchange are used to a lesser extent as they are either limited by side effects upon chronic use, in the case of glucocorticoids, or invasiveness of the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

Our Solution: efgartigimod

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

Efgartigimod targets FcRn with high affinity, thereby reducing levels of all four classes of IgG antibodies, which are referred to as IgG1, IgG2, IgG3 and IgG4. In the case of MG, the large majority of patients have autoantibodies of the IgG1 and IgG3 classes, while in the case of ITP these autoantibodies consist mainly of the IgG1 class. In the case of PV, the pathogenic autoantibodies consist mainly of the IgG1 and IgG4 class. As shown in Figure 6, efgartigimod's mechanism of action is to block the recycling of IgG antibodies and remove them from circulation. Antibodies are routinely removed from circulation by being internalized into cells, where they can either become destined for degradation in the lysosomes or recycled back into circulation. IgG antibodies not bound to FcRn are degraded, while those bound to FcRn are recycled back into circulation. (1) As a result of our ABDEG™ technology and the modifications we made to the Fc region, efgartigimod binds to FcRn with high affinity making this receptor unavailable to circulating IgG antibodies. (2) The IgG antibodies can then no longer effectively be rescued and end up in the lysosomes where they are degraded. Compared to alternative immunosuppressive approaches, such as B-lymphocyte, or B-cell, depleting agents, efgartigimod acts in a highly selective manner by reducing IgG antibody levels, while leaving levels of antibodies of the immunoglobulin A, or IgA, immunoglobulin M, or IgM, and immunoglobulin D, or IgD, types as well as all components of the innate immune system intact.

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



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

In addition to MG, ITP, PV and CIDP, we believe there are other autoimmune diseases that may benefit from the mechanism of action of efgartigimod therapy. We intend to pursue initial approval for MG and then plan to expand potentially to ITP, PV and CIDP because these diseases

have significant unmet medical needs. We then intend to expand our clinical development efforts for efgartigimod into additional indications also mediated by pathogenic IgG antibodies. Pathogenic auto-antibodies have been shown to be associated with other neuromuscular diseases such as Guillain-Barré, Lambert Eaton, chronic inflammatory demyelinating polyradiculoneuropathy; with other hematological diseases such as hemolytic anemia; and with other autoimmune blistering diseases such as bullous pemphigoid and epidermyolysis bullosa; as well as with systemic lupus erythematosus and multiple sclerosis, which affect larger numbers of patients.

Global and Broad Clinical Development Plan

We are currently evaluating efgartigimod in Phase 3 clinical trials in MG and ITP. A global, multi-center Phase 3 ADAPT clinical trial, including ADAPT+ one-year open-label extension study, is currently ongoing. The ADAPT trial completed patient enrolment at the end of 2019 and topline data was announced on May 26, 2020. For ITP, a global Phase 3 program includes two potential registrational trials to be run concurrently. The first trial, ADVANCE is launched and will evaluate 10mg/kg IV efgartigimod on top of standard of care medication. The second trial is launched in the fourth quarter of 2020 and will evaluate the 1000 mg SC ENHANZE® efgartigimod.

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

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

Phase 2 Clinical Trial in MG

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

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

Phase 2 Topline Results

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

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

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

Table 1. Abbreviation: TEAE = treatment-emergent adverse event. Data are in (%).

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

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

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

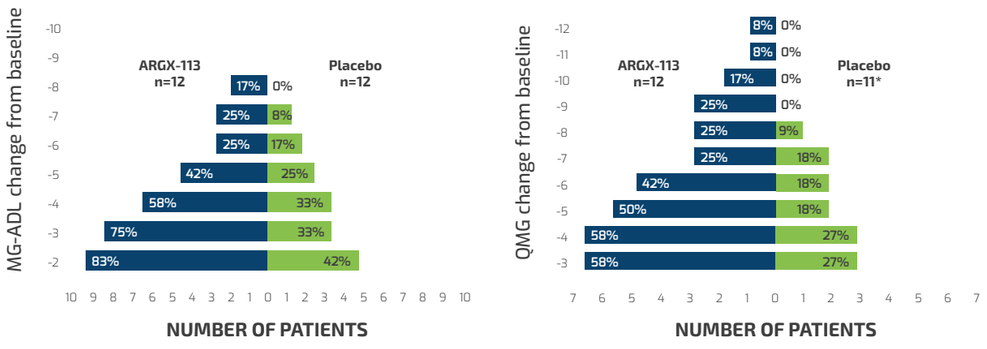


Figure 7. Increasing differentiation in patient MG-ADL and QMG thresholds (treatment group vs. placebo)
* Missing data point in one patient

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

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

Phase 2 Clinical Trial in ITP

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

Phase 2 Topline Results

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

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

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

Table 2: Overview of TEAEs and drug related TEAEs reported in at least two patients in efgartigimod Phase 2 Clinical Trial in ITP. Abbreviations: N, number of patients in the analysis set; n, number of patients with event within each treatment group under safety analysis set; TEAE, treatment emergent adverse event.

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

Clinically meaningful improvements in platelet counts were seen across ITP classifications and standard of care. 46% of patients demonstrated improved platelet count to ≥ 50x109/L during two or more visits in each of the 5 mg/kg and 10 mg/kg dosing cohorts compared to 25% in the placebo cohort. 67% of patients in the OLE trial demonstrated improved platelet count to ≥ 50x109/L during two or more visits following the first dosing cycle. Responders from the 10 mg/kg arm in the primary trial all responded again upon retreatment in the OLE trial. Onset of platelet count reaching 50x109/L for the first time ranged from week 1 to week 10, consistent with disease heterogeneity. For efgartigimod-treated patients with clinically meaningful platelet responses (≥ 50x109/L during two or more visits), the mean duration of platelet response was 40 days versus 16 days for placebo treated patients, with responses lasting the trial duration.
38% of efgartigimod-treated patients showed durable platelet count improvements to clinically meaningful and statistically significant levels of ≥ 50x109/L for at least 10 cumulative days, compared to 0% of placebo patients (p=0.03). These data are summarized in figures 8 and 9.

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

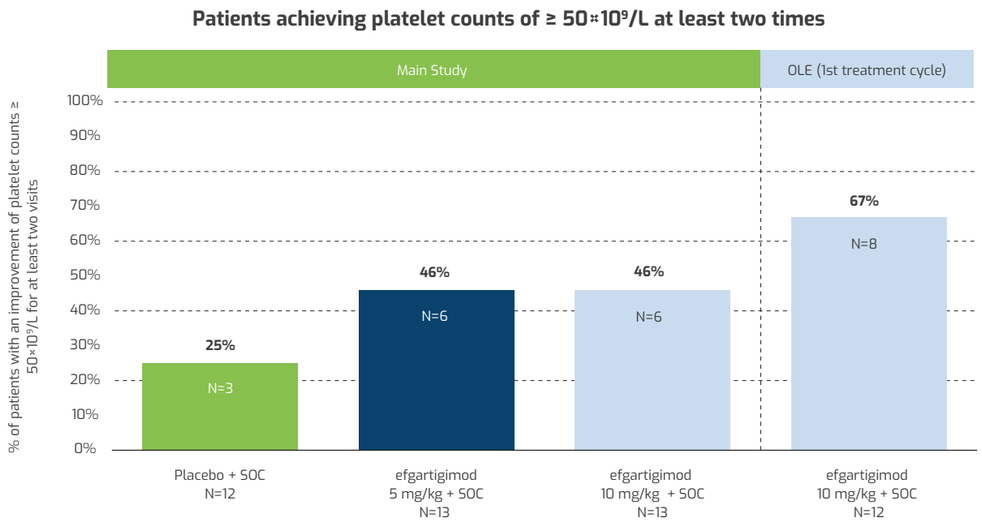
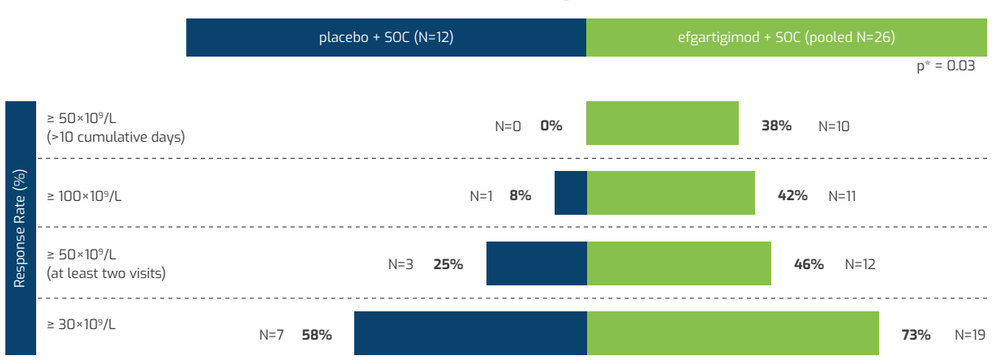


Figure 9: Post-hoc analysis of increasing thresholds of efficacy

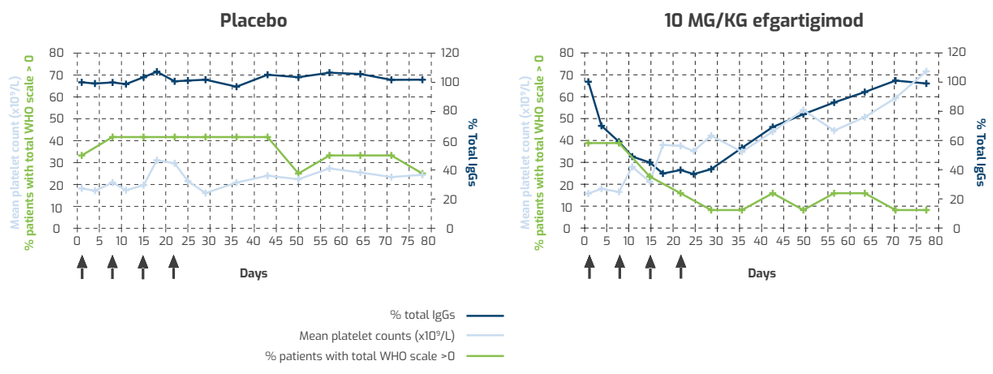


Note: Increasing threshold analysis based exact logistic regression model with the baseline result as a factor

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

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

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



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

Phase 2 Interim Results and Next Steps

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

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

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

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

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

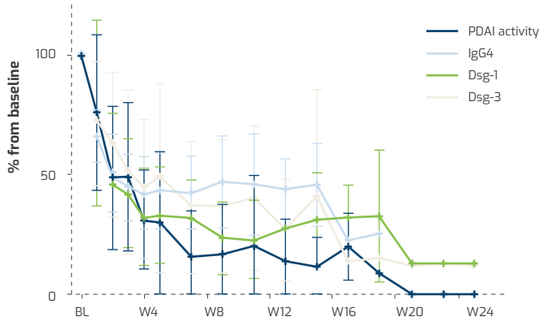


Figure 11: IgG reduction correlates to PDAI score improvement in responders

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

Phase 1 Clinical Trial for Subcutaneous Formulation of efgartigimod (fixed maintenance dose used after IV induction)
In addition to the intravenous product formulation of efgartigimod, we are also developing a subcutaneous product formulation designed to enable administration of efgartigimod to larger patient populations, including patients requiring chronic therapy, potentially outside the hospital setting.

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

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

Phase 1 Clinical Trial ENHANZE® SC efgartigimod (standalone SC formulation)
In addition to the subcutaneous product formulation of efgartigimod, we developed a standalone SC formulation of efgartigimod as part of our collaboration with Halozyme based on a co-formulation of efgartigimod with Halozyme's proprietary ENHANZE® drug delivery technology (hyaluronidase, rHuPH20), designed to enable a smooth and convenient SC administration with larger volumes of efgartigimod with short injection times.

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

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

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

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

We announced interim data from this Phase 1 clinical trial in June 2016 and at a workshop we sponsored in conjunction with the American Society of Hematology annual meeting in December 2016. The full results from this clinical trial have been published in a peer reviewed during 2017.

Single Ascending Dose
We observed that a single two-hour infusion of 10 mg/kg efgartigimod was associated with an approximate 50% reduction of circulating IgG antibody levels. We observed that a reduction of circulating IgG antibody levels persisted for more than four weeks after the last dose, as shown in Figure 12. We believe this sustained reduction would be clinically meaningful if replicated with respect to pathogenic IgG antibodies because IVIg and plasmapheresis typically result in a 30% to 60% reduction in pathogenic IgG antibody levels.

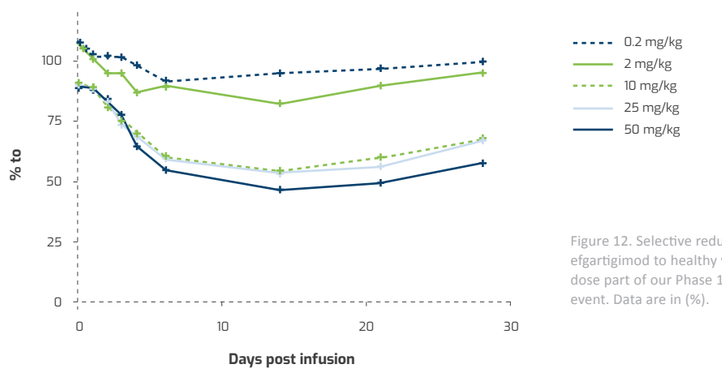


Figure 12. Selective reduction of IgG by administration of efgartigimod to healthy volunteers in the single ascending dose part of our Phase 1 clinical trialemergent adverse event. Data are in (%).

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

Multiple Ascending Dose

In the multiple ascending dose part of the Phase 1 clinical trial, repeat administration of both 10 mg/kg and 25 mg/kg of efgartigimod every seven days, four doses in total, and 10 mg/kg every four days, six doses in total, was associated with a gradual reduction in levels of all four classes of IgG antibodies by 60% to 85%, with 10 mg/kg dose results shown in Figure 13. For all doses, we observed the reduction in circulating IgG antibody levels to persist for more than four weeks after the last dose with levels below 50% at approximately three weeks and did not return to baseline levels for more than one month. Pharmacokinetic analysis of serum baseline levels of efgartigimod indicates that it has a half-life of approximately three to four days with no drug accumulation following subsequent weekly dosing. The prolonged activity on the levels of IgG antibodies is consistent with the mechanism of action of efgartigimod and the effect of the ABDEG™ technology on increasing the intracellular recycling of efgartigimod. Similar to the single ascending dose part, no significant reductions in IgM, IgA or serum albumin were observed.

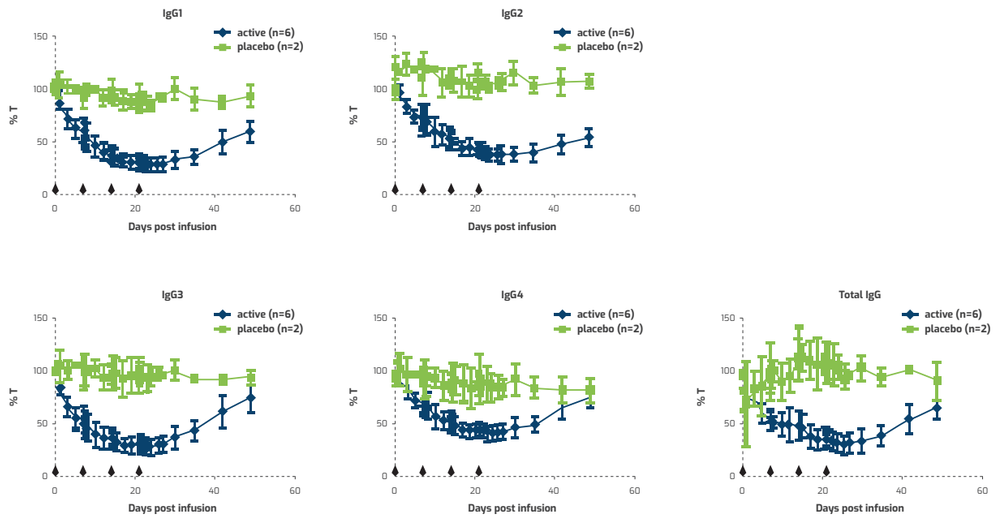


Figure 13. Reduction in the levels of four IgG antibody classes and total IgG levels in the multiple ascending dose part of our Phase 1 clinical trial of efgartigimod in healthy volunteers at a dose of 10 mg/kg every seven days

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

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

Cusatuzumab (formerly referred to as ARGX-110)

We are developing cusatuzumab in hematological cancer indications, currently AML, as well as high-risk MDS. We are developing cusatuzumab with our collaborator Janssen. See section 3.6 “Collaboration Agreements” on page 107 and further.
AML is rare and aggressive hematological cancer for which significant unmet medical needs exist. MDS, a rare bone marrow disorder, is often a precursor to AML. cusatuzumab is a SIMPLE Antibody™ designed to potently block the CD70/CD27 interaction and kill CD70-positive cells via its potent antibody effector functions through the use of POTELLIGENT® technology.

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

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

In addition, we reported results of the Phase 2 part of the Phase 1/2 clinical trial in relapsed or refractory CD70-positive CTCL patients and an open-label Phase 1 clinical trial in patients with nasopharyngeal carcinoma.
In June, 2020, we presented maturing data from the Phase 2 CULMINATE trial of cusatuzumab in combination with azacytidine in newly diagnosed, elderly patients with AML who are ineligible for intensive chemotherapy which have shown that complete response rates are not likely to exceed those from the VIALE-A trial of venetoclax in combination with azacytidine. In this trial, we observed that:

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

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

Overview of Acute Myeloid Leukemia and Myelodysplastic Syndrome

AML is a hematological cancer characterized by excessive proliferation of myeloid stem cells and their failure to properly differentiate into mature white blood cells. AML is the second most common subtype of leukemia in adults. In the United States, AML has an incidence of approximately 22,000 new cases annually (Siegel et al., Cancer J Clin 2015) AML is generally a disease of elderly people, with more than 60% of diagnosed patients being older than 60 years, and AML is uncommon before the age of 45. The average five-year survival rate for patients with AML is 27%, but there are significant differences in prognosis depending on several factors, including the age of the patient at diagnosis. For patients under the age of 45, the five-year survival rate is approximately 57%, while for those over the age of 65 it is only 6%. There are likely multiple reasons for this discrepancy, including the ability of younger patients to tolerate more aggressive therapy. Current first-line treatments in AML typically involve aggressive chemotherapy, including alkylating agents and cytarabine

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

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

Our Solution: cusatuzumab

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

Clinical Development Plan

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

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

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

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

We are evaluating cusatuzumab in an open-label, dose-escalating Phase 1/2 clinical trial to evaluate its safety, tolerability and efficacy in combination with azacitidine in newly diagnosed AML patients unfit for chemotherapy or high-risk MDS patients. The clinical trial was initiated in December 2016. All patients in this clinical trial are receiving cusatuzumab in combination with 75 mg/m2 azacitidine (standard of care for AML). Patients receive two weeks of cusatuzumab monotherapy prior to starting the combination dosing. During the Phase 1 dose-escalation part of the clinical trial, four doses of cusatuzumab, 1 mg/kg, 3 mg/kg,10 mg/kg and 20 mg/kg administered bi-weekly are being evaluated. We enrolled 12 patients in the Phase 1 part. 26 AML patients were enrolled in the Phase 2 part of its Phase 1/2 clinical trial using a 10 mg/kg dose of cusatuzumab. This is a multi-center clinical trial conducted in Europe.

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

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

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

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

More specifically at the time of the interim data, 12 out of 12 AML (100%) patients showed a response, including complete remission in eight out of 12 patients, complete remission with incomplete blood count recovery in two out of 12 patients and partial remission in two out of 12 patients. One of the patients who achieved a complete remission successfully bridged to allogeneic stem cell transplant after five cycles. One patient discontinued from the study following an adverse event. Three patients responded during cusatuzumab monotherapy in the first two weeks.

Phase 2 Part of Clinical Trial in Patients with Relapsed or Refractory CD70-positive CTCL and Phase 1 Safety-Expansion Cohorts in Patients with CD70-positive CTCL

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

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

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

Phase 1 Part of Phase 1/2 Clinical Trial in Patients with Advanced Malignancies Expressing CD70
Cusatuzumab was evaluated in an extensive Phase 1 part of a Phase 1/2 clinical trial in patients with advanced malignancies expressing CD70, following a stepwise adaptive clinical trial design enrolling a total of 86 patients (of whom 85 patients have been treated). No dose-limiting toxicities were observed. The most frequent grade 3 and 4 drug-related adverse events were fatigue in 48.2% of patients and mild (Grade 1–2) infusion-related reactions in 34.1% of patients. Other monoclonal antibodies engineered using POTELLIGENT® or similar third-party products that augment ADCC such as mogamulizumab, obinutuzumab and imgatuzumab also have infusion-related reaction rates of 24% to 77%. Premedication with acetaminophen, antihistamines and/or corticosteroids are used to reduce the impact of infusion-related reactions.

There were 83 serious adverse events seen in 42 of these pre-treated patients. Many patients who enrolled in this study have failed more than one prior therapy. All drug-related adverse events referenced in this paragraph 3.2.2 were evaluated by the investigators according to the Common Terminology Criteria for Adverse Events guidelines (CTCAE v4.03). One Grade 1 (pyrexia), seven Grade 2 (infusion-related reactions), four Grade 3 (febrile neutropenia, anaemia, thrombocytopenia and fatigue—included in Table 6) and no Grade 4 serious adverse events were reported by the investigator as being drug-related. 23 patient deaths were reported in the phase 1 clinical trial, of which 17 deaths were attributed to disease progression. One patient death (Grade 5), which was deemed drug-related by the investigator, occurred in a heavily pre-treated patient with Waldenstrom Macroglobulinemia and was attributed to sepsis and general condition deterioration.

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

DOSE-ESCALATION PART AND COHORTS 1-4	5 mg/kg	10 mg/kg	0.1 mg/kg	1 mg/kg	2 mg/kg
Number of patients	**6**	**10**	**7**	**42**	**5**
Fatigue	1	—	—	3	—
Anemia	—	—	—	1	—
Decreased appetite	1	—	—	—	—
Electrocardiogram qt prolonged	—	1	—	—	—
Febrile neutropenia	—	—	—	1	—
Hypoxia	1	—	—	—	—
Infusion related reactions	—	—	—	1	—
Thrombocytopenia	—	—	—	1	—

Note: All Grade 3 drug-related adverse events. No Grade 4 drug-related adverse events reported. All other serious adverse events were considered non-drug-related by the treating investigator. In the dose-escalation part of this clinical trial, the half-life of ARGX-110 was observed to be approximately 13 days. Anti-drug antibodies were detected in 50% of all patients, the majority of which were seen at the 0.1 mg/kg and 1 mg/kg doses.

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

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

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

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

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

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

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

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

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

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

PRODUCT CANDIDATE	Target	Indication	Pre-clinical	Phase 1	Phase 2	Phase 3	BLA
Partnered Product Candidates							
ARGX-112	IL-22R	Skin Inframmation					
ARGX-115 (ABBV-151)	GARP	Cancer Immunotherapy					
ARGX-116	ApoC3	Dyslipidemia					
ARGX-114	Met	Fibrosis					

The following is the pipeline for our partnered product candidates and discovery programs. For more information on our collaborations, see section 3.6 “Collaboration Agreements” on page 107 and further.

LP0145 (formerly ARGX-112) (partnered with LEO Pharma)
We are developing LP0145for the treatment of dermatologic indications involving inflammation, together with our collaboration partner LEO Pharma.

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

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

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

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

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

STT-5058 (formerly ARGX-116) (partnered with Staten Biotechnology)
We are developing STT-5058 for the treatment of dyslipidemia, together with our collaboration partner Staten Biotechnology.

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

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

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

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

ARGX-114 (partnered with AgomAb)
ARGX-114 is an HFG-mimetic SIMPLE Antibody™ directed against the MET receptor.

ARGX-109 (partnered with Genor Biopharma)
ARGX 109 employs our SIMPLE Antibody™ and NHance® technologies and blocks interleukin 6, or IL 6, a cell signaling protein that is an important driver of inflammatory response implicated in the transition from acute to chronic inflammation.

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

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

One example of the value of the Immunology Innovation Program is ARGX-115 (ABBV-151), which was developed in collaboration with the de Duve Institute / Université Catholique de Louvain. We provided antibodies to the academic groups to help validate the target. This in turn, allowed the groups to advance their work successfully, including the facilitation of supportive publications. Subsequently, this program formed the basis of our collaboration with AbbVie. ARGX-115 (ABBV-151) exemplifies how our Immunology Innovation Program enables us to generate product candidates against novel targets that may be of high interest for collaboration with biopharmaceutical partners. Another example is STT-5058, which was discovered in close collaboration with disease biology experts from Staten Biotechnology, an emerging biotechnology company specialized in the field of dyslipidemia.

In March 2017, we entered into a collaboration under our Immunology Innovation Program with Broteio Pharma B.V. to develop an antibody against a novel target in the complement cascade, ARGX-117. Under the terms of the agreement, we and Broteio jointly developed the complement-targeted antibody to seek to establish preclinical proof-of-concept using our proprietary suite of technologies. Upon successful completion of these studies, we exercised an exclusive option to license the program in March 2018 and assumed responsibility for further development and commercialization.

3.3 Manufacturing and Supply

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

Efgartigimod, cusatuzumab, ARGX-111 and LP0145 are each manufactured using an industry-standard mammalian cell culture of a Chinese hamster ovary cell line that expresses the product, followed by multiple purification and filtration steps typically used in producing monoclonal antibodies.

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

Eri

MG Patient, Railroad Inspector and Father of Six

"When I was younger, they told me I would never walk again, but I grew up playing basketball, running and just doing everything possible… I was able to beat the odds on that, and I intend to beat to odds on MG."

Patient Story

Eri has always been a fighter

He recalls a defining moment as a young boy where he was able to overcome a physical challenge: "I played on the escalator and lost two and a half toes. They told me I would never walk again or I would need special shoes if I do walk. I ended up growing up playing basketball, running and just doing everything possible without special shoes. I was able to beat the odds on that, and I intend to beat to odds with MG."

Eri reflects on the time from when he first had symptoms until the time he was diagnosed with MG:

"I was playing basketball and I kept falling. I didn't know why. All I knew is that one part of my body wasn't working. At some point I noticed that my voice started changing, I could feel that in my throat. I couldn't eat normally and I couldn't talk. If I got stressed out, my voice would change and I couldn't swallow. I ate bananas and oatmeal for like a month, because I couldn't eat anything else. While I was working I would just eat oatmeal and cough a lot, nothing that I ate would go down. During that time, I lost like 20 pounds. I didn't know what it was.

The early tests did not come back right away for MG. They ran like… 50 or 60 tests on me. Everything came back normal. The doctors said: "You are perfectly healthy". I told the doctors: "Well, I'm not, but if you say I'm healthy, I don't need to be here." So I checked out and they called me back a week later, and said: "We found out that you have MG." I remember asking, "What is it?" The doctors answered, "Well, it's a muscular autoimmune disease."

A positive mindset has contributed to Eri's happiness:

"There were a lot of people in my life that were positive, and they were coaching me through this. My great-grandma and my mother said: 'Okay. We're not going to give you any special treatment. You're going to be a normal kid and you'll do what you need to do.' I was able to get through with that mindset."

3.4 Intellectual Property

3.4.1 Introduction

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

Our commercial success depends upon our ability to obtain and maintain patent and other proprietary protection for commercially important technologies, inventions and know-how related to our business, defend and enforce our intellectual property rights, particularly our patent rights, preserve the confidentiality of our trade secrets and operate without infringing valid and enforceable intellectual property rights of others. Specifically, we are materially dependent on patent and other proprietary protection related to our core platform technologies, described in paragraph 3.4.2 “Platform Technologies” on page 104, and our product candidates, as described in paragraph 3.4.3 “Product Candidates: Wholly-Owned Programs” and paragraph 3.4.4 “Product Candidates: Partnered Programs”, on page 106 and further.

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

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

3.4.2 Platform Technologies

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

With regard to our SIMPLE Antibody™ discovery platform, we own a patent family containing six issued U.S. patents with composition of matter claims directed to chimeric antibodies containing variable domains comprising CDRs obtained from conventional heterotetrameric llama antibodies fused to one or more domains of a human antibody, polynucleotides encoding such chimeric antibodies, libraries of expression vectors comprising cDNA sequences encoding camelid antibodies, method claims directed to the preparation of such chimeric antibodies, and methods of modulating the binding of a human target antigen to its ligand or receptor by administering such a chimeric antibody. The U.S. patents are expected to expire in 2029 to 2033. In addition, the patent family contains patents that have been granted in Australia, Canada, Europe, United Kingdom, Israel, India and Japan, and pending applications in China and Japan (divisional). In addition, we have a second patent family containing patents granted in the United States (two), Australia, Europe, United Kingdom, Israel, India and Japan, and one patent application pending in Canada, with composition of matter claims directed to a chimeric antibody containing variable regions with CDRs derived from a llama antibody and certain amino acid substitutions corresponding to amino acids present in a human germline variable region. The granted patents have a basic patent expiry date in 2031.

With regard to the ABDEG™ platform, we co-own with, and exclusively license from, the University of Texas, a patent family containing a granted U.S. patent with composition of matter claims directed to an isolated FcRn-antagonist comprising an variant immunoglobulin Fc region having an increased affinity for an Fc gamma receptor relative to a wild-type IgG1 Fc region, and method of use claims directed to a method of using such an FcRn-antagonist to treat certain antibody mediated disorders. The U.S. patentis expected to expire in 2036. In addition, in this patent family, we also have granted patents in Australia, China, Eurasia, Europe, Japan, Mexico, New Zealand and Singapore, and we have 13 patent applications pending in U.S. (divisional) and various other countries and regions in North America, South America, Europe, Asia and South Africa. The granted patents have a basic expiry date in 2034. In addition, we own a second patent family containing pending patent applications in the United States and 15 other jurisdictions with claims directed to methods of reducing the serum levels of an Fc-containing agent in a subject by administering to the subject an FcRn-antagonist containing a variant immunoglobulin Fc region containing certain amino acid substitutions. A U.S. patent, if issued from the U.S. patent application, is expected to expire in 2036.

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

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

3.4.3 Product Candidates: Wholly-Owned Programs

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

With regard to the cusatuzumab product candidate, we have three issued U.S. patents, one with composition of matter claims directed to the cusatuzumab antibody, one with claims directed to the epitope cusatuzumab binds to, and one with claims directed to a polynucleotide that encodes antibodies that bind to the epitope cusatuzumab binds to and two pending U.S. patent applications with method of use claims directed to the treatment of cancer and immunological disorders with the cusatuzumab antibody. The issued U.S. patents expire in 2032 and 2033, and the U.S. patent applications, if issued as a U.S. patent, is expected to expire in 2032, without taking a potential patent term extension into account. In addition, we have patents that have been granted in Australia, China, Europe, Israel, India, Japan and Russia and five patent applications pending in Brazil, Canada, Indonesia and U.S. (two divisionals pending). Furthermore, cusatuzumab incorporates or employs the SIMPLE Antibody™ and POTELLIGENT® technology platforms, which are covered by one or more of the patents and patent applications discussed above under “Platform Technologies”.

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

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

3.4.4 Product Candidates: Partnered Programs

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

With regard to the ARGX-109 product candidate, we have one patent family with composition of matter claims directed to ARGX-109. This patent family has granted patents in Australia, Canada, China, Colombia, Hong Kong, Israel, Japan, Mexico, New Zealand, Russia, U.S. and South Africa, and four pending patent applications in Brazil, Chili, India and U.S. (continuation application). The patent family has a basic expiry date in 2033. Furthermore, ARGX-109 incorporates or employs the SIMPLE Antibody™ technology and the NHance® technology, which is covered by one or more of the patents and patent applications discussed above under "Platform Technologies".

With regard to the ARGX-112 product candidate, we have one patent family with composition of matter claims directed to an antibody that binds human IL-22R. The patent family has a basic expiry date in 2037. Furthermore, ARGX-112 incorporates the SIMPLE Antibody™ technology, which is covered by one or more of the patents and patent applications discussed above under "Platform Technologies".

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

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

3.4.5 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.

3.5 Tendencies

The Company is currently preparing for potential commercial production and sales and, in 2020, has had product manufactured which are held in stock and, if approved, would be intended for sale.

There has been no significant change in the financial performance or the financial position of the Company's group since the balance sheet date of December 31, 2020 up to the date of this Registration Document. For more information, please refer to chapter 1 "Risk Factors", chapter 3 "Business" and to note 29 "Commitments" of ours consolidated financial statements, incorporated by reference in this Registration Document (see chapter 7 "Information Incorporated by Reference" on page 244).

3.6 Collaboration Agreements

We have a disciplined strategy to maximize the value of our pipeline whereby we plan to retain all development and commercialization rights to those product candidates that we believe we can ultimately commercialize successfully, if approved.

We have partnered, and plan to continue to partner, product candidates that we believe have promising utility in disease areas or patient populations that are better served by resources of other biopharmaceutical companies. We expect to continue to collaborate selectively with pharmaceutical and biotechnology companies to leverage our discovery platform and accelerate product candidate development. We have entered into multiple collaboration agreements with pharmaceutical partners. Below are summaries of our agreements with pharmaceutical partners.

3.6.1 Our Strategic Partnership with Janssen (for cusatuzumab)

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

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

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

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

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

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

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

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

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

We have granted AbbVie an exclusive option, for a specified period following completion of IND-enabling studies, to obtain a worldwide, exclusive license to the ARGX-115 (ABBV-151) program to develop and commercialize products. Following the exercise of the option, AbbVie is subject to diligence obligations in respect of continuation of development and commercialization of the licensed product(s), and AbbVie will be solely responsible for all research, development and regulatory costs relating to the products. We received an upfront, non-refundable, non-creditable payment of $40.0 million (€35.1 million based on the exchange rate in effect as of the date the payment was received) from AbbVie for the exclusive option to license ARGX-115 (ABBV-151). During the course of the collaboration, we achieved two pre-defined preclinical milestones, each of which triggered a $10.0 million payment (€8.9 million based on the exchange rate in effect as of the date the first pre-clinical milestone payment was received and €8.7 million based on the exchange rate in effect as of the date the second pre-clinical milestone payment was received). In addition, in March 2019 we have achieved the first pre-defined clinical milestone, triggering a $30 million payment.

In August 2018, AbbVie exercised its option to develop and commercialize ARGX-115 (ABBV-151) and has now assumed development obligations, including being solely responsible for all research, development and regulatory costs relating to ARGX-115 (ABBV-151)-based products. Subject to the continuing progress of ARGX-115 (ABBV-151) by AbbVie, we are eligible to receive development, regulatory and commercial milestone payments in aggregate amounts of up to $110.0 million, $190.0 million and $325.0 million, respectively, as well as tiered royalties on product sales at percentages ranging from the mid-single digits to the lower teens, subject to customary reductions.

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

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

AbbVie may terminate the agreement for any reason upon prior written notice to us. AbbVie's royalty payment obligations expire, on a product-by-product and country-by-country basis, on the date that is the later of (i) such time as there are no valid claims covering such product, (ii) expiration of regulatory or market exclusivity in respect of such product or (iii) 10 years after the first commercial sale of such product sold in that country under the agreement.

3.6.3 Our Collaboration with Genor Biopharma (for ARGX 109)

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

3.6.4 Our Strategic Partnership with LEO Pharma (for LP0145)

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

We received a non-refundable, non-creditable upfront payment from LEO Pharma of €3.0 million in cash. In February 2016, June 2017 and April 2018, we achieved preclinical milestones under this collaboration for which we received milestone payments. Up through specified periods following the latest to occur of (i) submission of an application to commence a Phase 2b dose finding trial (or Phase 3 clinical trial if a Phase 2b is not conducted) or (ii) the availability of an International Preliminary Examination report for LP0145 patent rights after completion of a Phase 2a clinical trial, LEO Pharma may exercise an option to obtain an exclusive, worldwide license to further develop and commercialize products. Following the exercise of the option, LEO Pharma would assume full responsibility for the continued development, manufacture and commercialization of such product. In such case LEO Pharma is subject to diligence obligations in respect of continuation of development and commercialization of such product. If LEO Pharma elects to exercise this option, it must pay us an option fee. We are also eligible to receive additional development, regulatory and commercial milestone payments in aggregate amounts of up to €11.5 million, €6.0 million and €102.5 million, respectively, as well as tiered royalties on product sales at percentages ranging from the low single digits to the low teens, subject to customary reductions.

If LEO Pharma does not exercise its option prior to expiration of the applicable option period, if it does not meet agreed development diligence obligations within a specified time, or if the agreement is terminated other than for reasons of our breach or insolvency, then we have the right to develop and commercialize LP0145 alone, subject to our obligation to pay LEO Pharma low-single digit percentage royalties on net sales of any product covered by any LEO Pharma patents, know-how or rights in research results generated under the collaboration. If the agreement is terminated for reasons of our breach or insolvency, rights to product candidates in development at the time of such termination will be allocated to the parties through a mechanism specified in the agreement.

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

3.6.5 Our Research Collaboration with Staten (for STT-5058)

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

On a research program-by-research program basis, up through a specified period within such research program, we have granted Staten an option to obtain an exclusive, worldwide, permanent license to research, develop and commercialize products identified in that program. If Staten elects to exercise this option for a product (as it has for STT-5058), it would be obligated to pay us a percentage of any payments payable to or on behalf of Staten's shareholders in the event of (i) a change of control of Staten, (ii) any licensing, sale, disposition or similar transaction relating to any such product, or (iii) otherwise from the research, development or commercialization of that product. This percentage varies by stage of development for an applicable product and ranges up to the low-twenties, subject to downward proportional adjustment in the event a portion of the proceeds from the applicable transaction does not include payment for the product candidate we developed with Staten. Following exercise of its exclusive option, Staten is under the diligence obligation to continue to develop and commercialize at least one product during the term of the agreement.

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

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

Unless earlier terminated upon mutual agreement, for material breach or as otherwise specified in the agreement, the collaboration term ends on the later of (i) January 2020, (ii) expiration of the last license granted by us under the agreement, (iii) expiration of last option period for Staten and (iv) fulfilment of all payment obligations which have arisen or may arise pursuant to the agreement. In addition, we may terminate the agreement in whole or with respect to a research program if no targets have been selected within 24 months of the effective date of the agreement, other than the target selected for the STT-5058 research program.

3.6.6 Our Strategic Collaboration with Shire

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

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

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

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

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

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

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

3.7 License Agreements – General

We are a party to several license agreements under which we license patents, patent applications and other intellectual property to third parties. We have also entered into several license agreements under which we license patents, patent applications and other intellectual property from third parties.The licensed intellectual property covers some

of our product candidates and some of the Fc engineering technologies that we use. Some of these licenses impose various diligence and financial payment obligations on us. We expect to continue to enter into these types of license agreements in the future.

3.7.1 Our Exclusive License with Halozyme (ENHANZE®)

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

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

In return for the FcRn exclusive license, we have made a $30 million upfront payment to Halozyme. In return for the nomination of and exclusive license on C2 we made a $10 million milestone payment to Halozyme in May 2019. In return for achieving the first patient dosed for ARGX-113 Ph3 for ITP we made a $15 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 agreement, we must provide Halozyme on an annual basis a guidance forecast setting out all projected milestone payments for products for the following four calendar quarters. We are also obligated to pay Halozyme a percentage of net sales as a royalty of any licensed product that uses ENHANZE®. This royalty varies with net sales volume, ranging from the low to mid-single digits, and it is reduced by a maximum of 50% if following 10 years from the first commercial sale of the product in a country, the last valid claim within the licensed ENHANZE® patent(s) expires. Throughout the term of the agreement, we must provide Halozyme on an annual basis an estimate of royalty payments anticipated for the following four calendar quarters. We have diligence obligations with respect to the continuation of development and commercialization of product candidates, but we are not obligated to utilize ENHANZE® for every product candidate directed to a given exclusive target(s).

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

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

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

As also set out in chapter 6 “Corporate Governance”, our non-executive director James M. Daly is also a non-executive member of the board of directors of Halozyme. Despite the foregoing, our entering into the license agreement with Halozyme was not a related party transaction in accordance with IAS 24 – Related Party Disclosures, since Mr. Daly, in his role as non-executive director, does not control or have significant influence over our company or Halozyme. Mr. Daly did not participate in any discussions and decision making relating to the Halozyme license agreement. Consequently, no further disclosures regarding Halozyme have been added in paragraph 6.6.5 “Related Party Transactions” on page 222 and further.

3.7.2 Our Exclusive License with AgomAb (ARGX-114)

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

3.7.3 Our Exclusive License with Broteio (ARGX-117)

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

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

3.7.4 Our Exclusive License with VIB (ARGX-118)

In November 2016, we entered into a collaboration under our Immunology Innovation Program with VIB vzw, or VIB, an inflammation research center in Ghent, Brussels, to develop antibodies against Galectin-10, the protein of Charcot-Leyden Crystals, which play a major role in severe asthma and the persistence of mucus plugs, including ARGX-118. Under the terms of the agreement, we and VIB jointly developed antibodies against Galectin-10 using our proprietary suite of technologies. Upon successful completion of this initial research, we exercised an exclusive option to license the program and assumed responsibility for further development and commercialization. Under this agreement, including a November 2018 amendment, we are obligated to make milestone payments upon the occurrence of certain develop-

ment milestones (up to an aggregate of €4.0 million), commercialization milestones (up to an aggregate of €11.0 million) and pay tiered royalties on net sales in the low single digits. We may terminate this agreement for convenience upon 90 days prior written notice. This agreement is also subject to mutual termination for material breach, insolvency or certain patent challenges and automatically expires upon the expiration of VIB's licensed patent rights.

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

In February 2012, we entered into an exclusive license with The Board of Regents of The University of Texas System, or UoT, for use of certain patents rights relating to the NHance® platform, for any use worldwide. The agreement was amended on December 23, 2014 to also include certain additional patent rights relating to the ABDEG™ platform. Upon commercialization of any of our products that use the in-licensed patent rights, we will be obligated to pay UoT a percentage of net sales as a royalty until the expiration of any patents covering the product. This royalty varies with net sales volume and is subject to an adjustment for royalties we receive from a sublicensee of our rights under this agreement, but in any event does not exceed 1%. In addition, we must make annual license maintenance payments to UoT until termination of the agreement. We have assumed certain development and commercial milestone payment obligations and must report on our progress in achieving product sales on a quarterly basis. The maximum milestone payments we would be required to make is approximately $0.5 million in total. Through December 31, 2020, we have paid UoT an aggregate of $0.8 million, which includes reimbursement for UoT's patent prosecution and maintenance costs and development milestones on products using the in-licensed patent rights. We also have diligence requirements with respect to development and commercialization of products which use the in-licensed patent rights.

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

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

3.7.6 Our Non-Exclusive License with BioWa (POTELLIGENT®)

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

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

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

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

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

To scale up production of our product candidates cusatuzumab and ARGX-111 for clinical trial and commercial supply, we required a license to a GMP cell line in which POTELLIGENT® antibodies could be expressed. This cell line, POTELLIGENT® CHOK1SV, was jointly developed by BioWa and Lonza. In December 2013 and August 2014, respectively, we entered into non-exclusive commercial license agreements for cusatuzumab and ARGX-111 with BioWa and Lonza Sales AG, or Lonza, for the use of certain patents and know-how relating to the POTELLIGENT® CHOK1SV Technology, which is a combination of Lonza's GS System and BioWa's POTELLIGENT® Technology, for use in the field of prevention and treatment of human diseases. Under the terms of each commercial license, we received a non-exclusive right to research, develop and commercialize products containing an antibody generated specifically against a specific target using POTELLIGENT® CHOK1SV, namely the target CD70 in the case of cusatuzumab and c-Met in the case of ARGX-111. Both targets are designated as reserved targets under our 2010 license agreement with BioWa, which continues to govern our research, development and commercialization of products utilizing BioWa's POTELLIGENT® Technology. Under the terms of each commercial license, BioWa retains a right of first negotiation for the exclusive right to develop and commercialize, in certain countries only, any product we develop using POTELLIGENT® CHOK1SV. This right of first negotiation is not applicable in cases where we intend to grant a global license to a third party to develop and commercialize a product - as was the case with our exclusive, global collaboration and license agreement for cusatuzumab with Cilag GmbH International, an affiliate of Janssen, which was entered into on December 3, 2018. BioWa retains a right of first negotiation for the exclusive right to develop and commercialize our anti-c-Met antibody ARGX-111, in certain countries only.

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

We have assumed certain development, regulatory and commercial milestone payment obligations to both BioWa and Lonza and must report on our progress toward achieving these milestones on an annual basis. We are required to pay such milestones to BioWa under only one license—either the POTELLIGENT® agreement or the POTELLIGENT® CHOK1SV agreement, but not both. Payments related to the development and commercialization of cusatuzumab and ARGX-111 are foreseen under their respective POTELLIGENT® CHOK1SV agreements. Milestones are to be paid on a product-by-product basis, and we are obligated to make development, regulatory and commercial milestone payments to BioWa in aggregate amounts of up to $36.0 million per product should we achieve global annual sales of $1.0 billion. We are obligated to make development, regulatory and commercial milestone payments to Lonza in aggregate amounts of up to approximately £1.1 million per product, if such product is manufactured by Lonza, us or one of our affiliates or strategic partners, or £3.1 million per product, otherwise. Through December 31, 2020, we have paid BioWa an aggregate amount of $2.5 million, which includes a one-off milestone payment, target reservation fees and annual research license fees under our POTELLIGENT® agreement and commercial license fees and milestone payments under our POTELLIGENT®

CHOK1SV agreement. Through December 31, 2020, we have paid Lonza an aggregate amount of £0.4 million, which includes milestone payments under our POTELLIGENT® CHOK1SV agreement.

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

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

3.7.8 Our Collaboration with UCL and Sopartec (GARP)

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

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

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

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

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

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

3.8 Regulatory Framework

3.8.1 Introduction

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

3.8.2 Licensure and Regulation of Biologics in the United States

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

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

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

- payment of user fees and securing FDA approval of the BLA and licensure of the new biological product; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, and any post-approval studies required by the FDA.

Nonclinical Studies and Investigational New Drug Application

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

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

Human Clinical Trials in Support of a BLA

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

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

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

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

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

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

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

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

Compliance with cGMP Requirements

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

Manufacturers and others involved in the manufacture and distribution of products must also register their establishments with the FDA and certain state agencies. Both domestic and foreign manufacturing establishments must register and provide additional information to the FDA upon their initial participation in the manufacturing process. Any product manufactured by or imported from a facility that has not registered, whether foreign or domestic, is deemed misbranded under the FDCA. Establishments may be subject to periodic unannounced inspections by government authorities to

ensure compliance with cGMPs and other laws. Manufacturers may have to provide, on request, electronic or physical records regarding their establishments. Delaying, denying, limiting, or refusing inspection by the FDA may lead to a product being deemed to be adulterated.

Review and Approval of a BLA

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

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

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

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

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

Fast Track, Breakthrough Therapy and Priority Review Designations

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

The FDA may designate a product for fast track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For fast track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a fast track application does not begin until the last section of the application is submitted. Fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

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

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

Accelerated Approval Pathway

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

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

intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a product.

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

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Post-Approval Regulation

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

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

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

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

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

Orphan Drug Designation

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

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

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

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

Pediatric Studies and Exclusivity

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

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

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent and orphan exclusivity. This six-month exclusivity may be granted if a BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

Biosimilars and Exclusivity

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

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

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

U.S. Patent Term Restoration

Depending upon the timing, duration and specifics of FDA approval of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit restoration of the patent term of up to five years as compensation for patent term lost during the FDA regulatory review process. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date and only those claims covering such approved product, a method for using it or a method for manufacturing it may be extended. The patent-term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved biologic is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

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

In order to market any medicinal product outside of the United States, a company also must comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable regulatory authorities before it can initiate clinical trials or marketing of the product in those countries or jurisdictions. Specifically, the process governing approval of medicinal products in the European Union and the United Kingdom generally follows the same lines as in the United States. It entails satisfactory completion of pharmaceutical development, nonclinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the medicinal product for each proposed indication. It also requires the submission to relevant competent authorities for clinical trials authorization and to the EMA or to competent authorities in European Union Member States for a marketing authorization application, or MAA, and granting of a marketing authorization by these authorities before the product can be marketed and sold in the European Union. Following the UK's departure from the European Union, a separate marketing authorization will be required in order to place medicinal products on the market in Great Britain (under the Northern Irish Protocol, the European Union regulatory framework will continue to apply in Northern Ireland and centralized European Union authorizations will continue to be recognized).

Clinical Trial Approval

Pursuant to the currently applicable Clinical Trials Directive 2001/20/EC and the Directive 2005/28/EC on GCP, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the Member States. Under this system, an applicant must obtain approval from the competent national authority of a European Union Member State in which the clinical trial is to be conducted or in multiple member states if the clinical trial is to be conducted in a number of member states. Furthermore, the applicant may only start a clinical trial at a specific study site after the independent ethics committee has issued a favorable opinion. The clinical trial application, or CTA, must be accompanied by an investigational medicinal product dossier with supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and corresponding national laws of the Member States and further detailed in applicable guidance documents.

In April 2014, the European Union adopted a new Clinical Trials Regulation (EU) No 536/2014, which is set to replace the current Clinical Trials Directive 2001/20/EC. It is expected that the new Clinical Trials Regulation will come into effect following confirmation of the full functionality of the Clinical Trials Information System, the centralized European Union portal and database for clinical trials foreseen by the new Clinical Trials Regulation, through an independent audit. This is currently expected to occur in December 2021. It will overhaul the current system of approvals for clinical trials in the European Union. Specifically, the new Regulation, which will be directly applicable in all Member States, aims at simplifying and streamlining the approval of clinical trials in the European Union. For instance, the new Clinical Trials Regulation provides for a streamlined application procedure via a single-entry point and strictly defined deadlines for the assessment of clinical trial applications. The UK has implemented Directive 2001/20/EC into national law through the Medicines for Human Use (Clinical Trials) Regulations, so UK regulation of clinical trials is currently aligned with European Union regulations. The extent to which the regulation of clinical trials in the UK will mirror the new European Union Clinical Trials Regulation once that comes into effect is unknown at present.

Orphan Drug Designation and Exclusivity

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

An orphan drug designation provides a number of benefits, including fee reductions and, regulatory assistance. If a marketing authorization is granted for an orphan drug, this results in a ten-year period of market exclusivity. During this market exclusivity period, neither the EMA nor the European Commission or the Member States can accept an application or grant a marketing authorization for a "similar medicinal product." A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The market exclusivity period for the authorized therapeutic indication may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation because, for example, the product is sufficiently profitable not to justify market exclusivity. Market exclusivity may also be revoked in very select cases, such as if (i) it is established that a similar medicinal product is safer, more effective or otherwise clinically superior; (ii) the marketing authorization holder consents; or (ii) the marketing authorization holder cannot supply enough orphan medicinal product.

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

Marketing Authorization

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

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all EEA Member States. Pursuant to Regulation (EC) No. 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of cancer and auto-immune diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which the centralized procedure is in the interest of public health, the centralized procedure may be optional.

Under the centralized procedure, the Committee for Medicinal Products for Human Use, or the CHMP, established at the EMA is responsible for conducting the assessment of a product to define its risk/benefit profile. The CHMP recommendation is then sent to the European Commission, which adopts a decision binding in all EEA Member States. Under the centralized procedure, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Clock stops may extend the timeframe of evaluation of an MAA considerably beyond 210 days. Accelerated evaluation may be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts such a request, the time limit of 210 days will be reduced to 150 days (excluding clock stops), but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that it is no longer appropriate to conduct an accelerated assessment. Now that the UK has left the European Union, Great Britain will no longer be covered by centralized marketing authorizations (under the Northern Irish Protocol, centralized European Union authorizations will continue to be recognized in Northern Ireland). All medicinal products with a current centralized authorization were automatically converted to Great Britain marketing authorizations on 1 January 2021. For a period of two years from 1 January 2021, the MHRA may rely on a decision taken by the European Commission on the approval of a new marketing authorization in the centralized procedure, in order to more quickly grant a new Great Britain marketing authorization. A separate application will, however, still be required.

Periods of Authorization and Renewals

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

Regulatory Requirements after Marketing Authorization

Following approval, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of the medicinal product. These include compliance with the European Union's stringent pharmacovigilance or safety reporting rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed. In addition, the manufacturing of authorized products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the EMA's GMP requirements and comparable requirements of other regulatory bodies in the European Union, which mandate the methods, facilities and controls used in manufacturing, processing and packing of drugs to assure their safety and identity. Finally, the marketing and promotion of authorized products, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the European Union under Directive 2001/83EC, as amended. Great Britain has implemented European Union legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended). The regulatory regime in Great Britain at present therefore aligns with European Union Regulation, however it is possible that these regimes will diverge in future now that Great Britain's regulatory system is independent from the European Union.

3.8.4 Regulation and Procedures Governing Approval of Medicinal Products in Japan

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

Business License

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

Marketing Approval

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

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

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

Price Regulation
In Japan, public medical insurance systems cover virtually the entire Japanese population. The public medical insurance system, however, does not cover any medical product which is not listed on the National Health Insurance (NHI) price list published by the Minister. Accordingly, a marketing license-holder of medical products must first have a new medical product listed on the NHI price list in order to obtain its coverage under the public medical insurance system.
The NHI price of a medical product is determined either by price comparison of comparable medical products with necessary adjustments for innovativeness, usefulness or size of the market; or, in the absence of comparable medical products, by the cost calculation method, determined after considering of the opinion of the manufacturer. Prices on the NHI price list will be subject to revision, generally once every year, on the basis of the actual prices at which the medical products are purchased by medical institutions.

3.8.5 Coverage, Pricing and Reimbursement

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

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

In China, the newly created National Healthcare Security Administration, or NHSA, an agency responsible for administering China's social security system, organized a price negotiation with drug companies for certain new drugs that had not been included in the National Reimbursable Drug List, or the NRDL, at the time of the negotiation in November 2019, which resulted in an average price reduction by over 60% for 70 of the 119 drugs that passed the negotiation. NHSA, together with other government authorities, review the inclusion or removal of drugs from China's National Drug Catalog for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance, or provincial or local medical insurance catalogues for the national medical insurance program regularly, and the tier under which a drug or device will be classified, both of which affect the amounts reimbursable to program participants for their purchases of those drugs. These determinations are made based on a number of factors, including price and efficacy. We may also be invited to attend the price negotiation with NHSA upon receiving regulatory approval in China, but we will likely need to significantly reduce our prices, and to negotiate with each of the provincial healthcare security administrations on reimbursement ratios. On the other hand, if the NHSA or any of its local counterpart includes our drugs and devices in the NRDL or provincial RDL, which may increase the demand for our drug candidates and devices, our potential revenue from the sales of our drug candidates and devices may still decrease as a result of lower prices. Moreover, eligibility for reimbursement in China does not imply that any drug or device will be paid for in all cases or at a rate that covers our costs, including licensing fees, research, development, manufacture, sale and distribution.

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

The containment of healthcare costs also has become a priority of U.S. federal, state and international governments and the prices of pharmaceuticals have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive

policies in jurisdictions with existing controls and measures, could further limit our potential revenue from the sale of any products for which we may obtain approval. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more of our products for which we or our collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Obtaining and maintaining reimbursement status is time-consuming and costly. No uniform policy for coverage and reimbursement for drug products exists among third-party payors in the United States. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely. Outside the United States, we will face challenges in ensuring obtaining adequate coverage and payment for any product candidates we may develop. Pricing of prescription pharmaceuticals is subject to governmental control in many countries. Pricing negotiations with governmental authorities can extend well beyond the receipt of regulatory marketing approval for a product and may require us to conduct a clinical trial that compares the effectiveness of any product candidates we may develop to other available therapies to support cost-effectiveness. The conduct of such a clinical trial could be expensive, involve additional risk and result in delays in our commercialization efforts.

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

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

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

3.8.6 Healthcare Law and Regulation

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

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

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

- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or obtaining by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the pay (e.g., public or private) or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; similar to the U.S. federal Anti Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, and as amended again by the Omnibus Rule in 2013, , which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the Final HIPAA Omnibus Rule, i.e. certain covered health plans, healthcare clearinghouses and healthcare providers, as well as their business associates, those independent contractors or agents of covered entities that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

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

- the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively the ACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or CMS, within the U.S. Department of Health and Human Services, information related to payments and other transfers of value made by that entity to physicians (currently defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in civil monetary penalties for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners;

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

- analogous state laws and regulations, including: state anti kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and local laws that require the licensure of sales representatives; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect; and state laws related to insurance fraud in the case of claims involving private insurers; and

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

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

We will be required to spend substantial time and money to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations. Recent healthcare reform legislation has strengthened these federal and state healthcare laws. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

Other laws that may affect our ability to operate include:

- the anti-inducement law prohibits, among other things, the offering or giving of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person know or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a federal or state governmental program;
- the U.S. Federal Food, Drug, and Cosmetic Act, or FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices; and
- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

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

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

3.8.7 Healthcare Reform

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

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

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic products, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;

- expansion of manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices and extending rebate liability to prescriptions for individuals enrolled in Medicare Advantage plans;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for products that are inhaled, infused, instilled, implanted or injected;
- expanding the types of entities eligible for the 340B drug discount program;
- establishing the Medicare Part D coverage gap discount program, which requires manufacturers to provide a 50% (increased to 70% effective January 1, 2019 pursuant to subsequent legislation) point-of-sale-discount off the negotiated price of applicable products to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient products to be covered under Medicare Part D;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of the Center for Medicare and Medicaid Innovation, or CMMI within CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription product spending.

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

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

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

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

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. The Trump administration's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Additionally, the Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out-of-pocket costs of drug products paid by consumers. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. The Department of Health and Human Services (HHS) has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. However, it is unclear whether the Biden administration will challenge, reverse, revoke or otherwise modify these executive and administrative actions after January 20, 2021.

Recently there has been other types of heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Specifically, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs.

On July 24, 2020 and September 13, 2020, former President Trump announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. As a result, on November 20 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers

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

We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

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

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

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

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

3.8.8 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.

3.9 Legal and Arbitration 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. 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. During the previous 12 months, there have not been any legal, governmental or arbitration proceedings (including any such proceedings which are pending or threatened of which we are aware) which may have, or have had in the recent past significant effects on the Company and/or the Company's group's financial position or profitability.

4

Management's Discussion and Analysis of Financial Condition and Results of Operations

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4 Management's Discussion and Analysis of Financial Condition and Results of Operations

4.1 Operating and Financial Review

4.1.1 Overview

Since our inception in 2008, we have focused most of our financial resources and efforts towards developing our SIMPLE AntibodyTM Platform and antibody engineering technologies, identifying potential product candidates, establishing process, development and manufacturing capabilities for our product candidates and advancing multiple discovery programs into the clinic. We are advancing a deep pipeline of both clinical- and preclinical-stage product candidates for the treatment of severe autoimmune diseases, hematological disorders and cancer. Leveraging our technology suite and clinical expertise, we have advanced six product candidates into clinical development —efgartigimod, cusatuzumab, ARGX-111, ARGX-109, LP0145 (formerly ARGX-112) and ARGX-115 (ABBV-151); three into the preclinical stage — STT-5058 (formerly ARGX-116), ARGX-117 and ARGX-118; and we currently have multiple programs in the discovery stage. Through December 31, 2020, we have raised aggregate gross proceeds of €2,127.7 million, including:

(i) an aggregate of €46.0 million from the private placement of equity securities in 2008, 2009 and 2011;
(ii) €41.8 million from our initial public offering on the Euronext Brussels in 2014;
(iii) €46.0 million from the private placement of equity securities, primarily to U.S. based institutional investors, in 2016;
(iv) $114.7 million (€102.1 million) from our initial U.S. public offering on the Nasdaq Global Select Market in May 2017;
(v) $265.5 million (€225.6 million) from our second U.S public offering on the Nasdaq Global Select Market in December 2017;
(vi) $300.6 million (€255.7 million) from our third U.S public offering on the Nasdaq Global Select Market in September 2018;
(vii) €176.7 million from the private placement of equity securities as part of the closing of the global collaboration and license agreement with Janssen in January 2019;
(viii) €502.2 million from a global offering in November 2019 ; and
(ix) $590.5 million (€531.2 million) from our U.S. public offering on the Nasdaq Global Select Market and €200.4 million from a concurrent private placement in May 2020.

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

Our balance sheet shows our total assets accumulate to €1,857.7 million for the year ended December 31, 2020, compared to €1,433.3 million for the year ended December 31, 2019 and €587.5 million for the year ended December 31, 2018.The main reason for the material change in balance sheet total are the various equity financing rounds (described in paragraph 5.2.3 "History of Share Capital" on page 163 and further), completed over the period covered by the financial statements incorporated herein by reference (see chapter 7 "Information Incorporated by Reference" on page 244).

Since our inception, we have incurred significant operating losses. We do not currently have any approved products and have never generated any revenue from product sales. Our ability to generate revenue sufficient to achieve profitability will depend significantly upon the successful development and eventual commercialization of one or more of our product candidates, which may never occur. For the years ended December 31, 2019 and 2020, we incurred total comprehensive losses of €163.0 million and €528.9 million, respectively. As of December 31, 2020, we had accumulated losses of €861.5 million.

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

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

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

Other activities
- seek to enhance our technology platform and discover and develop additional product candidates;
- maintain, expand and protect our intellectual property portfolio, including litigation costs associated with defending against alleged patent infringement claims;
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts; and
- experience any delays or encounter any issues, including failed studies, ambiguous trial results, safety issues or other regulatory challenges.

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

Capitalization and Indebtedness

The table below sets forth our capitalization and indebtedness as of December 31, 2020 on an actual basis:

	AT DECEMBER 31, 2020 (AUDITED) (THOUSAND EUROS)
Total current debt (including current position of non-current debt)	**0**
Guaranteed	0
Secured	0
Unguaranteed/unsecured	0
Total non-current debt (excluding current portion of non-current debt)	**0**
Guaranteed	0
Secured	0
Unguaranteed/unsecured	0
Shareholders' equity	1,364,373
Share capital [4]	4,757
Share Premium [4]	2,058,123
Accumulated losses	(861,491)
Other reserves	162,984
Total	1,364,373
Cash	242,161
Cash equivalents [1]	749.448
Other current financial assets [2]	635.359
Liquidity	**(1,626,968)**
Current financial debt (including debt instruments, but excluding current portion of non-current financial debt)	0
Current portion of non-current financial debt [3]	2,833
Current financial indebtedness	**2,833**
Net Current Financial Indebtedness	**(1,624,135)**
Non-current financial debt (excluding current portion and debt instru-ments) [3]	5,035
Debt instruments	0
Non-current trade and other payables	0
Non-current financial indebtedness	**5,035**
Net financial indebtedness (Cash)	**(1,619,100)**

(1) See note 12 "Cash and cash equivalents" to our consolidated financial statements incorporated by reference in this Registration Document (see chapter 7 "Information Incorporated by Reference" on page 244).
(2) See note 11 "Financial assets – current" to our consolidated financial statements incorporated by reference in this Registration Document (see chapter 7 "Information Incorporated by Reference" on page 244).
(3) Please note that financial debt balances as presented in the table above do not include any indirect or contingent indebtedness. For more information on the Company's indirect and contingent indebtedness, please see note 29 "Commitments" to our consolidated financial statements, incorporated by reference in this Registration Document (see chapter 7 "Information Incorporated by Reference" on page 244).
(4) Since December 31, 2020, the Company has received total net cash proceeds from a global offering which took place on February 1, 2021, which amounted to €908.0 million. Please note that the net cash proceeds received from the global offering are not reflected in the cash, cash equivalents and other current financial line item, and will, upon recognition, have a material increasing impact on the aggregate of these financial statement line items, with a corresponding impact to the Company's share capital and share premium.

More information is included in our consolidated financial statements and related notes incorporated by reference in this Registration Document, as set out in chapter 7 "Information Incorporated by Reference" on page 244.

4.1.2 Basis of Presentation

Revenue from Collaborations and license agreements

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

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

• Identify the contracts

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

• Identify performance obligations

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

The Company has assessed that there is one single performance obligation in our material ongoing collaboration and license agreements, being the transfer of a license combined with performance of research and development services. This is because the Company considers the performance obligations cannot be distinct in the context of the contract as the license has no stand-alone value without the Company being further involved in the research and development collaboration and that there is interdependence between the license and the research and development services to be provided.

• 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.

1. Non-refundable upfront payments or license fees

If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable upfront fees allocated to this license at the point in time the license is transferred to the customer and the customer has the right to use the license. For all our material ongoing collaboration and license agreements, the Company considers the performance obligations related to the transfer of the license as not distinct from the other promises to transfer goods and/or services. The Company utilizes judgement to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time. If over time, revenue is then recognized based on a pattern that best reflects the transfer of control of the service to the customer.

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 perfor-

mance 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. 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.

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

- Allocate the transaction price

In principle, an entity shall allocate the transaction price to each performance obligation identified in the contract on a relative stand-alone selling price basis. As our ongoing license and collaboration arrangements only contain one single performance obligation, the transaction price is entirely allocated to this single performance obligation.

- Recognize revenue

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

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

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

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

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

- Government Grants

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

- Research and Development Incentives

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

- Payroll Tax Rebates

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

Research and Development Expenses
Research and development expenses consist principally of:

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

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

(IN THOUSANDS OF €)	2018	2019	2020
Research and development expenses (thousand euros)	83,609	197,665	325,479

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 are not reimbursed. Research and development expenses are recognized in the period in which they are incurred. Under our agreement with Janssen, we assume certain development obligations, and are jointly responsible with Janssen for all research, development and regulatory costs relating to the product. Under our agreement with Zai, we are responsible for certain costs relating to future clinical trials involving efgartigimod conducted partially by Zai.

Our research and development expenses may vary substantially from period to period based on the timing of our research and development activities, including the timing of the initiation of clinical trials, production of product batches and enrolment of patients in clinical trials. Research and development expenses are expected to increase as we advance the clinical development of efgartigimod and cusatuzumab and further advance the research and development of our other preclinical and discovery stage programs. The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing and estimated costs of the efforts that will be necessary to complete the development of, or the period, if any, in which material net cash inflows may commence from, any of our product candidates. This is due to numerous risks and uncertainties associated with developing drugs, as fully described in chapter 1 "Risk Factors" on page 14 and further, and including the uncertainty of:

- the scope, rate of progress and expense of our research and development activities;
- the successful enrollment in, and completion of clinical trials;
- the ability to market, commercialize and achieve market acceptance for efgartigimod, cusatuzumab or any other product candidate that we may develop in the future, if approved;
- establishing and maintaining a continued acceptable safety profile for our product candidates;

- the terms, timing and receipt of regulatory approvals from applicable regulatory authorities;
- the successful completion of preclinical studies necessary to support IND applications in the United States or similar applications in other countries;
- the expense of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; and
- our current and future collaborators continuing their collaborations with us.

Selling, General and Administrative Expenses
Selling, general and administrative expenses consist primarily of (i) personnel expenses relating to salaries and related costs for personnel, including share-based compensation, of our employees in executive, finance, business development, marketing, commercial and support functions, (ii) consulting fees relating to professional fees for business development, marketing, IT, audit, commercial, legal services and investor relations costs, (iii) board expenses consisting of directors' fees, travel expenses and share-based compensation for non-executive board members, (iv) allocated facilities costs and (v) other selling, general and administrative expenses, including leasing costs, office expenses, travel costs.

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

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

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

Exchange Gains (Losses)
Our exchange gains (losses) relate to (i) our transactions denominated in foreign currencies, mainly in U.S. dollars, Swiss francs, British pounds and Japanese yens which generate exchange gains or losses and (ii) the translation at the reporting date of assets and liabilities denominated in foreign currencies into euros, which was our functional and presentation currency until January 1, 2021 and therefore the presentation currency throughout this Registration Document. For more information on currency exchange fluctuations on our business, please see paragraph 1.7.5 "Exchange rate fluctuations or abandonment of the euro currency may materially affect our results of operations and financial condition" on page 47. We have no derivative financial instruments to hedge interest rate and foreign currency risk.

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

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

Critical Accounting Policies and Significant Judgements and Estimates
In the application of the Company's accounting policies, which are described above, the Company is required to make judgments, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates.
The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period or in the period of the revision and future periods if the revision affects both current and future periods.
The following areas are areas where key assumptions concerning the future, and other key sources of estimation uncertainty at the end of the reporting period, have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year.

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

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

Comparison of Years Ended December 31, 2020, 2019 and 2018

(IN THOUSANDS OF €)	Year ended December 31, 2018	Year ended December 31, 2019	Year ended December 31, 2020	% change (2020 compared to 2019)
Revenue	21,482	69,783	36,425	48
Other operating income	7,749	12,801	18,109	41
Total operating income	**29,231**	**82,584**	**54,534**	**(34)**
Research and development expenses	(83,609)	(197,665)	(325,479)	(65)
Selling, general and administrative expenses	(27,471)	(64,569)	(149,367)	(131)
Total operating expenses	**(111,080)**	**(262,234)**	**(474,846)**	**(81)**
Change in fair value on non-current financial assets	–	1,096	2,544	132
Operating loss	**(81,849)**	**(178,554)**	**(417,769)**	**(134)**
Financial income/(expenses)	3,694	14,275	(1,414)	–
Exchange gains (losses)	12,308	(6,066)	(106,956)	–
Loss before taxes	**(65,847)**	**(158,213)**	**(526,139)**	**(233)**
Income tax expense	(794)	(4,752)	(2,784)	41
Loss for the period and total comprehensive loss	**(66,641)**	**(162,965)**	**(528,923)**	**(225)**
Weighted average number of shares outstanding	33,419,356	38,619,121	45,410,442	18
Basic and diluted loss per share (in €)	(1.99)	(4.22)	(11,65)	(177)

Kathy

Kathy and Her Wife Diane on MG, Marriage and Communication

Kathy Lemenu and her wife, Diane, were caring for their baby daughter when Kathy was first diagnosed with MG. Surrounded by loving family and friends in Detroit, MI, this couple adjusted to their new reality with open and honest talks. MG United spoke with Kathy and Diane on how they've changed the way they communicate in the face of MG.

Patient Story

Kathy, your MG worsened gradually. When did it become real for you?

Kathy: As a nurse, I worked mostly in obstetrics. It's a pretty physical department to work in. You're active and have to react quickly to changing situations. But I was having more and more difficulty doing things that weren't a problem before. I hadn't been diagnosed yet, so I figured it was just age.

But after I was diagnosed, when my sister and I were shopping, I started getting very short of breath and I could barely move. I felt very strange. So we went to the hospital right away. I think being in the hospital was kind of a turning point for Diane too, that this mysterious illness became a real thing with consequences

What challenges has MG placed on your relationship?

Kathy: From the time I got diagnosed until now, I've had this terrible fatigue. Diane would say, "The doctor said you shouldn't be tired." I know she was probably thinking, "Get out there and do the dishes." She'd ask if this was something I could power through. That doesn't feel good. The misconceptions about fatigue in MG really sets up problems for couples.

Diane: Before she was diagnosed, I couldn't understand why she was so tired. I was confused and sometimes I would get frustrated by it. I think back on that time and I think, well, she probably had MG symptoms long before she was diagnosed and I had just assumed that she just didn't want to get out of bed, didn't want to feed the baby. MG is one of those conditions where you can't really see clearly what the effects are. So we started getting smarter about how to communicate. I had to develop a lot more empathy.

What advice do you have for other couples trying to talk about MG?

Kathy: It takes such a burden off of me when people understand the fatigue and make it easier for me to live life the way I need to, when they don't try to convince me to do things I can't or make me feel like I am losing out on something.

Revenue

(IN THOUSANDS OF €)	Year ended December 31, 2018	Year ended December 31, 2019	Year ended December 31, 2020	% change (2020 compared to 2019)
Upfront payments	**8,635**	**22,360**	**30,348**	**(36)**
Janssen	—	20,056	29,818	(49)
AbbVie	8,455	761	497	(35)
Agomab	—	1,499	—	(100)
Other	180	44	33	(25)
Milestone payments	**11,440**	**28,085**	**3,021**	**(89)**
Janssen	—	1,569	2,333	(49)
AbbVie	10,510	26,494	671	(97)
Other	930	22	17	(25)
Research and development service fees	**1,407**	**19,338**	**3,056**	**(84)**
Janssen	—	18,968	2,807	(85)
Other	1,407	370	249	(33)
Total	**21,482**	**69,782**	**36,425**	**(48)**

Our revenue decreased by €33.4 million for the year ended December 31, 2020 to €36.4 million, compared to €69.8 million for the year ended December 31, 2019, a result of a decrease in revenue recognition from milestone payments and research and development service fees, partly offset by an increase in revenue recognition from upfront payments. Upfront payments recognized for the year ended Demceber 31, 2018 correspond primarily to the recognition of payments received in connection with entering into the collaboration agreements with LEO Pharma in May 2015 and with AbbVie in April 2016.

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

The decrease in revenue recognition from milestone payments of €25.0 million is mainly driven by revenue recognition in 2019 of the $30.0 million (€26.6 million) milestone payment under the AbbVie collaboration, following the first-in-human clinical trial with ABBV-151, achieved in 2019, whereas in 2020 no such milestone payments were achieved. Milestone payments recognized for the year ended December 31, 2018 correspond primarily to the recognition of milestone payments received under the AbbVie and LEO Pharma collaboration agreements.

The decrease in revenue recognition from research and development service fees of €16.2 million is primarily driven by the decrease under the Janssen collaboration. In 2020, the Company transferred the activities related to the development of cells banks, development of manufacturing process and the production of drug substance to Janssen, resulting in a decrease in costs reimbursement under the cost sharing arrangement. Research and development services recognized for the year ended December 31, 2018 are primarily linked to payments received under the collaboration agreements with LEO Pharma and Shire.

Other Operating Income

(IN THOUSANDS OF €)	Year ended December 31, 2018	Year ended December 31, 2019	Year ended December 31, 2020	% change (2020 compared to 2019)
Grants	1,842	2,289	1,226	(46)
Research and development incentives	2,151	4,818	8,875	84
Payroll tax rebates	3,756	5,694	8,008	41
Total	**7,749**	**12,801**	**18,109**	**41**

Other operating income increased by €5.3 million for the year ended December 31, 2020 to €18,1 million, compared to €12.8 million for the year ended December 31, 2019. The increase is primarily driven by:

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

For more information regarding governmental policies that could affect our operations, see chapter 1 “Risk Factors” and paragraph 3.8.6 “Healthcare Law and Regulation” on page 131 and further.

Research and Development Expenses

(IN THOUSANDS OF €)	Year ended December 31, 2018	Year ended December 31, 2019	Year ended December 31, 2020	% change (2020 compared to 2019)
Personnel expense	26,519	45,733	75,121	64
External research and development expenses	48,859	137,050	228,438	67
Materials and consumables	1,464	2,027	3,099	53
Depreciation and amortization	494	1,641	2,472	51
Other expenses	6,273	11,214	16,349	46
Total	**83,609**	**197,665**	**325,479**	**65**

Our research and development expenses totaled €325.5 million and €197.7 million for the years ended December 31, 2020 and 2019, respectively. The increase of €127.8 million and €241.9 million compared to 2019 and 2018, respectively, primarily results from an increase in external research and development expenses and personnel expenses, primarily related to the efgartigimod program in various indications, cusatuzumab program and other clinical and preclinical programs. Furthermore, the personnel expenses increased due to a planned increase in headcount.

The increase of €29,4 million in personnel expense for the year ended December 31, 2020 as compared to €45.7 million for the year ended December 31, 2019, and €26.5 million for the year ended December 31, 2018, corresponded primarily to (i) an increase of €13.9 million for share-based compensation expenses related to the grant of stock options to our research and development employees as compared to the year ended December 31, 2019, and (ii) increased costs associated with additional research and development personnel. We employed on average 213.0 full time equivalents in our research and development functions in the year ended December 31, 2020, compared to 121.6 in the year ended December 31, 2019, and 76.1 in the year ended December 31, 2018.

Our external research and development expenses for the year ended December 31, 2020 totaled €228.4 million, compared to €137.1 million and €48.9 million for the year ended December 31, 2019 and December 31, 2018, respectively. 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:

(IN THOUSANDS OF €)	Year ended December 31, 2018	Year ended December 31, 2019	Year ended December 31, 2020	% change (2020 compared to 2019)
efgartigimod	30,944	84,180	160,379	91
cusatuzumab	9,289	38,692	43,672	13
Other programs	8,626	14,178	24,388	72
Total	**48,859**	**137,050**	**228,438**	**67**

External research and development expenses for our lead product candidate efgartigimod totaled €160,4 million for the year ended December 31, 2020, compared to €84.2 million and 30.9 million for the year ended December 31, 2019 and 2018, respectively. This increase of €76.2 million corresponds primarily to increased manufacturing and clinical development activities in relation to:

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

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

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

External research and development expenses on other programs increased by €10.2 million to €24.4 million for the year ended December 31, 2020, compared to €14.2 million and €8.6 million for the year ended December 31, 2019 and 2018, respectively. 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

(IN THOUSANDS OF €)	Year ended December 31, 2018	Year ended December 31, 2019	Year ended December 31, 2020	% change (2020 compared to 2019)
Personnel expense	18,292	40,082	94,251	135
Consulting fees	5,472	16,343	42,459	160
Supervisory board	1,088	2,792	4,243	52
Office costs	2,619	5,352	8,414	57
Total	**27,471**	**64,569**	**149,367**	**131**

Our selling, general and administrative expenses totaled €149.4 million, €64.6 million and €27.5 million for the years ended December 31, 2020, 2019 and 2018, respectively. The increase in our selling, general and administrative expenses for the year ended December 31, 2020 was principally due to an increase of personnel expense and consulting fees, resulting from:

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

We employed on average 119.5 full time equivalents in our selling, general and administrative functions in the year ended December 31, 2020, compared to 56.3 and 27.6 in the year ended December 31, 2019 and 2018, respectively.

Financial Income (Expense)

For the year ended December 31, 2020, financial expense amounted to a financial income of €1.4 million compared to €14.3 and €3.7 million for the year ended December 31, 2019 and 2018, respectively. The decrease of €15.7 million in 2020 related primarily to financial expenses incurred as a result of a decrease in net asset value on the current financial assets following the impact of the COVID-19 outbreak on the financial markets, partly offset by the interest received on our cash and cash equivalents and current financial assets.

Exchange Gains (Losses)

Exchange losses totaled €107.0 million for the year ended December 31, 2020, compared to exchange gains of €6.1 million and €12.3 million for the year ended December 31, 2019 and 2018, respectively. The decrease was mainly attributable to unrealized exchange rate losses on the cash, cash equivalents and current financial assets position in U.S. dollars.

4.1.3 Liquidity and Capital Resources

Sources of Funds

Since our inception in 2008, we have invested most of our resources to developing our product candidates, building our intellectual property portfolio, developing our supply chain, conducting business planning, raising capital and providing general and administrative support for these operations. We do not currently have any approved products and have never generated any revenue from product sales. To date, we have funded our operations through public and private placements of equity securities, upfront, milestone and expense reimbursement payments received from our collaborators, funding from governmental bodies and interest income from the investment of our cash, cash equivalents and financial assets. Through December 31, 2020 we have raised gross proceeds of €2,127.7 million from private and public offerings of equity securities, received €442.8 million in revenue from our collaborators, and €29.0 million in grants and incentives from governmental bodies.

Our cash flows may fluctuate and are difficult to forecast and will depend on many factors. On December 31, 2020, we had cash, cash equivalents and current financial assets of €1,627.0 million, compared to €1,335.8 million on December 31, 2019 and €564.6 million on December 31, 2018.

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” to our consolidated financial statements, incorporated by reference in this Registration Document (see chapter 7 “Information Incorporated by Reference” on page 244).

For more information as to the risks associated with our future funding needs, see chapter 1 “Risk Factors” on page 14 and further.

For more information as to our financial instruments, please see note 26 “Financial instruments and financial risk management” to our consolidated financial statements, incorporated by reference in this Registration Document (see chapter 7 “Information Incorporated by Reference” on page 244).

Cash Flows

Comparison for the Years Ended December 31, 2020, 2019 and 2018

The table below summarizes our cash flows for the years ended December 31, 2020, 2019 and 2018.

(IN THOUSANDS OF €)	Year ended December 31, 2018	Year ended December 31, 2019	Year ended December 31, 2020	Variance
Cash and cash equivalents at beginning of the period	**190,867**	**281,040**	**331,282**	**50,242**
Net cash flows (used in)/ from operating activities	(53,839)	134,584	(349,349)	(480,933)
Net cash flows (used in)/ from investing activities	(107,542)	(774,338)	310,250	1,054,588
Net cash flows (used in)/ from financing activities	244,671	659,359	747,897	88,538
Effect of exchange rate differences on cash and cash equivalents	6,883	637	(51,471)	(52,108)
Cash and cash equivalents at end of the period	**281,040**	**331,282**	**991,609**	**660,327**

Net Cash Used in Operating Activities

Net cash outflow from our operating activities increased by €480.9 million to a net outflow of €349.3 million for the year ended December 31, 2020, compared to a net inflow of €134.6 million for the year ended December 31, 2019 and a net outflow of €53.8 million for the year ended December 31, 2018. The net cash outflow from operating activities for the year ended December 31, 2020 resulted primarily from (i) the research and development expenses incurred in relation to the manufacturing and clinical development activities of efgartigimod, cusatuzumab and the advancement of other preclinical and discovery-stage product candidate, (ii) the personnel expenses and consulting expenses incurred in preparation of the potential commercial launch of efgartigimod in the U.S., and (iii) the manufacturing of pre-launch inventory ahead of the potential commercial launch of efgartigimod in the U.S. The net cash inflow of €134.6 million for the year ended December 31, 2019 was primarily influenced by the closing of the exclusive global collaboration and license agreement for cusatuzumab with Janssen, which triggered a $300 million upfront payment, whereas in the year ended December 31, 2020 no such cash inflows occurred.

Net Cash Used in Investing Activities

Investing activities consist primarily of the divestment of current financial assets, interest received from the placements of our cash and cash equivalents and current financial assets. Cash flow from investing activities represented a net outflow of €310.3 million for the year ended December 31, 2020, compared to a net inflow of €310.2 million for the year ended December 31, 2019 and a net outflow of €107.5 million for the year ended December 31, 2018. The net inflow for the year ended December 31, 2020 related primarily to the net divestment of €307.6 million of current financial assets, including money market funds and U.S. term deposit accounts to money market funds classified as cash equivalents, compared to a net investment of €708.1 for the year ended December 31, 2019.

Net Cash Provided by Financing Activities

Financing activities primarily consist of net proceeds from our private placements and public offerings of our securities and exercise of stock options. The net cash inflow from financing activities was €747.9 million for the year ended December 31, 2020, compared to a net cash inflow of €659.4 million for the year ended December 31, 2019 and a net cash inflow of €244.7 million for the year ended December 31, 2018. The net cash inflow for the year ended December 31, 2020 was attributed to (i) €731.1 million net cash proceeds from our global offering and concurrent private placement in May 2020, compared to €655.9 million net cash proceeds from our global offering in November 2019 and our private placement in January 2019 following the closing of the exclusive global collaboration and license agreement for cusatuzumab with Janssen in January 2019, and €241.1 million net cash proceeds from our U.S. follow-on public offering of ADSs in September 2018, and (ii) €19.1 million proceeds received from the exercise of stock options in 2020, compared to €4.8 million and €2.3 million in 2019 and 2018, respectively.

Operating and Capital Expenditure Requirements

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

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

- the progress, timing and completion of preclinical testing and clinical trials for our current or any future product candidates;
- the number of potential new product candidates we identify and decide to develop;
- the time and costs involved in obtaining regulatory approval for our product candidates and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to any of our product candidates;
- selling and marketing activities undertaken in connection with the potential commercialization of our current or any future product candidates, if approved, and costs involved in the creation of an effective sales and marketing organization;
- manufacturing activities undertaken ahead of the potential commercialization of our current or any future product candidates, if approved, and costs involved in the creation of an effective supply chain;
- the costs involved in growing our organization to the size needed to allow for the research, development and potential commercialization of our current or any future product candidates;
- the costs involved in filing patent applications and maintaining and enforcing patents or defending against claims or infringements raised by third parties;
- the maintenance of our existing collaboration agreements and entry into new collaboration agreements;
- the amount of revenues, if any, we may derive either directly or in the form of royalty payments from future sales of our product candidates, if approved; and
- developments related to COVID-19 and its impact on the costs and timing associated with the conduct of our clinical trials, preclinical programs, manufacturing activities and other related activities.

For more information as to the risks associated with our future funding needs, see chapter 1 “Risk Factors” on page 14 and further.

4.1.4 Financial instruments

The Company does not use any financial derivatives.

4.1.5 Working capital statement

In accordance with item 3.1 of Annex 11 of the commission delegated regulation (EU) 2019/980 we make the following statement:

In our opinion, the working capital of the Company is sufficient for the Company’s present requirements, at least for a period of 12 months from the date of this Registration Document.

4.2 Financial Statements

The (consolidated) audited financial statements of the Company for the financial years ending on December 31, 2019 and 2018 are incorporated into this Registration Document by reference. These documents are freely accessible on the Company’s website www.argenx.com.

4.3 Information Regarding the Independent Auditor

The audited consolidated financial statements as of and for the financial years ended December 31, 2020 and 2019 and 2018 have been audited by our independent auditor, Deloitte, who rendered an unqualified audit report on these financial statements. The partner of Deloitte who signed the auditors’ reports is a member of the Netherlands Institute of Chartered Accountants (*Koninklijke Nederlandse Beroepsorganisatie van Accountants*). The office of Deloitte is located at Wilhelminakade 1, 3072 AP Rotterdam, the Netherlands.

4.4 Statutory Auditor Fees

The fees for services provided by our independent auditor Deloitte and its member firms and/or affiliates, to us and our subsidiaries were approved by the audit and compliance committee and can be broken down as follows:

(IN THOUSANDS OF €)	2018	2019	2020
Audit fees	648	730	808
Audit related fees	143	159	165
Tax and other services	—	—	—
Total	**791**	**889**	**973**

General description of the Company and it's Share Capital

Contents

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5 General description of the Company and it's Share Capital

5.1 General Description of the Company

5.1.1 Corporate Details

We were incorporated on April 25, 2008 in the Netherlands and under Dutch law. Our commercial name is 'argenx' and since April 26, 2017, our corporate name is 'argenx SE'. We are a Dutch European public company (*Societas Europaea* or *SE*) registered with the trade register of the Dutch Chamber of Commerce under number 24435214. Our corporate seat is in Rotterdam, the Netherlands, and our registered office is at Willemstraat 5, 4811 AH, Breda, the Netherlands. Our telephone number is +31 (0) 10 70 38 441. Our website address is http://www.argenx.com. Information on the website does not form part of this Registration Document unless that information is incorporated by reference into this Registration Document (see also chapter 7 "Information Incorporated by Reference" on page 244).

Our European legal entity identifier number (LEI) is 7245009C5FZE6G9ODQ71. Our ordinary shares are listed on Euronext Brussels under ISIN Code NL0010832176 under the symbol "ARGX". The ADSs are listed on the Nasdaq Stock Market, or Nasdaq, under the symbol "ARGX".

The financial years of argenx and each of its subsidiaries run from 1 January to 31 December.

5.1.2 Group Structure

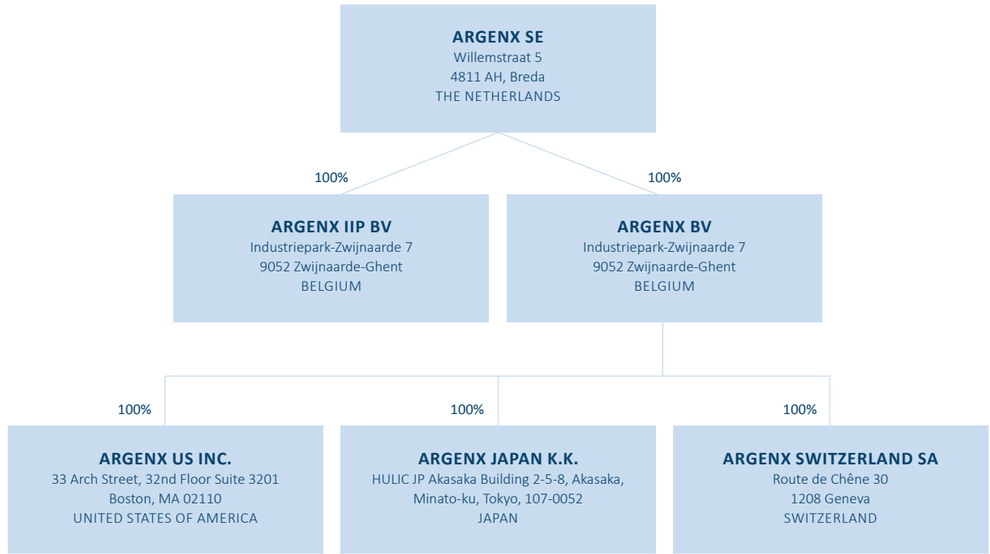
argenx SE is the top entity in our group and operates under Dutch law. argenx SE is the sole shareholder of argenx IIP BV, a private company with limited liability (besloten vennootschap) incorporated under the laws of Belgium, having its registered seat in Zwijnaarde, Belgium. Furthermore, argenx SE is the sole shareholder of argenx BV, a private company with limited liability (besloten vennootschap) incorporated under the laws of Belgium, having its registered seat in Zwijnaarde, Belgium. argenx BV is the sole shareholder of:

(i) argenx US Inc, incorporated under the laws of Delaware, United States of America, having its registered office in Wilmington, Delaware and its address at 33 Arch Street, Boston, Massachusetts 02110;

(ii) argenx Japan K.K., incorporated under the laws of Japan, having its registered office in Tokyo, Japan and its address at HULIC JP Akasaka Building 2-5-8, Akasaka, Minato-ku, Tokyo, 107-0052, Japan; and

(iii) argenx Switzerland SA, incorporated under the laws of Switzerland, having its registered office in Geneva, Switzerland, and its address at Route de Chêne 30, 1208 Geneva, Switzerland.

Schematically, our legal group structure can be shown as follows:



5.1.3 Statutory/corporate objectives

Pursuant to Article 3 of our Articles of Association, our corporate objectives are: (a) to exploit, including all activities relating to research, development, production, marketing and commercial exploitation; biological, chemical or other products, processes and technologies in the life sciences sector in general, and more specifically in the diagnostic, pharmaceutical, medical, cosmetic, chemical and agricultural sector; (b) to design and develop instruments which may be used in medical diagnosis and affiliated areas; (c) the worldwide distribution of, sale of and rendering services relating to our products and subsidiaries directly to customers as well as through third parties; (d) to incorporate, to participate in any way whatsoever, to manage, to supervise, to operate and to promote enterprises, businesses and companies; (e) to render advice and services to businesses and companies with which we form a group and to third parties; (f) to finance businesses and companies; (g) to borrow, to lend and to raise funds, including the issue of bonds, promissory notes or other securities or evidence of indebtedness as well as to enter into agreements in connection with the aforementioned; (h) to render guarantees, to bind us and to pledge our assets for obligations of the companies and enterprises with which we form a group and on behalf of third parties; (i) to obtain, alienate, manage and exploit registered property and items of property in general; (j) to trade in currencies, securities and items of property in general; (k) to develop and trade in patents, trademarks, licenses, know-how and other industrial property rights; and (l) to perform any and all activities of industrial, financial or commercial nature, as well as everything pertaining the foregoing, relating thereto or conductive thereto, all in the widest sense of the word.

5.1.4 Facilities

We lease our operational offices and laboratory space, which consists of approximately 2,000 square meters on the date of this Registration Document, located in Zwijnaarde, Belgium. The lease for this facility expires in 2026. We expect that our current facility may not be sufficient to sustain our current rate of expansion, but we are confident that the options of renting additional space will prove sufficient to meet our needs for the foreseeable future. We have also initiated the process of renting a larger facility in Zwijnaarde, Belgium from approximately 2023 onwards. We also lease offices in Breda, the Netherlands, Boston, Massachusetts, Minato-ku, Tokyo, and have a flexible rental agreement for office facilities in Geneva, Switzerland.

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

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” to our consolidated financial statements, incorporated by reference in this Registration Document (see chapter 7 “Information Incorporated by Reference” on page 244).

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

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

Facility location	USE	Approx. size (m2)	Lease expiry
Zwijnaarde, Belgium (leased)	Operations and aboratory Space	4,086	March 31st, 2025
Breda, the Netherlands (leased)	Headquarters	12	July 31st, 2021
Boston, Massachusetts (leased)	Office Space	813	August 31st, 2025
Tokyo, Japan (leased)	Office Space	546	January 17th, 2024

5.2 General Description of the Share Capital

5.2.1 Authorized Share Capital

Under Dutch Law (Section 2:67 of the DCC), a company’s authorized share capital sets out the maximum amount and number of shares that it may issue without amending its articles of association. Our Articles of Association provide for an authorized share capital in the amount of €9 million divided into 90 million shares, each with a nominal value of €0.10. All issued and outstanding shares have been fully paid up and the shares are held in dematerialized form. As of March 16, 2021, our issued and paid up share capital amounted to € 5,130,561.0, represented by 51,305,610 ordinary shares with a nominal value of €0.10, each representing an identical fraction of our share capital. As of March 16, 2021, neither we nor any of our subsidiaries held any of our own shares.

5.2.2 Stock Options

In addition to the shares already outstanding, we have granted options which upon exercise will lead to an increase in the number of our outstanding shares. A total of 5,365,743 options (where each option entitles the holder to subscribe for one new ordinary share) were outstanding and granted as of December 31, 2020. Upon exercise of these 5,365,743 options, a total amount of €624.7 million in option exercise price would become payable to the Company by the optionees, increasing the Company’s share capital and share premium by the same amount. A total of 5,220,960 options (where each option entitles the holder to subscribe for one new ordinary share) were outstanding and granted as of March 16, 2021. Upon exercise of these 5,220,960 options, a total amount of €620.4 million in option exercise price would become payable to the Company by the optionees, increasing the Company’s share capital by the same amount. Apart from the options granted under the argenx employee stock option plan, or Option Plan, we do not currently have other stock options, options to purchase securities, convertible securities or other rights to subscribe for or purchase securities outstanding. For option information through December 31, 2020, see note 14 “Share-based payments” in this Registration Document (see chapter 7 “Information Incorporated by Reference” on page 244). No options have been granted in the period 1 January, 2021 up to the date of this Registration Document.

5.2.3 History of Share Capital

New Shares created during 2018
As a result of the exercise of options under the Option Plan, 318,329 new shares were created in 2018.

On September 18, 2018, argenx offered 3,475,000 of its ordinary shares through a public offering in the United States in the form of ADSs at a price to the public of $86.50 per ADS, before underwriting discounts and commissions and offering expenses. As a result, argenx received €255.7 million of gross proceeds from this offering, decreased by €14.8 million of underwriter discounts and commissions, and offering expenses, of which €14.6 million has been deducted from equity. The total net cash proceeds from the Offering amounted to €240.9 million.

New shares created during 2019
On January 18, 2019, Johnsen & Johnsen Innovation JJDC, Inc. purchased 1,766,899 ordinary shares issued by the Company at a price of €100.02 per share, totaling €176.7 million, as part of a broader license and collaboration arrangement further described in section 3.6 “ Collaboration Agreements” on page 107 and further. The shareholding of Johnson & Johnson Innovation at the time of the issuance represented approximately 4.68% of argenx’s outstanding shares.

As a result of the exercise of options under the Option Plan, 419,317 new shares were created in 2019.

On November 7, 2019, argenx offered 4,000,000 of its ordinary shares through a global offering which consisted of (i) a public offering of 2,010,057 ADSs in the U.S. and certain other countries outside the European Economic Area (EEA) at a price of $121.00 per ADS, before underwriting discounts and commissions and offering expenses; and (ii) a concurrent private placement of 2,589,943 of ordinary shares in the EEA at an offering price of €109.18 per share, before underwriting discounts and commissions and offering expenses. On November 8, 2019, the underwriters of the offering exercised their over-allotment option to purchase 600,000 additional ADSs in full. As a result, argenx received €502.2 million of gross proceeds from this offering, decreased by €23.2 million of underwriter discounts and commissions, and offering expenses, of which €23.0 million has been deducted from equity. The total net cash proceeds from the offering amounted to €479.0 million.

New shares created during 2020
As a result of the exercise of options under the Option Plan, 602,461 new shares were created in 2020.

On May 28, 2020, argenx offered 3,658,515 of its ordinary shares through a global offering which consisted of (i) a public offering of 2,584,138 ADSs in the U.S. and certain other countries outside the European Economic Area (EEA) at a price of $205.00 per ADS, before underwriting discounts and commissions and offering expenses; and (ii) a concurrent private placement of 1,074,377 ordinary shares in the EEA at an offering price of €186.52 per share, before underwriting discounts and commissions and offering expenses. On May 29, 2020, the underwriters of the offering exercised their over-allotment option to purchase 548,777 additional ADSs in full. As a result, argenx received €784.7 million of gross proceeds from this offering, decreased by €47.4 million of underwriter discounts and commissions, and offering expenses, of which €47.1 million has been deducted from equity. The total net cash proceeds from the offering amounted to €731.1 million.

On February 2, 2021, argenx offered 3,125,000 of its ordinary shares through a global offering which consisted of (i) a public offering of 1,608,000 ADSs in the U.S. and certain other countries outside the European Economic Area (EEA) at a price of $320.00 per ADS, before underwriting discounts and commissions and offering expenses; and (ii) a concurrent private placement of 1,517,000 ordinary shares in the EEA at an offering 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 received €954.8 million of gross

proceeds from this offering, decreased by €46.8 million of underwriter discounts and commissions, and offering expenses, of which €46.5 million has been deducted from equity. The total net cash proceeds from the offering amounted to €908.0 million.

The following table shows the developments in our share capital for the financial years 2018, 2019 and 2020 and up to March 16, 2021:

Number of shares outstanding on December 31, 2018	**35,975,312**
Exercise of options in January 2019	163,170
Share subscription from Johnson & Johnson Innovation Inc.	1,766,899
Exercise of options in February 2019	13,393
Exercise of options in March 2019	73,005
Exercise of options in April 2019	13,729
Exercise of options in May 2019	35,054
Exercise of options in June 2019	66,965
Exercise of options in July 2019	56
Exercise of options in August 2019	8,710
Exercise of options in September 2019	5,730
Exercise of options in October 2019	611
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
Exercise of options in November 2019	16,714
Exercise of options in December 2019	22,180
Number of shares outstanding on December 31, 2019	**42,761,528**
Exercise of options in January 2020	25,930
Exercise of options in February 2020	418
Exercise of options in March 2020	4,600
Exercise of options in April 2020	2,000
Exercise of options in May 2020	65,230
Global public offering on Euronext and Nasdaq on May 28, 2020	3,658,515
Over-allotment option exercised by underwriters on May 29, 2020	548,777
Exercise of options in June 2020	41,501
Exercise of options in July 2020	34,240
Exercise of options in August 2020	84,241
Exercise of options in September 2020	114,949
Exercise of options in October 2020	18,134
Exercise of options in November 2020	143,329
Exercise of options in December 2020	67,891
Number of shares outstanding on December 31, 2020	**47,571,283**
Exercise of options in January 2021	110,969
Exercise of options in February 2021	19,000
Global offering on Nasdaq and Euronext on February 2, 2021	3,125,000
Over-allotment option exercised by underwriters on February 4, 2021	468,750
Exercise of options in March 2021 (up to March 16, 2021)	10,608
Number of shares outstanding on March 16, 2021	**51,305,610**

5.2.4 American Depository Shares

In connection with our IPO on Nasdaq, the Bank of New York Mellon, as depositary, registered and delivered American Depositary Shares, also referred to as ADSs. Each ADS represents 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 also represents any other securities, cash or other property which may be held by the depositary. 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.

An ADS holder will not be treated as one of our shareholders and does not have shareholder rights. Dutch law governs shareholder rights. The depositary will be the holder of the shares underlying the ADSs. A registered holder of ADSs has ADS holder rights. 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.

The depositary has agreed to pay or distribute to ADS holders the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, upon payment or deduction of its fees and expenses. ADS holders will receive these distributions in proportion to the number of shares their ADSs represent. An ADS holder may surrender his ADSs at the depositary's office. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver the shares and any other deposited securities underlying the ADSs to the ADS holder or a person the ADS holder designates at the office of the custodian. Or, at an ADS holder's request, risk and expense, the depositary will deliver the deposited securities at its office, if feasible.

The depositary may charge the ADS holder a fee and its expenses for instructing the custodian regarding delivery of deposited securities. ADS holders may instruct the depositary how to vote the number of deposited shares their ADSs represent. If we request the depositary to solicit the ADS holders' voting instructions (and we are not required to do so), the depositary will notify them of a General Meeting and send or make voting materials available to them. Those materials will describe the matters to be voted on and explain how ADS holders may instruct the depositary how to vote. For instructions to be valid, they must reach the depositary by a date set by the depositary. The depositary will try, as far as practical, subject to Dutch law and the provisions of our Articles of Association or similar documents, to vote or to have its agents vote the shares or other deposited securities as instructed by ADS holders. If we do not request the depositary to solicit the ADS holders' voting instructions, an ADS holder can still send voting instructions, and, in that case, the depositary may try to vote as he instructs, but it is not required to do so. In any event, the depositary will not exercise any discretion in voting deposited securities and it will only vote or attempt to vote as instructed or as described in the following sentence. If we asked the depositary to solicit an ADS holder's instructions at least 45 days before the meeting date but the depositary does not receive voting instructions from an ADS holder by the specified date, it will consider such ADS holder to have authorized and directed it to give a discretionary proxy to a person designated by us to vote the number of deposited securities represented by its ADSs. The depositary will give a discretionary proxy in those circumstances to vote on all questions to be voted upon unless we notify the depositary that:

- we do not wish to receive a discretionary proxy;
- there is substantial shareholder opposition to the particular question; or
- the particular question would have an adverse impact on our shareholders.

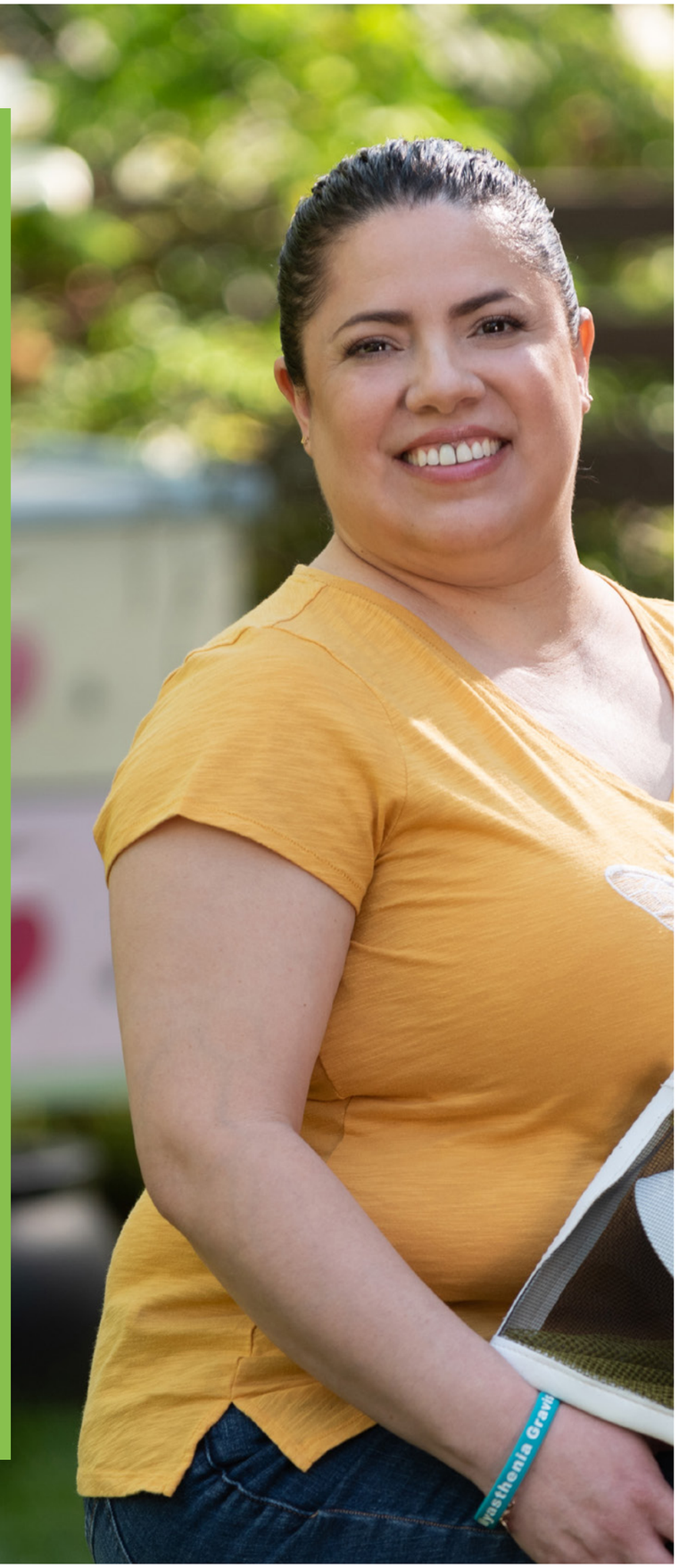
We are required to notify the depositary if one of the conditions specified above exists. In order to give an ADS holder a reasonable opportunity to instruct the depositary as to the exercise of voting rights relating to our shares, if we request the depositary to act, we agree to give the depositary notice of any meeting and details concerning the matters to be voted upon at least 30 days in advance of the meeting date.

Leah

Leah Gaitan-Diaz and the Empowerment of Positive Thinking

This married Los Angeles native has been living with myasthenia gravis for five years, becoming a dedicated advocate for the community along the way. Leah talks with MG United about what doctors don't seem to grasp about living with MG, the importance of positivity and her former—and perhaps future—life as a beekeeper.

Patient Story



What's something about MG you think doctors struggle to understand?

That's an easy one: the fatigue! For example, my menstrual cycle just wipes me out. Yesterday I was in bed until one o'clock in the afternoon. I could not get out of bed or wake up. I know that fatigue is a normal part of having your period, but with MG it has become three times worse for me. And no doctor has figured that part out. They might look at us and say, "You're a woman, that's normal." But no, this is not normal. I never experienced that kind of fatigue before I got diagnosed.

Lots of women don't talk about their age, but you do. Why?

Yes, I'm 44. I talk about it because it's a big part of my MG story. I got diagnosed at 40, right when we were seriously thinking about having a child. But with the ongoing struggle to stabilize my MG, I realized I couldn't. I'm not stable. I have to focus on taking care of myself.

For a lot of women, that goes against their instincts. That's why I share it. I want to say to women with MG, "It's okay to focus on your own health." You have to give yourself permission to do that.

Any advice for handling daily life with MG?

This is the one thing that I tell everybody in the MG community: Get to know your body. Listen to it. That means if you're tired, take a nap. If you don't feel up to taking a shower or putting away laundry, that stuff can wait. It's okay.

That was a *huge* change of mindset for me. I was such a perfectionist; everything needed to be done just right. But with MG, that's stress you don't need. It's alright if something's in the wrong place, you know? It's not the end of the world. You can always fix it later. Give yourself that permission.

5.2.5 Modification of Share Capital or Rights Attached to the Shares

Issue of Shares

The Articles of Association provide that shares may be issued or rights to subscribe for our shares may be granted pursuant to a resolution of the shareholders at the General Meeting, or alternatively, by our board of directors if so designated by the shareholders at the General Meeting. A resolution of the shareholders at the General Meeting to issue shares, to grant rights to subscribe for shares or to designate our board of directors as the corporate body of the company authorized to do so can only take place at the proposal of our board of directors with the consent of the majority of the non-executive directors. Shares may be issued or rights to subscribe for shares may be granted by resolution of our board of directors, if and insofar as our board of directors is designated to do so by the shareholders at the General Meeting. Designation by resolution of the shareholders at the General Meeting cannot be withdrawn unless determined otherwise at the time of designation. The scope and duration of our board of directors' authority to issue shares or grant rights to subscribe for shares (such as granting stock options or issuing convertible bonds) is determined by a resolution of the shareholders at the General Meeting and relates, at the most, to all unissued shares in the Company's authorized capital at the relevant time. The duration of this authority may not exceed a period of five years. Designation of our board of directors as the body authorized to issue shares or grant rights to subscribe for shares may be extended by a resolution of the shareholders at the General Meeting for a period not exceeding five years in each case. The number of shares that may be issued is determined at the time of designation.

No shareholders' resolution or board of directors' resolution is required to issue shares pursuant to the exercise of a previously granted right to subscribe for shares. A resolution of our board of directors to issue shares and to grant rights to subscribe for shares can only be taken with the consent of the majority of the non-executive directors.

On May 12, 2020, the shareholders at the General Meeting designated our board of directors as the corporate body competent to issue shares under the Option Plan up to a maximum of 4% of the outstanding capital at the date of the general meeting and to limit or exclude pre-emptive rights of shareholders for such shares and option rights to subscribe for shares with the prior consent of the majority of the non-executive directors for a period of 18 months. On May 12, 2020, the shareholders at the General Meeting designated our board of directors as the corporate body competent to issue additional shares and grant rights to subscribe for shares up to a maximum of 10% of the outstanding capital at the date of the general meeting, and to limit or exclude pre-emptive rights of shareholders for such shares with the prior consent of the majority of the non-executive directors for a period of 18 months.

In addition, on May 12, 2020, the shareholders at the General Meeting designated our board of directors as the corporate body competent to issue additional shares and grant rights to subscribe for shares up to a maximum of 10% of the outstanding share capital of the Company at the date of the general meeting, for a period starting on May 12, 2020, and ending on December 31, 2020, for the purpose of a possible public offering of such shares and to limit or exclude pre-emptive rights of shareholders for such shares with the prior consent of the majority of the non-executive directors. While there is no current intention to benefit any specific person with this authorization to restrict the pre-emptive rights of the existing shareholders, when using this authorization the board will be able to restrict the pre-emptive rights in whole or in part, including for the benefit of specific persons. The board's ability to restrict the pre-emptive rights in whole or in part could be used by the board as a potential anti-takeover measure, although there is currently no likely scenario in which we expect that such ability would be used as an anti-takeover measure.

Pre-emptive rights

Dutch law (Section 2:96a of the DCC) and the Articles of Association give shareholders pre-emptive rights to subscribe on a pro rata basis for any issue of new shares or, upon a grant of rights, to subscribe for shares. Holders of shares have no pre-emptive rights upon (1) the issue of shares against a payment in kind (being a contribution other than in cash); (2) the issue of shares to our employees or the employees of a member of our group; and (3) the issue of shares to persons exercising a previously granted right to subscribe for shares.

A shareholder may exercise pre-emptive rights during a period of at least two weeks from the date of the announcement of the issue of shares. Pursuant to the Articles of Association, the shareholders at the General Meeting may restrict or exclude the pre-emptive rights of shareholders. A resolution of the shareholders at the General Meeting to restrict or exclude the pre-emptive rights or to designate our board of directors as our body authorized to do so, may only be adopted on the proposal of our board of directors with the consent of the majority of the non-executive directors. A resolution of the shareholders at the General Meeting to exclude or restrict pre-emptive rights, or to authorize our board of directors to exclude or restrict pre-emptive rights, requires a majority of at least two-thirds of the votes cast, if less than 50% of our issued and outstanding share capital is present or represented at the General Meeting.

With respect to an issuance of shares pursuant to a resolution of our board of directors, the pre-emptive rights of shareholders may be restricted or excluded by resolution of our board of directors if and insofar as our board of directors is designated to do so by the shareholders at the General Meeting. A resolution of our board of directors to restrict or exclude pre-emptive rights can only be taken with the consent of the majority of the non-executive directors.

The designation of our board of directors as the body competent to restrict or exclude the pre-emptive rights may be extended by a resolution of the shareholders at the General Meeting for a period not exceeding five years in each case. Designation by resolution of the shareholders at the General Meeting cannot be withdrawn unless determined otherwise at the time of designation.

Please refer to the third section of this paragraph 5.2.5 with respect to the right of the board of directors to limit or exclude pre-emptive rights.

Acquisition of Shares by the Company

We may not subscribe for our own shares on issue. We may acquire fully paid-up shares at any time for no consideration or, if:

- our shareholders' equity less the payment required to make the acquisition, does not fall below the sum of called-up and paid-in share capital and any statutory reserves;
- we and our subsidiaries would thereafter not hold shares or hold a pledge over shares with an aggregate nominal value exceeding 50% of our issued share capital; and
- our board of directors has been authorized thereto by the shareholders at the General Meeting.

As part of the authorization, the shareholders at the General Meeting must specify the number of shares that may be repurchased, the manner in which the shares may be acquired and the price range within which the shares may be acquired. An authorization by the shareholders at the General Meeting to our board of directors for the repurchase of shares can be granted for a maximum period of 18 months. No authorization of the shareholders at the General Meeting is required if ordinary shares are acquired by us with the intention of transferring such ordinary shares to our employees under the Option Plan. A resolution of our board of directors to repurchase shares can only be taken with the consent of the majority of the non-executive directors.

Shares held by us in our own share capital do not carry a right to any distribution. Furthermore, no voting rights may be exercised for any of the shares held by us or our subsidiaries unless such shares a are subject to the right of usufruct or to a pledge in favor of a person other than us or its subsidiaries and the voting rights were vested in the pledgee or usufructuary before us or its subsidiaries acquired such shares. Neither we nor our subsidiaries may exercise voting rights in respect of shares for which we or our subsidiaries have a right of usufruct or a pledge.

Reduction of Share Capital

The shareholders at the General Meeting may, upon a proposal of our board of directors with the consent of the majority of the non-executive directors, resolve to reduce the issued share capital by cancelling shares or by amending the Articles of Association to reduce the nominal value of the shares. Only shares held by us or shares for which we hold the depositary receipts may be cancelled. A resolution of the shareholders at the General Meeting to reduce the number of shares must designate the shares to which the resolution applies and must lay down rules for the implementation of the resolution. A resolution to reduce the issued share capital requires a majority of at least two-thirds of the votes cast, if less than 50% of our issued and outstanding share capital is present or represented at the General Meeting.

5.3 Shareholdings and Voting Rights

5.3.1 Principal Shareholders

At the date of this Registration Document the issued share capital of argenx SE amounts to €5,128,774.20 and is represented by 51,287,742 ordinary shares. There are only ordinary shares, and there are no special rights attached to any of the ordinary shares, nor special shareholder rights for any of the shareholders of argenx SE. The following major shareholdings fall under the mandatory notice provisions of Section 5:38 of the DFSA on the basis of information provided by the shareholders and/or the public register of all notifications made available pursuant to the DFSA at the AFM's website up to the date of this Registration Document (see also section 5.2 "General Description of Share Capital" on page 162 and further). No shareholdings above 3% were reported to the Company directly.

NAME OF BENEFICIAL OWNER	Number of Shares	Capital Interest (percentage)	Number of Voting Rights	Voting Rights (percentage)
T. Rowe Price Group, Inc. [1]	4,998,028 [2]	11.68	4,927,064	11.51
FMR LLC [1]	5,025,092 [3]	9.80	5,025,092	9.80
Artisan Investments GP LLC	2,575,257 [4]	5.02	2,559,462	5.02
Entities affiliated with Baker Bros [1] [5]	2,257,138	5.28	2,257,138	5.28
Federated Equity Management Company of Pennsylvania [1]	1,895,001 [6]	4.97	1,895,001	4.97
The Goldman Sachs Group, Inc. [1] [7]	See breakdown in footnote [8]	4.92	See breakdown in footnote [8]	4.92
Johnson & Johnson Innovation – JJDC, Inc. [1]	1,766,899	4.66	1,766,899	4.66
The Vanguard Group [1]	1,978,464	4.16	0	0
BlackRock, Inc. [1]	2,088,766 [9]	4.07	2,431,314	4.74
Baillie Gifford & Co. [1]	0	0	2,966,216	6.24
Wellington Management Group LLP [1]	0	0	2,276,361 [10]	4.81
	1,290,201	1,290,201	1,290,201	-

(1) Based on the number of shares reported in, and at the time of, the most recent transparency notification filed with the AFM.
(2) Consisting of 1,571 ordinary shares and 4,996,457 ADSs. There is a more recent SEC filing which sets out a number of 4,921,980 shares.
(3) There is a SEC filing of the same date as the AFM filing which sets out a number of 4,757,128 shares.
(4) Consisting of 105,864 ordinary shares and 2,469,393, according to the AFM filing, depository receipts.
(5) From the notifications filed with the AFM we understand that it concerns the following entities: Baker Brothers Life Sciences Capital (GP), LLC and Baker Bros. Advisors GP LLC.
(6) Consisting of 1,522,200 ordinary shares and 372,801 ADSs.
(7) From the notification filed with the AFM we understand that the Goldman Sachs Group, Inc. is partici-pating through various entities.
(8) Consisting of 80,359 ordinary shares, 403,018 ADSs, 60,000 call-options, 2,168 warrants, 985,271 contracts for difference, 963,835 swaps and 20,000 put options. Number of shares (short): 1,970,975. Capital interest percentage (short): 3,84% (indirectly).
(9) Consisting of 1,648,122 ordinary shares and 440,644, according to the AFM filing, depository receipts.
(10) Consisting of voting rights on 1,545,652 ordinary shares, 729,479 ADSs and 1,230 equity swaps.

The total number of stock options outstanding on March 16, 2021 amounts to 5,220,960.

At the date of this Registration Document, we are not directly or indirectly owned or controlled by any shareholder, whether individually or acting in concert. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

5.3.2 Relationships with Principal Shareholders

Currently, as far as we are aware, there are no direct or indirect relationships between us and any of our significant shareholders, other than our collaboration agreement with J&J Innovation, Inc., as described in detail in this Registration Document in paragraph 3.6.1 "Our Strategic Partnership with Janssen (for cusatuzumab)" on page 107.

5.4 Dividend Policy

5.4.1 General

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. All of our outstanding Securities will have the same dividend rights. We intend to retain all available funds and any future earnings to fund the development and expansion of our business.

Even if future operations lead to significant levels of distributable profits, we currently intend that any earnings will be re-invested 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.

Under Dutch law, a Dutch European public company with limited liability (Societas Europaea or SE) may only pay dividends if the shareholders' equity (eigen vermogen) exceeds the sum of the paid-up and called-up share capital plus the reserves required to be maintained by Dutch law or our Articles of Association. Subject to such restrictions, any future determination to pay dividends would be at the discretion of the shareholders at our General Meeting.

5.4.2 Articles of Association on Profits, Distributions and Losses

Our articles of association contain the following provision on the distribution of profits:

Article 20. Profits, distributions and losses.

1. The company shall have a policy on reserves and dividends which shall be determined and may be amended by the board of directors. The adoption and thereafter each material change of the policy on reserves and dividends shall be discussed at the general meeting under a separate agenda item.
2. From the profits, shown in the annual accounts, as adopted, the general meeting shall determine which part shall be reserved. Any profits remaining thereafter shall be at the disposal of the general meeting. The board of directors shall make a proposal for that purpose. A proposal to pay a dividend shall be dealt with as a separate agenda item at the general meeting.
3. Distribution of dividends on the shares shall be made in proportion to the nominal value of each share.
4. If a loss was suffered during any one year, the board of directors may resolve to offset such loss by writing it off against a reserve which the company is not required to keep by virtue of the law.
5. The distribution of profits shall be made after the adoption of the annual accounts, from which it appears that the same is permitted.
6. The board of directors may, subject to due observance of the policy of the company on reserves and dividends, resolve to make an interim distribution.
7. At the proposal of the board of directors, the general meeting may resolve to make a distribution on shares wholly or partly not in cash but in shares.
8. The board of directors may, subject to due observance of the policy of the company on reserves and dividends, resolve that distributions to holders of shares shall be made out of one or more reserves.

Corporate Governance

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6 Corporate Governance

6.1 Our Board of Directors

6.1.1 Board structure

We have a one-tier board structure consisting of an executive director who is responsible for our day-to-day management and non-executive directors who are (amongst others) responsible for the supervision of the executive director. Set out below is a summary of certain provisions of Dutch corporate law as at the date of this Registration Document, as well as a summary of relevant information concerning our board of directors and certain provisions of the Articles of Association and Board By-Laws (terms of reference) concerning our board of directors.

6.1.2 General

The summaries of parts of our Articles of Association and By-Laws in this section 6.1 do not purport to give a complete overview and should be read in conjunction with, and are qualified in its entirety by reference to the relevant provisions of Dutch law as in force on the date of this Registration Document and the Articles of Association and Board By-Laws. The Articles of Association are available in the governing Dutch language and an unofficial English translation thereof, and the Board By-laws are available in English, on our website.

6.1.3 Duties

Under Dutch law (Section 2:129 paragraph 1 of the DCC), our board of directors is collectively responsible for our general affairs. Pursuant to our Articles of Association, our board of directors will divide its duties among its members, with our day-to-day management entrusted to the executive directors. The board is responsible for the general affairs of the company and the business connected with it. The non-executive directors are tasked with supervising the management of the Company and providing the executive director with advice. In addition, both the executive director and the non-executive directors must perform such duties as are assigned to them pursuant to the Articles of Association. The division of tasks within our board of directors is determined (and amended, if necessary) by our board of directors. Each director has a duty to properly perform the duties assigned to him or her and to act in our corporate interest. As a principle under Dutch law, the corporate interest extends to the interests of all corporate stakeholders, such as shareholders, creditors, employees and other stakeholders.

Our sole executive director, Tim Van Hauwermeiren, may not be allocated the tasks of: (i) serving as chairperson of our board of directors; (ii) determining his remuneration; or (iii) nominating directors for appointment. The executive director may not participate in the adoption of resolutions (including any deliberations in respect of such resolutions) relating to his remuneration. Certain resolutions of our board can only be adopted with the consent of a majority of the non-executive directors.

6.1.4 Role of the Board in the adoption and implementation of our strategy

The board of directors, our executive director as well as our non-executive directors, define our strategy (as further set out in paragraph 3.1.2 “Strategy and Objectives” on page 74 and further). Our strategy is regularly discussed and monitored at our board meetings, which take place by means of physical meetings (generally in Amsterdam, the Netherlands) or via teleconference facilities. For a description of the specific topics of responsibility of the board of directors and each of its committees, please refer to section 6.1 “Our Board of Directors” on page 174 and further.

6.1.5 Role of the Board in Risk Oversight

Our board of directors is responsible for the oversight of our risk management activities and has delegated to the audit and compliance committee the responsibility to assist our board in this task. While our board oversees our risk management, our management is responsible for day-to-day risk management processes. Our board of directors expects our management to consider risk and risk management in each business decision, to proactively develop and monitor risk management strategies and processes for day-to-day activities and to effectively implement risk management strategies adopted by the board of directors. We believe this division of responsibilities is the most effective approach for addressing the risks we face.

6.1.6 Composition, Appointment and Dismissal

The Articles of Association provide that our board of directors will consist of our executive director(s) and non-executive directors. The number of executive directors must at all times be less than the number of non-executive directors. The number of directors, as well as the number of executive directors and non-executive directors, is determined by our board of directors, provided that the board of directors must consist of at least three members.

Our directors are appointed by the shareholders at the General Meeting for a period of four years. In accordance with best practice principle 2.2.1 of the Dutch Corporate Governance Code, executive directors may be re-appointed for periods of not more than four years at a time. In accordance with best practice principle 2.2.2 of the Dutch Corporate Governance Code, non-executive directors are appointed for a period of four years and may subsequently be re-appointed for another four-year period, which appointment may be extended by at most two years. The board of directors is required to make one or more proposals for each seat on our board of directors to be filled. A resolution to nominate a director by our board of directors (with support from the remuneration and nomination committee) may be adopted by a simple majority of the votes cast. A nomination for appointment of an executive or non-executive director must state the candidate’s age and the positions he or she holds, or has held, insofar as these are relevant for the performance of the duties of an executive director. The nomination must state the reasons for the nomination of the relevant person. A nomination for appointment of a non-executive director must state the candidate’s age, his or her profession, the number of shares he or she holds and the employment positions he or she holds, or has held, insofar as these are relevant for the performance of the duties of a non-executive director. Furthermore, the names of the legal entities of which he or she is already a supervisory board member or a non-executive member of the board shall be indicated; if those include legal entities which belong to the same group, a reference to that group will be sufficient. The nomination must state the reasons for the nomination of the relevant person.

Our directors are appointed as either an executive director or as a non-executive director by the shareholders at the General Meeting. Our board of directors designates one executive director as Chief Executive Officer. In addition, the board of directors may grant other titles to executive directors. Our board of directors designates a non-executive director as chairperson of the board of directors and a non-executive director as vice chairperson of the board of directors. The legal relationship between an executive member of the board of directors and the Company will not be considered as an employment agreement. Employment agreements between an executive director and a group company (other than argenx SE) are permitted. In the absence of an employment agreement, members of a board of directors generally do not enjoy the same protection as employees under Dutch labor law.

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

Directors may be suspended or removed by the shareholders at the General Meeting at any time, with or without cause, by means of a resolution passed by a simple majority of the votes cast. Under Dutch law (Section 2:134 paragraph 1 of the DCC), executive directors may also be suspended by the board of directors. A suspension of an executive director by the board of directors may be discontinued by the shareholders at any time at the General Meeting.

6.1.7 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:
(i) an audit and compliance committee; and
(ii) a remuneration and nomination committee.

In addition to the aforementioned legally required subcommittees, the non-executive directors may also opt to incorporate committees consisting of non-executive directors and other internal and external persons in the Company, in order to facilitate discussions and act as a sounding board on specific projects, as well as on a more permanent basis. Such committees of non-executive directors and other members shall in any case include a research and development committee and a commercial committee.

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

Only non-executive directors qualify for membership of the committees. The audit and compliance committee and the remuneration and nomination committee may not be chaired by the chairperson of the board of directors or by a former executive director of the Company.

6.1.8 Meeting Frequency and Decision Making

Our board of directors has adopted rules (the Board By-Laws), that describe the procedure for holding meetings of the board of directors, for the decision-making by the board of directors and the board of directors' operating procedures.

In accordance with our Articles of Association, our board of directors will meet at least once every three months to discuss the state of affairs within the Company and the expected developments.

Under the Board By-Laws, the members of our board of directors must endeavor, insofar as is possible, to ensure that resolutions are adopted unanimously. Where unanimity cannot be achieved and Dutch law, the Articles of Association or the Board By-Laws do not prescribe a larger majority, all resolutions of our board of directors must be adopted by a simple majority of the votes cast in a meeting at which at least a majority of the members of our board of directors then in office are present or represented. The Articles of Association and the Board By-Laws provide that in case of a tie of votes, the chairperson does not have a casting vote and as such the proposal will be rejected in case of a tie.

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 the Company 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. At the date of this Registration Document there are no other executive directors in office.

6.1.9 Independence of the Board of Directors and Committee Members

As a foreign private issuer, under the listing requirements and rules of Nasdaq, we are not required to have independent directors on our board of directors, except that our audit and compliance committee is required to consist fully of independent directors, subject to certain phase-in schedules. However, our board of directors has determined that, under current listing requirements and rules of Nasdaq and taking into account any applicable committee independence standards, all of our non-executive directors, including the members of our audit and compliance committee, are "independent directors" under Rule 10A-3 of the Exchange Act and the applicable rules of the Nasdaq Stock Market and all members of our audit and compliance committee are independent under the applicable rules of the Dutch Corporate Governance Code. In making such determination, our board of directors considered the relationships that each non-executive director has with us and all other facts and circumstances our board of directors deemed relevant in determining the director's independence, including the number of ordinary shares beneficially owned by the director and his or her affiliated entities (if any).

The Dutch Corporate Governance Code requires that the composition of the non-executive directors is such that the members are able to operate independently and critically vis-à-vis one another, the executive directors, and any particular interests involved. At the date of this Registration Document, all non-executive directors meet the independence criteria contained in the Dutch Corporate Governance Code. Therefore, in the opinion of the non-executive directors, the composition of our non-executive directors complies with the independence requirements of best practice provisions 2.1.7 to 2.1.9 of the Dutch Corporate Governance Code. Our board of directors has consequently also determined that all members of our committees are independent under the applicable rules of the Dutch Corporate Governance Code.

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

6.1.10 Confirmation of No Past Offenses

As of the date of this Registration Document and except as set out below, none of the members of our board of directors and executive management for at least the previous five years:

- has been convicted of any fraudulent offenses;
- has been a senior manager or a member of the administrative, management or supervisory bodies of any company at the time of or preceding any bankruptcy, receivership, 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.

6.1.11 Diversity

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 our Company 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.

On May 12, 2020, the shareholders at the General Meeting reappointed Mrs. Pamela Klein to our Board of Directors. No other (re)appointments were made.

6.1.12 Liability of Board Members

Under Dutch law (Section 2:138 of the DCC), members of our board of directors may be liable to us for damages in the event of improper or negligent performance of their duties. They may be jointly and severally liable for damages to us and third parties for infringement of the Articles of Association or certain provisions of the Dutch Civil Code, or DCC. In certain circumstances, they may also incur additional specific civil and criminal liabilities.

The liability of members of our board of directors and executive management is covered by a directors' and officers' liability insurance policy. This policy contains customary limitations and exclusions, such as wilful misconduct or intentional recklessness (*opzet of bewuste roekeloosheid*). In addition, according to article 15 of our Articles of Association, we will indemnify our directors against liabilities, claims, judgements, fines and penalties in relation to acts or omissions in or related to his or her capacity as director.

6.1.13 Conflict-of-Interest Transactions

Directors will immediately report any (potential) direct or indirect personal interest in a matter which is conflicting with the interests of the company and the business connected with it to the chairperson of our board of directors and to the other directors and will provide all relevant information, including information concerning their spouse, registered partner or other partner, foster child and relatives by blood or marriage up to the second degree as defined under Dutch law (Section 1:3 paragraph 1 of the DCC).

The non-executive directors will decide, without the director concerned being present, whether there is a conflict of interest. A conflict of interest in relation to a director in any event exists if we intend to enter into a transaction with a legal entity (i) in which such director personally has a material financial interest, (ii) which has an executive director or a member of the management board who is related under family law to such director or (iii) in which such director has an executive or non-executive position. A director will not participate in any discussions and decision making if he has a conflict of interest in the matter being discussed. If for this reason no resolution can be taken by our board of directors as a whole, the shareholders at a General Meeting will resolve on the matter. All transactions in which there are conflicts of interest with directors will be agreed on terms that are customary in the sector concerned. Decisions to enter into transactions in which there are conflicts of interest with directors that are of material significance to us or to the relevant director require the approval of the non-executive directors. All transactions between us and legal or natural persons who hold at least one tenth of our shares will be agreed on terms that are customary in the sector in which we and our combined businesses are active. The non-executive directors are required to approve such transactions that are of a material significance to us or to such persons.

There are no arrangements or understandings in place with major shareholders, customers, suppliers or others pursuant to which any member of our board of directors or executive management has been appointed. There are no conflicts of interests between the Company and any administrative, management and supervisory bodies and senior management, nor are there any potential conflicts of interests between any duties to the Company, the members of our board of directors and executive management and their private interests and or other duties.

6.1.14 Code of Business Conduct and Ethics

We adopted a Code of Business Conduct and Ethics, or the Code of Conduct, that is applicable to all of our employees and directors. The Code of Conduct is available on our website at www.argenx.com. The audit and compliance committee of our board of directors is responsible for overseeing the Code of Conduct and is required to approve any waivers of the Code of Conduct for employees and directors. We expect that any amendments to the Code of Conduct, and any waivers of its requirements, will be disclosed on our website.

6.2 Our Non-Executive Directors

6.2.1 Current Composition

Our board of directors is currently comprised of one executive director and seven non-executive directors, who we refer to individually as a director.

The following table sets forth certain information with respect to the current members of our board of directors, including their ages, as of the date of the Registration Document.

Please note that Mrs. Yvonne Greenstreet has been nominated to the board of directors to fill the position of Dr. David L. Lacey, who intends to resign from the board of directors and transition to an advisory role for the Company. The appointment of Mrs. Yvonne Greenstreet will be on the agenda for the General Meeting to be held in May, 2021.

Name	Date of birth	Age	Gender	Postion	Nationality	Date of Initial Appointment	Date of last (re-) Appointment	Term Expiration
Tim Van Hauwermeiren	March 19, 1972[1]	49	M	Executive Director (Chief Executive Officer)	BE	September 9, 2018[1]	May 8, 2018	2022
Peter K. M. Verhaeghe	November 9, 1958[2]	62	M	Non-Executive Director (chairperson)	BE	October 15, 2008[2]	May 8, 2018	2022
David L. Lacey	July 25, 1952	68	M	Non-Executive Director	US	August 1, 2012[3]	May 8, 2018	2022
Werner Lanthaler	September 2, 1968	52	M	Non-Executive Director (vice-chairperson)	AT	April 8, 2014	May 8, 2018	2022
J. Donald deBethizy	December 11, 1950[3]	70	M	Non-Executive Director	US	May 13, 2015	May 7, 2019	2023
Pamela Klein	October 13, 1961	59	F	Non-Executive Director	US	April 28, 2016	May 12, 2020	2024
Anthony A. Rosenberg	February 8, 1953	68	M	Non-Executive Director	UK	April 26, 2017	April 26, 2017	2021
James M. Daly	September 12, 1961	59	M	Non-Executive Director	US	May 8, 2018	May 8, 2018	2022

(1) date of appointment of Tim Van Hauwermeiren as executive director of arGEN-X B.V., the Company's legal predecessor;
(2) date of appointment of Peter Verhaeghe as supervisory director of arGEN-X B.V., the Company's legal predecessor; and
(3) date of appointment of Donald deBethizy as supervisory director of arGEN-X B.V., the Company's legal predecessor.

The address for our directors is our registered office, Willemstraat 5, 4811 AH, Breda, the Netherlands.
Anthony A. Rosenberg is expected to be nominated for re-appointment at the General Meeting to be held in 2021.

6.2.2. Details of Individual Directors

The following is the biographical information of the members of our board of directors:

Tim Van Hauwermeiren

co-founded our Company in 2008 and has served as our Chief Executive Officer since July 2008. He has served as a member of our board of directors since July 2014. Mr. Van Hauwermeiren has more than 20 years of general management and business development experience across the life sciences and consumer goods sectors. Mr. Van Hauwermeiren holds a B. Sc. and M. Sc. in bioengineering from Ghent University (Belgium) and an Executive MBA from The Vlerick School of Management. Mr. Van Hauwermeiren currently holds the positions set out in paragraph 6.3.2 “Details of individual executive directors” on page 188 and further.

Peter K. M. Verhaeghe

has served as a member and chairperson of the supervisory board of arGEN-X B.V. since October 2008 and as non-executive director on our board of directors since July 2014. Mr. Verhaeghe is the managing partner of VVGB Advocaten-Avocats, a corporate finance law and tax law firm, a position he has held since July 1999. He is currently lead counsel to a number of Belgian, Dutch, French, US and Swiss life sciences companies. Mr. Verhaeghe served as the president of the board of directors of Merisant France SAS, as a member of the management board of Merisant Company 2 sàrl and as a member of the board of directors of CzechPak Manufacturing s.r.o. He previously also served as director of Innogenetics (Belgium), Tibotec- Virco NV, Biocartis SA, and as the chairman of the board of directors of PharmaNeuroBoost NV and as liquidator in charge of KBC Private Equity Fund Biotech NVfrom April 2009 to December 2012. Mr. Verhaeghe serves the board of directors of Participatiemaatschappij Vlaanderen (PMV) NV since May 2018, as chairman of the board of Haretis SA (Luxembourg) since March 2011, and as member of the Board of Directors of miDiagnostics since April 2020. Mr. Verhaeghe also serves as the chairman of the LP & advisory committeeof Bioqube Factory Fund I Nv. Mr. Verhaeghe holds a degree in law from the University of Leuven and an LLM degree from Harvard Law School.

Dr. David L. Lacey

has served as a member of our board of directors since July 2014. Dr. Lacey is a biopharmaceutical consultant at David L. Lacey LLC, where he advises academic institutions, biotechnology companies and venture capital firms, a position he has held since July 2011. He currently serves as a director of Inbiomotion SL, Atreca, Inc. and Nurix, Inc. From 1994 until his retirement in 2011, he held various positions, including head of discovery research, at Amgen Inc., where he played a fundamental scientific role in the discovery of the OPG/RANKL/RANK pathway, which led to the development of the anti-RANKL human mAb denosumab, for both osteoporosis (Prolia) and cancer-related bone diseases (XGEVA). He holds a Bachelor’s degree in biology and an M. D. from the University of Colorado, and has his board certification in anatomic pathology.

Dr. Werner Lanthaler

has served as a member of our board of directors since July 2014. Dr. Lanthaler is the chief executive officer of Evotec AG, a global drug discovery research organization, a position he has held since March 2009. Dr. Lanthaler previously served on the supervisory boards of Bioxell SpA and Pantec Biosolutions AG. Dr. Lanthaler holds a degree in psychology, a Ph. D. in business administration from Vienna University of Economics and Business and a Master’s degree in public administration from Harvard University.

Dr. J. Donald deBethizy

has served as a member of our board of directors since May 2015. Dr. deBethizy has 30 years of experience in research and development and financial, business and operating management and board work in the biotechnology and consumer products industry. He is the president of White City Consulting ApS. Previously, Dr. deBethizy served as president and chief executive officer of Santaris Pharma A/S until October 2014, when the company was sold to Roche. From August 2000 to June 2012, Dr. deBethizy was co-founder and chief executive officer of Targacept, Inc., a U.S. biotechnology company listed on Nasdaq. He currently serves on the supervisory boards of Albumedix A/S, Lophora ApS Newron Pharmaceuticals SpA, Noxxon Pharma NV and AG, Rigontec GmbH and Proterris, Inc. From May 2013 to November 2014, he served as executive chairman of Contera Pharma ApS , and from July 2015 to November 2017, he served as chairman of Rigotec GmbH. He previously served on the boards of Asceneuron SA, Serendex Pharmaceuticals A/S, Enbiotix Inc., Targacept Inc. and Biosource Inc. Dr. deBethizy has held adjunct appointments at Wake Forest University Babcock School of Management, Wake Forest University School of Medicine and Duke University. Dr. deBethizy holds a B. Sc. in biology from the University of Maryland, and an M. Sc. and a Ph. D. in toxicology from Utah State University.

Dr. Pamela Klein

has served as a member of our board of directors since April 2016. Dr. Klein is a principal and founder of PMK BioResearch, which offers strategic consulting in oncology drug development to corporate boards, management teams and the investment community, a position she has held since 2008. She currently serves as a member of various scientific advisor boards and is a Consulting CMO for Olema Oncology in San Francisco, Calif. Previously, Dr. Klein spent seven years at the National Cancer Institute as Research Director of the NCI-Navy Breast Center, after which she joined Genentech and was VP, Development until 2001. She served as Chief Medical Officer for Intellikine which was acquired by Takeda. She was previously Vice President, Development for Genentech. Dr. Klein holds a Bachelor’s degree in biology from California State University and an M.D. from Stritch School of Medicine, Loyola University Chicago and is trained in internal medicine and medical oncology.

Msc. A. A. Rosenberg

has served as a member of our board of directors since April 2017. He currently serves as CEO of TR Advisory Services GmbH, his own consultancy firm advising on business development, licensing and mergers and acquisitions and as consultant to PJT Ltd and SB Biotech. Previously Mr. Rosenberg held the positions of Managing Director at MPM Capital, a venture capital firm (2015 until 2020). Head of M&A and Licensing of Novartis International (2013 to 2015) and Head of Business Development and Licensing at Novartis Pharma (2005 to 2012). Mr. Rosenberg currently serves on the boards of directors of SiO2 Material Science, Oculis SA (chairman) and Cullinan Oncology (chairman), and previously served on the boards of directors at Radius Health Inc., TriNetX, Inc., iOmx Therapeutics AG, and Clinical Ink. Msc. A.A. Rosenberg has a B.Sc. (Hons) from the University of Leicester and a M.Sc. Physiology from the University of London.

James M. Daly

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

The following table sets forth the companies and partnerships of which the current non-executive members of our board of directors have been a member of the administrative, management or supervisory bodies or partner at any time in the previous five years, indicating whether or not the individual is still a member of the administrative, management or supervisory bodies or partner, as of the date of this Registration Document, other than argenx or our subsidiaries:

NAME	CURRENT	PAST
Peter K. M. Verhaeghe	VVGB Advocaten – Avocats	PharmaNeuroBoost NV
	Haretis SA	Biocartis SA
	Participatiemaatschappij Vlaanderen (PMV) NV	Fujirebio Europe NV (formerly Innogenetics NV)
	miDiagnostics NV	KBC Private Equity Fund Biotech NV
	Bioqube Factory Fund I	Merisant France SAS
		Merisant Company 2 sàrl
		CzechPak Manufacturing s. r. o.
		Bever Zwerfsport BV
		Tibotec-Virco
David L. Lacey	David L. Lacey LLC	UNITY Biotechnology, Inc.
	Inbiomotion SL	
	Atreca, Inc.	
	Nurix, Inc.	
	Arcus	
Werner Lanthaler	Evotec AG	Bioxell SpA
	AC Immune	Pantec Biosolutions AG
J. Donald deBethizy	White City Consulting ApS	Contera Pharma ApS
	Albumedix A/S	Asceneuron SA
	Newron Pharmaceuticals SpA	Serendex Pharmaceuticals A/S
	Noxxon Pharma NV and AG	Santaris Pharma A/S
		Targacept, Inc.
	Protteris, Inc.	LigoCyte Pharmaceuticals Inc.
	Lophora ApS	Enbiotix Inc
	Saniona AB	Biosource Inc.
		Rigontec GmbH
Pamela Klein	PMK BioResearch	Intellikine
	Patrys Limited	
	I-Mab Biopharma	
	F-Star Therapeutics, Inc.	
	Jiya Acquisition Corp.	
A. A. Rosenberg	Cullinan Oncology Inc.	Radius Health, Inc.
	Oculis SA	TriNetX, Inc.
	SiO2 Material Science	Clinical Ink, Inc.
		iOmx Therapeutics AG
James M. Daly	Acadia Pharmaceuticals Inc.	Incyte
	Halozyme Therapeutics, Inc.	AMGEN
	Bellicum Pharmaceuticals, Inc.	GlaxoSmithKline
	Madrigal Pharmaceuticals	Chimerix, Inc.
		Coherus Biosciences

6.2.3 Board Meetings

The Board of Directors has deliberated seven times in the course of 2020. At these meetings, the main points of discussion were the June 2020 equity financing and issuance of new shares, discussing the operational plan for 2021, discussing statutory and governance topics, such as the re-appointment of Mrs. Pamela Klein and members of board committees, discussing business updates, review and approval of forecasts, dis-cussing the corporate dashboard and product portfolios, discussing business & corporate development, re-view and approval of consolidated financial statements, discussing update research & developments, dis-cussing an update of the remuneration policy, discussing remuneration and nomination committee report, discussing updates and the report from the audit and compliance committee, discussing adjustments to the Company's equity incentive plan, valuation model and financing of the Company, board rotation and suc-cession process and plan, and the approval of the proposed agenda, explanatory notes and convocation notice for the (extraordinary) general meetings.

The meeting attendance rate of our directors in 2020 is set out in the table below:

BOARD OF DIRECTORS	Number of meetings attended in 2020 since appointment	Attendance %
Peter Verhaeghe	7/7	100
Werner Lanthaler	5/7	71
David Lacey	7/7	100
Pamela Klein	7/7	100
Don deBethizy	7/7	100
Anthony Rosenberg	7/7	100
Jim Daly	7/7	100
Tim Van Hauwermeiren	7/7	100

6.2.4 Audit and Compliance Committee

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

Our audit and compliance committee assists our board of directors in overseeing the accuracy and integrity of our accounting and financial reporting processes and audits and reviews of our consolidated financial statements, the implementation and effectiveness of an internal control system and our compliance with legal and regulatory requirements, the independent auditors' qualifications and independence and the performance of the independent auditors.
The audit and compliance committee is governed by a charter that complies with Nasdaq listing rules and the Dutch Corporate Governance Code. Our audit and compliance committee is responsible for, among other things, establishing methods and procedures for supervising, and where necessary requiring improvements of, the financial reporting, compliance and organization of the Company for the purpose of making appropriate recommendations to the Board of Directors in that regard.

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

Our audit and compliance committee reports regularly to our board of directors on the exercise of its functions. It informs our board of directors about all areas in which action or improvement is necessary in its opinion and produces recommendations concerning the necessary steps that need to be taken. The audit review and the reporting on that review cover us and our subsidiaries as a whole. The members of the audit and compliance committee are entitled to receive all information which they need for the performance of their function, from our board of directors and employees. Every member of the audit and compliance committee shall exercise this right in consultation with the chairperson of the audit and compliance committee.

The audit and compliance committee has deliberated seven times in the course of 2020. At these meetings, the main points of discussion were discussion of the Compliance Gap Analysis, review of the 2019 financial statements and press release, Deloitte's 2019 audit report, 2020 audit fee proposal and renewal of Deloitte mandate, review of interim consolidated financial statements and press releases, Deloitte's report on interim financial statements, review of quarterly forecasts, updates on internal control activities, updates on corporate audit activities, updates on cash, cash equivalents and financial assets, review of the 20-F and universal registration document with respect to the annual year 2019, review of compliance committee charter, and the review of quarterly consolidated financial statements, related press releases and forecasts.

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

AUDIT AND COMPLIANCE COMMITTEE	Number of meetings attended in 2020	Attendance %
Peter Verhaeghe	7	100
Werner Lanthaler	7	100
Anthony Rosenberg	7	100

6.2.5 Remuneration and Nomination Committee

We have established a remuneration and nomination committee, which serves as both the remuneration committee and selection and appointment committee as prescribed by the Dutch Corporate Governance Code.Our remuneration and nomination committee consists of three members: J. Donald deBethizy (chairperson), Peter K. M. Verhaeghe and Werner Lanthaler.

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

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

The remuneration and nomination committee consists of at least three members. The remuneration and nomination committee meets as often as is required for its proper functioning, but at least once per year to evaluate its functioning.

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

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

REMUNERATION AND NOMINATION COMMITTEE	Number of meetings attended in 2020	Attendance %
Peter Verhaeghe	2/2	100
Werner Lanthaler	2/2	100
Don deBethizy	2/2	100

6.2.6 Other Committees

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

The research and development committee is responsible for, among other things:

- monitoring and overseeing the research and development goals, strategies and measures of the Company;
- serving as a sounding board to the Company's research and development management, general management and the board of directors;
- performing strategic reviews of the Company's key research and development programs;
- reporting to the board of directors on the outcome of the strategic reviews;
- reviewing the Company's scientific publication and communications plan;
- evaluating and challenging the effectiveness and competitiveness of the research and development endeavours of the Company;
- reviewing and discussing emerging scientific trends and activities critical to the success of research and development of the Company;
- reviewing the Company's clinical and preclinical product pipeline; and
- engaging in attracting, retaining and developing senior research and development personnel of the Company.

All members of the research and development committee shall have adequate industrial, academic and/or practical experience with the research and development of biopharmaceuticals.

One purpose of our research and development committee is to engage in discussion with our research and development management, and the committee's responsibilities to carry out this purpose include, among others: monitoring the research and development activities, performing strategic reviews of the key research and development programs; and reviewing the scientific publication plan.

Our research and development committee meets as often as is required for its proper functioning, but at least prior to each meeting of our board of directors, and reports regularly to our board of directors on the outcome of the strategic reviews. The chairperson of our research and development committee shall report formally to our board of directors on the research and development committee's deliberations, findings and proceedings after each meeting on all matters within its duties and responsibilities.

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

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

The commercial committee is responsible for, among other things:

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

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

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

6.3 Our Executive Management

6.3.1 Executive Management Team or Executive Committee

We have an executive management team consisting of our senior management. Of these persons, only our Chief Executive Officer, Mr. Tim Van Hauwermeiren, is part of our statutory board of directors. We have opted for this structure to allow for a division of responsibilities between our board of directors and our executive management team, keeping our board of directors at a manageable size whilst being able to involve some or all members of our executive management team on discussions of the board if and when necessary.

In practice, all members of our executive 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 to 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 executive management team.

6.3.2 Details of individual member of our executive management team

The following table sets forth certain information with respect to the current members of our executive management team including their ages as of the date of this Registration Document:

Name	Age	Postion	Nationality	Date of first employment/engagement
Tim Van Hauwermeiren	49	Chief Executive Officer and Executive Director	BE	July 15, 2008
Eric Castaldi	56	Chief Financial Officer	FR	April 1, 2014
Keith Woods	53	Chief Operating Officer	US	April 5, 2018
Hans de Haard	61	Chief Scientific Officer	NL	July 1, 2008
Wim Parys	61	Chief Medical Officer	BE	July 1, 2019
Arjen Lemmen	36	Vice-President Corporate Development & Strategy	NL	May 1, 2016
Dirk Beeusaert	57	General Counsel	BE	April 1, 2017
Marc Schorpion	63	Global Head of Human Resources	BE	February 1, 2019
Andria Wilk	48	Global Head of Quality	UK	January 13, 2020

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

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

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

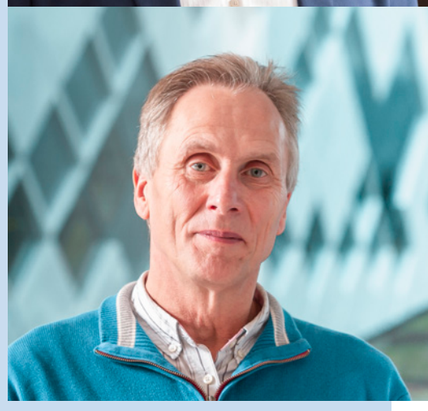
Eric Castaldi

has served as our Chief Financial Officer since April 2014 and served as a member of our board of directors from July 2014 to April 26, 2017. Mr. Castaldi has 29 years of international financial executive management experience, including 20 years in the biopharmaceutical industry. From 1998 to 2014, Mr. Castaldi served as chief financial officer and a member of the executive committee of Nicox SA, a Euronext-listed biotechnology company. From 2008 to 2012, he served as a member of the board of directors and as chairman of the audit committee of Hybrigenics SA, a Euronext-listed French biopharmaceutical company specializing in oncology. From 1987 to 1989, Mr. Castaldi served as chief financial officer/chief operating officer of Safety-Kleen Corp. From 1989 to 1997, he served as chief financial officer/chief operational officer of MY Kinda Town PLC. Mr. Castaldi graduated with a degree in finance, accountancy and administration from the University of Nice.

Keith Woods

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

Prof. Hans de Haard



has served as our Chief Scientific Officer since July 2008. Prof. de Haard has been active in the antibody engineering field since 1989. He also serves as a Professor of Immunology at University of Franche Comté (France). Prof. de Haard holds an M. Sc. in biochemistry from the Higher Professional Education for Laboratory Technicians (Oss, the Netherlands) and a M. Sc. in chemistry from the Institute of Technology (Rotterdam, the Netherlands) and a Ph. D. in molecular immunology from Maastricht University.

Dirk Beeusaert

has served as our General Counsel since April 1, 2017. Mr. Beeusaert has extensive general experience in corporate governance and as general counsel of a listed company. Mr. Beeusaert worked in various roles from February 1996 to July 2016 for Gimv NV, a European private equity company listed on Euronext Brussels, including chief legal officer from January 2001 to 2006, and general counsel from 2006 to July 2016, where he was co-responsible for operations and corporate governance. Mr. Beeusaert currently serves as a member of the board of directors of Cubigo NV and The Fourth Law NV. Mr. Beeusaert holds a Bachelor in Law and a Master Law degree from Ghent University and an MBA in Fiscal Studies and Accounting Research, Tax and Accounting from Vlerick School of Management.

Wim Parys

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

Arjen Lemmen

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

Marc Schorpion

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

Andria Wilk

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

The following table sets forth the companies and partnerships of which the current members of our executive management have been a member of the administrative, management or supervisory bodies or partner at any time in the previous five years, indicating whether or not the individual is still a member of the administrative, management or supervisory bodies or partner, as of the date of this Registration Document, other than argenx or our subsidiaries:

NAME	CURRENT	PAST
Tim Van Hauwermeiren	iTeos Inc	—
	Aelin Therapeutics NV	—
Keith Woods	—	Alexion Pharmaceuticals
		Synageva UK
Eric Castaldi	—	Nicox SA
		Hybrigenics Services SA
Hans de Haard	—	—
Wim Parys	—	—
Arjen Lemmen	—	—
Dirk Beeusaert	Cubigo NV	Gimv NV (and group companies of Gimv NV)
	The Fourth Law NV	TINC NV
	—	Pragma Capital SAS
	—	Grandeco NV
	—	DG Infra+ NV
	—	Finimmo NV
	—	CapMan plc
Marc Schorpion	IGNITE Growth Bands	USMCI
	International School Services (ISS)	—
Andria Wilk	—	—

6.4 Dutch Corporate Governance Code, "Comply or Explain"

6.4.1 General

The Dutch Corporate Governance Code contains both principles and best practice provisions for management boards, supervisory boards, shareholders and general meetings of shareholders, financial reporting, auditors, disclosure, compliance and enforcement standards. A copy of the Dutch Corporate Governance Code can be found on *www.mccg.nl*. As a Dutch company, we are subject to the Dutch Corporate Governance Code and are required to disclose in our annual report, filed in the Netherlands, whether we comply with the provisions of the Dutch Corporate Governance Code. If we do not comply with the provisions of the Dutch Corporate Governance Code (for example, because of a conflicting Nasdaq requirement or otherwise), we must list the reasons for any deviation from the Dutch Corporate Governance Code in our annual report.

We acknowledge the importance of good corporate governance. However, at this stage, we do not comply with all the provisions of the Dutch Corporate Governance Code, to a large extent because such provisions conflict with or are inconsistent with the corporate governance rules of Nasdaq and U.S. securities laws that apply to us, or because such provisions do not reflect best practices of global companies listed on Nasdaq.

6.4.2 Comply or Explain

We fully endorse the underlying principles of the Dutch Corporate Governance Code which is reflected in a policy that complies with the best practice provisions as stated in the Dutch Corporate Governance Code. However, we do not (yet) comply with or deviate from the best practice provisions in the following areas:

- We do not comply with best practice provisions 2.1.5 and 2.1.6 of the Dutch Corporate Governance Code. Best practice provision 2.1.5 requires that the non-executive directors shall draw up a diversity policy for the composition of the board and best practice provision 2.1.6 requires that we explain how we are currently applying such policy. We fully recognize the importance of diversity and promote an inclusive culture, but utilize other means than a diversity policy in pursuit of the same goals (e.g. our board profile includes the objective to achieve a diverse composition with respect to nationality, experience, background, age and gender). As we have not drawn up the policy, we also do not report on our application thereof. We are planning to establish a diversity policy in the course of 2021, which will describe (among other things) specific targets for gender quota in the board of directors and the senior leadership team.
- We do not comply with best practice provisions 3.1.2 under vii of the Dutch Corporate Governance Code, which states that options are not to be exercised within the first three years after the date of granting. Pursuant to our Option Plan, options are exercisable once vested, which means that one third of the options granted are exercisable after one year, and each month after one-twenty-fourth of the remaining options is exercisable. Our Option Plan was crafted recognizing that equity incentives are an important factor in the market for attracting and retaining qualified staff. Hence, we deviate from best practice provision 3.1.2 under vii to allow for a liquid and hence competitive Option Plan. At the same time, we believe our current option plan promotes long term value creation. For instance, the three year vesting period ensures that an option package granted cannot be fully exercised within three years after the grant date. Until the date of this Registration Document, none of the directors have exercised any options within the first three years after the date of grant of those options. The Option Plan is regularly reviewed by the board of directors and the remuneration and selection committee in particular, the main purpose of such review is to test if the Option Plan is sufficiently contributing to our ability to attract and retain talent. In 2019, our shareholders have re-approved our updated Option Plan, including the aforementioned vesting schemes. We currently do not expect such reviews will be geared at achieving full compliance with the Dutch Corporate Governance in this respect.
- We do not comply with best practice provision 3.2.3. of the Dutch Corporate Governance Code, which requires that the severance payment in the event of dismissal should not exceed one year's base compensation. As further explained in the section *Related Party Transactions – Agreements with Our Executive Management*, the agreement of our chief

executive officer stipulates that a severance payment equal to 18 months base compensation may become payable by the Company to our chief executive officer. The severance component of the remuneration package is, like all other components and in accordance with our remuneration policy as approved by the General Meeting, benchmarked against and aligned with the severance components as identified within the reference group. On this particular topic, considering the importance of competitive remuneration for our ability to attract and retain highly qualified persons, alignment with the reference group is prioritized over compliance with this best practice provision 3.2.3. We currently do not envision to change our practice in this respect.

- We do not comply with best practice provision 3.3.2. of the Dutch Corporate Governance Code, which requires that non-executive directors will not be granted any shares or rights to shares as remuneration. In accordance with our remuneration policy, non-executive directors may be granted options by way of remuneration, in recognition of the substantial industry expertise they bring to us. Our remuneration policy, as was presented to and approved by the General Meeting, and this equity element for non-executive directors in particular are geared at a fair but competitive compensation package and takes a number of relevant benchmarks into account. We currently do not envision to change our practice in this respect.

argenx has recently amended its rules for the board of directors by (among other things) including a section with respect to the interaction between the board of directors and the executive committee and as such complies with best practice provision 2.3.1 of the Dutch Corporate Governance Code. The latest version of the board rules is available on our website (www.argenx.com).

6.4.3 Differences between Our Corporate Governance Practices and the Listing Rules of the Nasdaq Stock Market

We are in the United States considered a foreign private issuer. As a result, in accordance with the listing requirements of Nasdaq, we may 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 in the Netherlands, our Articles of Association do not provide quorum requirements generally applicable to general meetings of shareholders. 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 and 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.

6.4.4 Evaluation Process

The board evaluates the functioning of the board of directors, its committees and of each individual director annually. This is done on the basis of prepared questionnaires, which are completed by each board member and collected by the chairman of the board. On the basis of an analysis of the outcome of the questionnaires, key topics are discussed with individual directors and/or by the board or the relevant committees. In 2020, among other things, the evaluations have led to the decision to, among other things, allow online board meetings and, where possible, organise committee meetings separate from the schedule board meetings.

6.5 Risk Appetite & Control

Before reading the rest of this section 6.5, please carefully review the following cautionary statement:

IN THIS SECTION 6.5 WE WILL MAKE THE REQUIRED DISCLOSURES REGARDING OUR RISK APPETITE AND MITIGATING ACTIONS. THE RISK MITIGATION ACTIONS AND RISK MANAGEMENT DESCRIBED IN THIS SECTION 6.5 HAVE BEEN FULLY TAKEN INTO ACCOUNT BY US WHEN PREPARING THE DESCRIPTION OF THE MAIN RISKS AND UNCERTAINTIES WE FACE, AS SET OUT IN CHAPTER 1 "RISK FACTORS". ANY MITIGATING LANGUAGE USED IN THIS SECTION 6.5 DOES NOT HAVE ANY IMPACT ON THE RISKS AND UNCERTAINTIES WE FACE OR THEIR POTENTIAL ADVERSE EFFECTS AS THEY ARE DESCRIBED IN CHAPTER 1 "RISK FACTORS".

CHAPTER 1 "RISK FACTORS" DESCRIBES THE MAIN RISKS AND UNCERTAINTIES WE FACE ALREADY FULLY HAVING TAKEN INTO ACCOUNT OUR RISK MANAGEMENT AND THE RISK MITIGATING ACTIONS DESCRIBED HEREIN.

6.5.1 Introduction

This Registration Document, in application of article 9 sub 12 of the Prospectus Regulation contains (whether in the body of the document or in the documents incorporated by reference) the information required for us to be disclosed in our annual financial reporting and as such also serves as our annual report for the financial year 2020.

Under Dutch law, we are required to include in our annual report a general description of our willingness to mitigate the risks and uncertainties we face (also called our 'risk appetite'), and to give a description of the mitigating actions we have taken with regard to our most relevant risks.

6.5.2 General Description of Our Risk Appetite

Our risk appetite serves as a guideline for us in deciding which measures we may take in mitigating some of the risks and uncertainties we face. Our risk appetite is aligned with our strategy and priorities. The business we operate in is inherently high-risk. In general, we are willing, and in our view required, to take significant risks to be able to operate successfully in our line of business. Some of the risks and uncertainties we face are entirely outside of our control whereas others may be influenced or mitigated.

6.5.3 Controlling Actions Taken by Us with Regard to Our Most Relevant Risks and Uncertainties

As required by Clause 2:391 sub 1 of the Dutch Civil Code in conjunction with Guideline 400.1.110c on Annual Reporting, the following is a description of the main risks and uncertainties we face (being the first risk of each category of risk factors set out in Chapter 1 "Risk Factors") and a description of the measures we took to control them. A description of the expected impact upon materialization of these risks is included for each risk in Chapter 1 "Risk Factors".

RISK FACTOR	MEASURES TAKEN TO CONTROL THESE RISKS
We have incurred significant losses since our inception and expect to incur losses for the foreseeable future. We may never achieve or maintain profitability. All of our product candidates are in preclinical, earlystage clinical or clinical development. Our trials may fail and even if they succeed we may be unable to commercialize any or all of our product candidates due to a lack of, or delay in, regulatory approval or for other reasons.	We have adopted a business model and strategic portfolio management approach to spread risks over wholly-owned programs as well as partnered programs, and to manage risks within our own proprietary product candidates pipeline. We ontinue to create novel, differentiated product candidates from our proprietary technology platforms which regularly feed our product candidate pipeline.
We will face significant challenges in successfully commercializing our products.	We plan to focus on the development and commercialization of the product candidates that we believe have a clear clinical and regulatory approval pathway and that we believe we can commercialize successfully, if approved. Our commercialization strategy for any product candidates that are approved will focus on key academic centers, specialist physicians and advocacy groups, as well as on providing patients with support programs and maximizing product access and reimbursement. We plan to partner product candidates that we believe have promising utility in disease areas or patient populations that are better served by the resources of larger biopharmaceutical companies.
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 are establishing a robust quality management system to ensure compliance with current good laboratory practices, current good manufacturing practices and current good clinical practices. We endeavor to stay abreast of changes to legislation and to ensure compliance. We have strengthened our team by establishing an in-house quality assurance department to ensure compliance. Experts at the EMA and FDA, as well as its consultants and CROs. We strive to develop good working relationships with regulators to ensure alignment on the selected clinical development and regulatory pathways to ensure optimal regulatory efficiencies are achieved. Furthermore, we seek to maintain a deep product candidate pipeline to allow us to potentially avoid being too dependent on the success of a single asset.
We rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.	We endeavor to meet our contractual obligations and any relevant milestone achievements under our collaboration contracts. We endeavor to maintain a rich pipeline of possible collaboration partners as well as a good relationship with existing and potential future collaboration partners in order to limit reliance on a limited number of collaboration partners. Furthermore, third-party contractor selection and management is subject to our quality management system. Customary contractual agreements are put in place in an effort to protect us from under-performance. We are typically spreading operational risks over various service providers. Project management belongs to our core internal competences.
We rely on patents and other intellectual property rights to protect our product candidates and platform technologies. Failure to enforce or protect these rights adequately could harm our ability to compete and impair our business.	We file and prosecute patent applications to protect our product candidates and technologies. We are doing this in close collaboration with leading expert firms in the field of intellectual property protection. In order to protect trade secrets, we maintain strict confidentiality standards and agreements with collaborating parties. We regularly monitor third-party intellectual property rights within our relevant fields and jurisdictions to avoid violating any third-party rights and secures licenses to such third-party rights on a need-to basis.
Our future growth and ability to compete depends on retaining our key personnel and recruiting additional qualified personnel.	We offer competitive remuneration packages and share based incentives in the form of Option Plan. We perform periodical benchmark analyses with an external service provider to ensure the competitiveness of the compensation offered to our key personnel in comparison to other (peer group) companies. We pay close attention to creating an environment that supports the further development of the talents of our key people.

6.5.4 Material Impact of Risk Materialization in 2020

In the period between January 1, 2020 and the date of this Registration Document, we have not identified any material impact on the Company as a result of materialization of previously identified risks and uncertainties.

We are monitoring the impact of the COVID-19 pandemic on our operations. 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.

For the trials our collaborator Cilag GmbH International, an affiliate of the Janssen Pharmaceutical Companies of Johnson & Johnson, or Cilag, is conducting, patient enrollment in the Phase 1b combination study of cusatuzumab with azacytidine and/or venetoclax has resumed but we have decided to delay the start of patient enrollment in the second part of the CULMINATE Phase 2 study to focus resources on the Phase 1b combination study. The launch of new trials has also been delayed. Timing to restart enrollment of all trials will depend on the trajectory of COVID-19 infection rates. We expect that we and/or our respective partners will further evaluate the advancement of each clinical program at a later moment depending on the trajectory of COVID-19 infection rates. 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 US 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 prepare for the commercial launch of efgartigimod, if approved. We are working closely with our manufacturing partners to mitigate those risks to the extent possible.

Since March 2020, foreign and domestic inspections by the FDA have largely been on hold with the FDA announcing plans in July 2020 to resume prioritized domestic inspections. 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 a complete response letter. Further, if there is inadequate information to make a determination on the acceptability of a facility, the FDA may defer action on the application until an inspection can be completed. In 2020, several 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 product candidates and have a material adverse effect on our business and financial results.

Please also see paragraph 1.2.2 "Risk Factors— Business interruptions resulting from the COVID-19 pandemic could cause a disruption of the development of our product candidates and adversely impact our business" on page 18.

In an effort to minimize the impact of COVID-19 on our employees, patients and their communities, physicians and ongoing business priorities, argenx has implemented the following measures across its organization and in the operation of its globally run clinical trials:

- A work-from-home mandate continues for employees in the U.S., Europe and Japan, excluding those providing essential services such as laboratory staff
- In order to enable patients in its clinical trials to receive study drug with continuity, argenx is implementing telehealth, remote monitoring activities and more flexible dosing schedules in its protocols where possible.
- Enrollment is expected continue to be delayed in ongoing trials conducted by argenx, but the extent of the full impact is not quantifiable until the full trajectory of the COVID-19 pandemic is known.

6.5.5 Financial Risks and Controls

In running our business, we seek to implement a sustainable policy regarding internal control and risk management. Our Board of Directors has delegated an active role to its audit and compliance committee in the design, implementation and monitoring of an internal risk management and control system to manage the significant risks to which we are exposed.

Our financial reporting is structured within a tight framework of budgeting, reporting and forecasting. A distinction is made between reports for internal and external use. External reporting at group level consists of an annual report (in the form of this Registration Document), including financial statements audited by the independent auditor, as well semi-annual reporting and quarterly updates, containing summarized financial information. The external reports are based on the internal financial reporting.

Internal financial reporting consists of extensive consolidated monthly reports in which current developments are compared to the monthly (cumulative) budgets and previous forecasts. In addition, each quarter we reiterate or update our forecast for the annual results, including the cash flow position at the end of the financial year. The quarterly budgets are part of the annual group budget, which is prepared every year by our executive management and approved by our Board of Directors. Our specialized finance and administration department are primarily responsible for evaluating the draft internal and external reporting, before these are finally approved by our Board of Directors.

The Board of Directors discusses the financial results of the group at all formal board meetings, which meetings are minuted.

The Company's internal controls over financial reporting are a subset of internal controls and include those policies and procedures that:

(i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company;
(ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with IFRS as adopted by the EU, and that receipts and expenditures of the Company are being made only by authorized persons; and
(iii) 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.

Since the Company has securities registered with the U.S. Securities and Exchange Commission, or SEC and is a large accelerated filer within the meaning of Rule 12b-2 of the U.S. Securities Exchange Act of 1934, the Company needs to assess the effectiveness of the internal controls over financial reporting and provide a report on the results of this assessment. The Company has reviewed its internal controls over financial reporting based on criteria established in the Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and engaged an external advisor to help assess the effectiveness of those controls.

6.5.6 Recent or Current Developments in our System of Risk Management

In 2020, we have extended the global internal controls team with an additional position in the U.S. The internal controls manager is responsible for the evaluation of the adequacy of the design and operating effectiveness of the Company's internal controls and processes through risk assessments, walkthroughs, testing of controls, continuous monitoring of control compliance and reporting the results to our CFO and subsequently the audit and compliance committee. Our internal controls manager is also responsible for the promotion of a risk-aware culture and to ensure efficient and effective risk and compliance management practices.

6.6 Compensation Statement and Remuneration Report

This section 6.5.1 contains the compensation statement required by article 2:135b of the Dutch Civil Code and the remuneration report required by the Dutch Corporate Governance Code.

6.6.1 Remuneration Policy

General
Our remuneration policy sets out that the remuneration of our executive and non-executive director(s) shall be determined by the board of directors. The Remuneration and Nomination Committee monitors and at least annually re-evaluates whether the remuneration policy is still suitable for the Company's purposes and proposes adjustments where necessary. The remuneration policy was last updated and approved by our general meeting on November 7, 2017. The board also evaluates the appropriateness of any change of total cash at target compensation in the context of the market environment. Based on the outcome of the benchmarking analysis described above, the Remuneration and Nomination Committee is implementing step-by-step adjustments of the remuneration packages to ensure that the remuneration offered is in line with the remuneration policy, prescribing a remuneration in line with (or slightly above) market practice (determined as around or slightly above the 75th percentile compensation level within the European companies of the peer group and the 50th percentile compensation level of US based companies of the peer group). Ensuring market conform compensation enables us to attract, reward and retain qualified individuals on which, largely, our success depends.

Amendments
The last benchmarking exercise was done mid-2020, with the assistance of external experts. Following such benchmark and taking into account the entry into force changes in Dutch legislation during 2019 and early 2020 pursuant to Directive (EU) 2017/828 of the European Parliament and of the Council of May 17, 2017 amending Directive 2007/36/EC as regards the encouragement of long-term shareholder engagement or shareholder rights directive, setting out various new and amended requirements for the way remuneration policies are drawn up, we have submitted a proposal with respect to an updated and amended remuneration policy to the General Meeting held on May 12, 2020, but the vote did not reach the 75% majority required for approval (69.9% of the votes were in favour). We will propose an updated and amended remuneration policy to our General Meeting in 2021.

Contribution of the remuneration policy to the Company's long-term value creation
Our shareholders have adopted a policy governing the remuneration of our board of directors and key personnel is aimed to attract, reward and retain highly qualified persons and to provide and motivate the members of the board and the senior management 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 our business plan.

Our Company has never been profitable and is also not expected to be profitable within the foreseeable future. As a result, the performance targets set for our management team are not aimed at short term goals such as share value or turnover, but are instead directly or indirectly targeted at achieving or enabling the further development of our product candidates and generally at the further development and expanding of the organization as a whole.

Part of the remuneration of our management team consists of stock options, which are granted annually and have a vesting period of three years. The vesting period and corresponding offering obligations are aimed at retaining our personnel and creating an incentive for long term value creation in the process.

6.6.2 Compensation of our Executive Management

The remuneration of our executive management (including our executive director) consists of the following fixed and variable components:

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

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

Short-term variable compensation
The objective of this short-term annual incentive is to ensure that our executive management is incentivized to achieve performance targets in the shorter term. Our executive management is eligible for an annual short-term variable incentive of his/her annual base compensation. The target percentage for this purpose was set to 55% of the annual base compensation of a member of the executive management team. Performance conditions are established by our board of directors before or at the beginning of the relevant calendar year and shall include criteria concerning our financial performance, qualitative criteria representing our performance and/or individual qualitative performance.

Long-term incentive awards
Our board of directors intends to incentivize our executive management by issuing options from time to time to be able to attract and retain well-qualified executive management in connection with the Option Plan, as set out below. Typically, options are granted annually in accordance with our stock option grant scheme which is regularly reviewed by our board of directors and particularly our remuneration and nomination committee.

Severance arrangements
We have entered into management contracts and employment agreements with our executive management, each of which provides for certain minimum notice periods if their service or employment with us is terminated in certain circumstances as described below in paragraph 6.6.5 “Related party transactions” on page 222 and further.

Pension and fringe benefits
Our executive management participates in a defined contribution pension scheme operated by a third-party pension insurance organization. Our executive management is entitled to customary fringe benefits, such as a company car and a hospitalization plan.

Performance of scenario analyses
In determining the remuneration package of each individual member of the management team, scenario analyses are performed annually and taken into account in setting the level of the base remuneration to be paid as well as the variable remuneration and the corresponding targets.

Relations between the remuneration of executives in comparison to lower level company personnel
The total company expense for the non-equity remuneration paid to our chief executive officer (and only statutory executive director) for the year ended 31 December 2020, equaled €958,125, representing 671% of the total company expense for the non-equity median compensation paid to our employees. This percentage was calculated on the basis of the last compensation payment period of the year ended 31 December 2020, over which the median non-equity remuneration of all Company employees relative to their full time percentage was taken into account and set off against the non-equity remuneration of our executive director for the same period. We calculate the aforementioned percentage on the last compensation payment of the relevant period, because due to our rapid growth we deem it relevant to also include our latest hires in the comparison, which includes a number of persons who are not (primarily) working at our facilities in Gent, Belgium.

Annual change of compensation, of the performance of the Company and of average remuneration on a full-time equivalent basis of employees of the Company other than executive directors over the five most recent financial years:

(IN THOUSANDS OF €)	2016	2017	2018	2019	2020
Non-equity remuneration of our CEO	354,598	605,576	784,600	851,288	958,125
Non-equity median salary paid to our employees	133,667	95,971	93,311	108,625	142,762
Ratio employee/CEO	38%	16%	12%	13%	15%
Average compensation paid to non-executive directors	44,786	53,333	50,714	53,929	50,714
Number of employees at end of year	58	73	105	188	336
Share price at end of year Euronext	15.94	52.52	85.20	143.60	242.00

The decrease in the remuneration ratio between our key executives and other employees between 2019 and 2020 is caused by the increased median salary paid to our employees, also as a result of our expansion in the U.S. and Japan.

The comparison of non-equity compensation above is made between the compensation paid to our single executive director, and the median compensation paid to our employees. We have opted to compare non-equity salaries in this comparison, because whereas the number of options granted is linked to the overall size of remuneration packages granted, the value of equity components depends on the evolvement of our share price, volatility and the risk free rate, which is unknown at granting and as such the forward looking valuation methods for options normally do not provide an accurate economic value.

Due to the global spread of our employees over multiple continents, we deem it relevant to also include the above comparison separately to our US Employees, EU Employees and Japan employees. Due to the overall higher compensation level in our business segment in the US and Japan compared to Europe, there is a significant difference in the pay ratio when the CEO’s compensation is compared to the median compensation of all our employees (the majority of which are EU persons), as set out above, or compared to employees in the United States and Japan. The following information is provided for reference purposes:

	Employee compared to CEO
All employees	15%
European employees	11%
US employees	22%
Japan employees	13%

For the share based payments the ratio's are as follows:

	2016	2017	2018	2019	2020
Stock options granted to our CEO	80,600	80,000	80,000	80,000	50,000
Median stock options granted to our employees	3,500	2,500	2,500	2,800	2,900
Ratio employee/CEO	4.34%	3.13%	3.13%	3.50%	5.80%
Average number of stock options granted to non-executive directors	10,000	15,000	12,143	10,000	10,000
Median stock options granted to our employees	3,500	2,500	2,500	2,800	2,900
Ratio non-executive directors/CEO	35.00%	16.67%	20.59%	28.00%	29.00%

The total employment costs paid by us in the financial year 2020 was charged to the Company and its subsidiaries as follows:

	Total remuneration paid in 2020 (in million euros)
argenx SE	0.2
argenx IIP BV	5.6
argenx BV	53.6
argenx Japan K.K.	2.3
argenx US Inc.	25.1
argenx Switzerland SA	0.1

The manner in which the variable compensation of our executive director contributes to the long term value creation of the Company

As a result of linking long term targets, designed to increase the Company's performance in the present as well as the future, the variable compensation of our management intends to align the interests of the management team to that of the (other) stakeholders of the Company. The board believes that a remuneration package comprised of a fixed compensation a variable compensation linked to individual targets as well as options linked to a vesting scheme is most suitable to achieve this goal.

Remuneration and Benefits

The following table sets forth information regarding compensation paid by us for Tim Van Hauwermeiren during the year ended December 31, 2020:

Tim Van Hauwermeiren

	Compensation (€)
Fixed base compensation	525,000
Short-term variable compensation	433,125
Long-term variable compensation, in the form of stock options	6,142,917
Employer social security contribution stock options	-
Non-equity incentive plan compensation	-
Pension contributions	22,609
Social security costs	10,587
Other [2]	10,522
Total	**7,144,760**

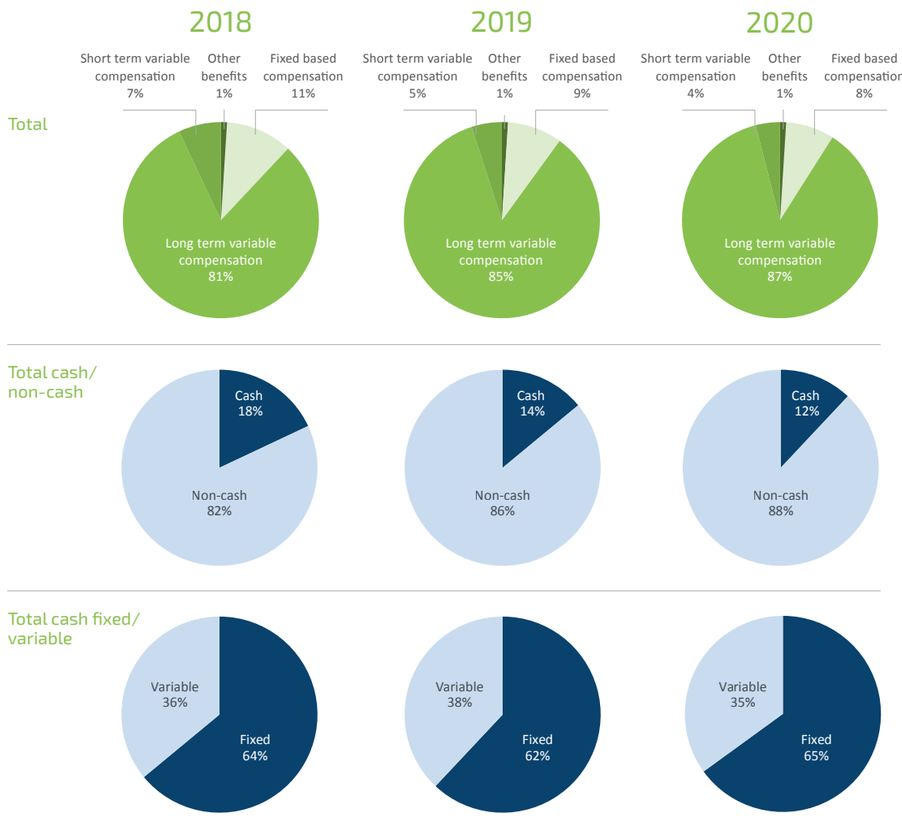
(1) Amount shown represents the expenses with respect to the option awards granted in 2020 to Mr. Van Hauwermeiren measured using the Black Scholes formula. For a description of the assumptions used in the valuing these awards, see note 14 "Share-based payments" to our consolidated financial statements incorporated by reference in this Registration Document (see chapter 7 "Information Incorporated by Reference" on page 244). These amounts do not reflect the actual economic value realized by Mr. Van Hauwermeiren.

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

(3) All of the targets were tailored to the long term value creation of our Company through progressing our clinical product candidates and through building and expanding our organization, each of which is vital to continuing our success and growth for the benefit of all stakeholders.

Variable compensation determination CEO

The mix between fixed and variable remuneration components for our executive director for at least the last 3 years is set out below.



In line with our remuneration policy, the remuneration of Mr. Van Hauwermeiren included short term variable compensationbased on pre-defined specific targets. During the year ended December 31, 2020, the performance targets for determination of the variable compensation for Tim Van Hauwermeiren related primarily to the submission of our BLA for efgartigimod in MG to the US FDA, meeting certain objectives under our core collaborations with third parties, targets relating to representing our company and our first potential commercial product, efgartigimod, with key stakeholders and preparing the company for FDA inspection in relation to the potential launch of our first commercial product.

All of the targets were tailored to the long term value creation of our Company through progressing our clinical product candidates and through building and expanding our organization, each of which is vital to continuing our success and growth for the benefit of all stakeholders.

Our board of directors determined that all of the targets were materially achieved (despite the impact of COVID-19), and that the corresponding pay-out of the variable compensation targets for 2020 is 100% of the target amount, equaling 55% of the fixed cash remuneration.

The ratio between fixed and variable payments to our CEO for the financial year ended December 31, 2020 equals €525,000/433,125 or 54.8%/45.2%.

Remuneration of other executive managers

The following table sets forth information regarding aggregate compensation paid by us for the members of our executive management (excluding Tim Van Hauwermeiren) during the year ended December 31, 2020. We note that these numbers also include compensation paid to persons who have been part of our executive management for part of 2020 (being Marc Schorpion).

	Compensation (€)
Fixed base compensation	2,316,641
Short-term variable compensation	888,738
Long-term variable compensation, in the form of stock options [1]	31,350,063
Employer social security contribution stock options [2]	9,811,342
Non-equity incentive plan compensation	–
Termination benefits	336,663
Pension contributions	118,090
Social security costs	648,965
Other [3]	126,935
Total	**45,597,437**

(1) Amount shown represents the expenses with respect to the option awards granted in 2020 to Mr. Keith Woods, Prof. Hans de Haard, Mr. Wim Parys, Mr. Arjen Lemmen, Mr. Dirk Beeusaert, Mr. Marc Schorpion, 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 "Share-based payments" to our consolidated financial statements incorporated by reference in this Registration Document (see chapter 7 "Information Incorporated by Reference" on page 244). These amounts do not reflect the actual economic value realized by these members of our executive management.

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

(3) Consists of €75,445 attributable to the leases of company cars, €24,627 in car, housing and other allowances and €26,863 in employer-paid medical insurance premiums.

The following table sets forth information regarding option awards granted to our executive management during the year ended December 31, 2020:

Name	Stock options	Expiration date	Exercise price (IN THOUSANDS OF €)
Tim Van Hauwermeiren [1]	50,000	21/12/2030	247.60
Hans de Haard [1]	50,000	21/12/2030	247.60
Keith Woods	50,000	21/12/2030	247.60
Wim Parys [1]	50,000	21/12/2030	247.60
Marc Schorpion	25,000	25/06/2030	196.15
Arjen Lemmen [1]	50,000	21/12/2030	247.60
Dirk Beeusaert	50,000	25/06/2025	196.15
Andria Wilk [1]	9,900	21/12/2030	247.60

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

Pursuant to our remuneration policy and practices, our CEO Tim van Hauwermeiren was offered 80,000 stock options in 2020, but at his request the Board of Directors agreed to reduce the number of options granted for 2020 to 50,000 and to distribute the difference to certain top performing lower level employees of the Company in 2021.

Together
We Discover

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

NAME	Total options held on January 1, 2020	Options granted in 2020	Options forfeited in 2020	Options exercised in 2020	Total options held on December 31, 2020		Exercise price (IN THOUSANDS OF €)	Options vested until 2019	Options vested in 2020	Options to vest in 2021	Options to vest in 2022	Options to vest in 2023
Tim Van Hauwermeiren	386,200	50,000	–	(146,200)	290,000		21.17	53,333	26,667			
							86.32	26,667	26,666	26,667		
							135.75		26,667	26,666	26,667	
							247.60			16,667	16,666	16,667
Total	**386,200**	**50,000**	**–**	**(146,200)**	**290,000**			**80,000**	**80,000**	**70,000**	**43,333**	**16,667**
Eric Castaldi	227,800	–	–	(56,400)	171,400		14.13	28,200				
							21.17	28,800	14,400			
							86.32	16,667	33,333			
							135.75		50,000			
Total	**227,800**	–	–	**(56,400)**	**171,400**			**73,667**	**97,733**	–	–	–
Keith Woods	150,000	50,000	–	(45,000)	155,000							
Total	**150,000**	**50,000**	**–**	**(45,000)**	**155,000**							
Hans de Haard	495,975	50,000	–	–	545,975		2.44	144,822				
							7.17	109,000				
							9.47	28,200				
							11.47	28,200				
							14.13	28,200				
							18.41	11,961	2,392			
							21.17	28,800	14,400			
							86.32	16,667	16,666	16,667		
							135.75		16,666	16,668	16,666	
							247.60			16,667	16,666	16,667
Total	**495,975**	**50,000**	**–**	**–**	**545,975**			**395,850**	**50,124**	**50,002**	**33,332**	**16,667**
Wim Parys	175,000	50,000	–	–	225,000		86.32	41,667	41,666	41,667		
							135.75		16,667	16,666	16,667	
							247.60			16,667	16,666	16,667
Total	**175,000**	**50,000**	**–**	**–**	**225,000**			**41,667**	**58,333**	**75,000**	**33,333**	**16,667**

NAME	Total options held on January 1, 2020	Options granted in 2020	Options forfeited in 2020	Options exercised in 2020	Total options held on December 31, 2020		Exercise price (IN THOUSANDS OF €)	Options vested until 2019	Options vested in 2020	Options to vest in 2021	Options to vest in 2022	Options to vest in 2023
Arjen Lemmen	101,276	50,000	–	(15,065)	136,211		11.47	3,215				
							14.13	3,215				
							18.41	3,110	1,196			
							21.17	2,995	3,333			
							80.82	695	1,666	834		
							86.32	952	7,500	7,500		
							135.75		24,963	12,519	12,518	
							247.60			16,667	16,666	16,667
Total	**101,276**	**50,000**	**–**	**(15,065)**	**136,211**			**14,182**	**38,658**	**37,520**	**29,184**	**16,667**
Dirk Beeusaert	154,682	50,000	–	–	204,682		18.41	33,068	6,614			
							21.17	10,000	5,000			
							80.82	14,.100	9,400	4,700		
							86.32	7,267	7,266	7,267		
							113.49	11,513	19,244	12,829	6,414	
							196.15		12,756	12,415	12,415	12,415
Total	**154,682**	**50,000**	**–**	**–**	**204,682**			**75,948**	**60,280**	**37,211**	**18,829**	**12,415**
Marc Schorpion	25,000	25,000	–	–	50,000		113.49	–	12,500	8,333	4,167	
							196.15			12,500	8,333	4,167
Total	**25,000**	**25,000**	**–**	**–**	**50,000**			**–**	**12,500**	**20,833**	**12,500**	**4,167**
Andria Wilk	9,400	9,900	–	–	19,300		135.75	–	4,693	2,354	2,354	
							247.60			3,300	3,300	3,300
Total	**9,400**	**9,900**	**–**	**–**	**19,300**			**–**	**4,693**	**5,653**	**5,654**	**3,300**

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

NAME	Number of Stock options	Remaining term on December 31, 2020 (rounded up)
Tim Van Hauwermeiren	80,000	7 years
	80,000	8 years
	80,000	9 years
	50,000	5 years / 10 years [1]
Eric Castaldi	17,360	3 years
	5,000	4 years
	28,200	6 years
	43,200	7 years
	32,640	8 years
	45,000	9 years
Keith Woods	5,000	7 years
	50,000	8 years
	50,000	9 years
	50,000	10 years
Hans De Haard	69,360	2.5 years
	39,636	3 years
	35,826	4 years
	109,000	4 years
	28,200	5 years
	28,200	5.5 years
	28,200	6 years
	14,353	6.5 years
	43,200	7 years
	50,000	8 years
	50,000	9 years
	50,000	5 years / 10 years [1]
Wim Parys	125,000	3 years
	50,000	9 years
	50,000	5 years / 10 years [1]
Arjen Lemmen	2,500	2.5 years
	50,000	4 years
	3,215	5.5 years
	3,215	6 years
	4,306	6.5 years
	6,328	7 years
	695	7.5 years
	15,952	8 years
Marc Schorpion	25,000	8.5 years
	25,000	9.5 years
Dirk Beeusaert	28,200	2.5 years
	21,800	3 years
	50,000	3.5 years
	50,000	4.5 years
	39,682	6.5 years
	15,000	7 years
Andria Wilk	9,400	4 years
	9,900	5 years / 10 years [1]

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

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

NAME	Number of Stock options	Exercise price
Tim Van Hauwermeiren	35.000	7,17
Tim Van Hauwermeiren	30.600	9,47
Tim Van Hauwermeiren	50.000	11,47
Tim Van Hauwermeiren	30.600	14,13
Eric Castaldi	28.200	9,47
Eric Castaldi	28.200	11,47
Keith Woods	45.000	21,17
Arjen Lemmen	585	11,47
Arjen Lemmen	785	14,13
Arjen Lemmen	1.670	18,41
Arjen Lemmen	3.670	21,17
Arjen Lemmen	1.805	80,82
Arjen Lemmen	6.548	86,32
Total	**262.665**	

6.6.3 Compensation of Our Non-Executive Directors

The remuneration of the individual members of the board of directors is determined by the non-executive directors, at the recommendation of the remuneration and nomination committee, within the limits of the remuneration policy adopted by the shareholders at the General Meeting. The description below reflects the status of our remuneration policy as updated by our board of directors on September 12, 2017 and giving effect to the update to the remuneration policy approved by our shareholders at the extraordinary shareholders' meeting held on November 7, 2017.

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

- a fixed fee, which fee will be prorated if the non-executive director does not attend all meetings where his or her presence is required;
- if applicable, a fee for chairing the audit and compliance committee, the research and development committee or the remuneration and nomination committee;
- a fixed fee for board committee membership; and
- a long-term variable incentive in the form of stock options.

Fixed fee

The board of directors has set the annual base remuneration for non-executive directors at €35,000, additional remuneration for the chairperson of the board of directors at €30,000, additional remuneration for the chairperson of the audit and compliance committee and the research and development committee of the board of directors at €15,000 and additional remuneration for the chairperson of the remuneration and nomination committee and the commercial committee of the board of directors at €10,000. Board committee members, other than the chairman of the relevant committee, receive an annual retainer of €5,000 for the remuneration and nomination committee and a €7,500 retainer for the members of the audit and compliance committee and the research and development committee.

Long-term incentive plan

The board of directors intends to incentivize the non-executive directors by issuing options from time to time to be able to attract and retain well-qualified non-executive directors in connection with the Option Plan. The board of directors grants options to the non-executive directors on the recommendation of the remuneration and nomination committee. Such option grants are based on an option allocation scheme established by the board of directors pursuant to the Option Plan. The conditions of our Option Plan apply to our non-executive directors, as set forth in paragraph 6.6.4 "Long-Term Incentives Granted to Key Persons - Option Plan" on page 221 and further.

Success payment

In exceptional circumstances, the board of directors may decide to reward a non-executive director with a success payment relating to the occurrence of specific events achieved through the exceptional efforts of that person (such as a platform licensing or product licensing deal brokered by that non-executive director). To date, no such success payments have been made or promised by us to our non-executive directors.

Pursuant to the remuneration policy, in case of a dismissal, non-executive directors will not be entitled to a severance payment.

The following table sets forth the information regarding the compensation earned by our non-executive directors during the year ended December 31, 2020:

Name (IN THOUSANDS OF €)	Fees earned or paid in cash	Option awards	Total
Peter K.M. Verhaeghe	77,500	1,288,583	1,306,083
David L. Lacey	50,000	1,192,599	1,242,599
Werner Lanthaler	55,000	1,192,599	1,247,599
Pamela Klein	42,500	1,192,599	1,235,099
J. Donald deBethizy	52,500	1,192,599	1,245,099
A.A. Rosenberg	42,500	1,192,599	1,235,099
James M. Daly	35,000	1,192,599	1,227,599

(1) These amounts do not reflect the actual economic value realized by the non-executive director. Amount shown represents the expenses with respect to the option awards granted in 2020 to the non-executive directors measured using the Black Scholes formula. For a description of the assumptions used in valuing these awards, see note 14 "Share-based payments" to our consolidated financial statements for the year ended December 31, 2020, incorporated by reference in this Registration Document (see chapter 7 "Information Incorporated by Reference" on page 244).

(2) 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.

Chris

Chris gets real about how MG has affected his life and his plans for the future in this interview.

Before being diagnosed with myasthenia gravis four years ago, Chris Givens was always on the move. He served in the U.S. Air Force for nearly 13 years. The Florida native would go spearfishing and lobstering. He was an avid scuba diver, dirt biker and motorcyclist. He lived abroad for several years. Now he's doing his best trying to adjust to a life with MG.

Patient Story

What were your early symptoms of myasthenia gravis?

At first, it was just really weird. It's not like it hits you all at once. I started choking a lot on food. After about a month, the symptoms really kicked in hard, like, weekly. My whole body felt like jelly. Walking made my legs achy, like running a marathon. I went from 190 pounds down to 140 pounds because I couldn't keep any food down. I thought, *What the heck is going on?* I never go to doctors, but finally I went to Veterans Affairs. They thought it was a gastrointestinal (GI) issue. I spent maybe eight months doing a GI workup, including esophagus testing. A throat doctor told me, 'You're fine. It's all in your head. Go see a shrink.' My GI doctor thought I had ALS* and sent me to a neurologist, who was right out of school. But it turned out she knew exactly what it was—myasthenia gravis.

It was a blessing to know what my condition was. Because the hardest part is the unknown.

And now? How are you doing?

While managing my condition, I gained weight, got rashes and lost bone density. I've aspirated or breathed in water. I can handle all that. The worst part is when you're told, 'It's all in your head.' You begin to think that it is in your head. But I'm not crazy. It's not in my head. People with myasthenia gravis can look just fine, but it's frustrating when people don't believe you have the condition.

I can choose to listen to that—or not. I've even worked to change how I talk to myself. I've always been proud. If I'd get cut, I'd deal with it for a couple of minutes and then go back to work. I never went to a doctor. I was raised to think that men who go to doctors are weak. Now I look for support from my care team and grown daughters.

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

NAME	Total options held on January 1, 2020	Options granted in 2020	Options exercised in 2020	Total options held on December 31, 2020		Exercise price (IN THOUSANDS OF €)	Options vested until 2019	Options vested in 2020	Options to vest in 2021	Options to vest in 2022	Options to vest in 2023
Peter Verhaeghe	54,585	10,000	(5,990)	58,595		2.44	11,626				
						3.95	1,969				
						7.17	5,000				
						11.38	10,000				
						86.32	3,333	3,334	3,333		
						135.75		3,333	3,334	3,333	
						247.60			3,333	3,334	3,333
Total	**54,585**	**10,000**	**(5,990)**	**58,595**			**31,928**	**6,667**	**10,000**	**6,667**	**3,333**
David L. Lacey	64,443	10,000	(6,643)	67,800		11.38	12,800				
						21.17	10,000	5,000			
						86.32	10,000	3,334	3,333		
						135.75	3,333	3,333	3,334	3,333	
						247.60	–		3,333	3,334	3,333
Total	**64,443**	**10,000**	**(6,643)**	**67,800**			**36,133**	**11,667**	**10,000**	**6,667**	**3,333**
Werner Lanthaler	20,000	10,000	–	30,000		86.32	3,333	3,334	3,333		
						135.75		3,333	3,334	3,333	
						247.60			3,333	3,334	3,333
Total	**20,000**	**10,000**	**–**	**30,000**			**3,333**	**6,667**	**10,000**	**6,667**	**3,333**
J. Donald deBethizy	45,000	10,000	(7.500)	47,500		11.44	10,000				
						11.38	7,500				
						86.32	3,333	3,334	3,333		
						135.75		3,333	3,334	3,333	
						247.60			3,333	3,334	3,333
Total	**45,000**	**10,000**	**(7.500)**	**47,500**			**20,833**	**6,667**	**10,000**	**6,667**	**3,333**
Pamela Klein	45,000	10,000	(5.000)	50,000		11.44	10,000				
						11.38	10,000				
						86.32	3,333	3,334	3,333		
						135.75		3,333	3,334	3,333	
						247.60			3,333	3,334	3,333
Total	**45,000**	**10,000**	**(5,000)**	**50,000**			**23,333**	**6,667**	**10,000**	**6,667**	**3,333**

NAME	Total options held on January 1, 2020	Options granted in 2020	Options exercised in 2020	Total options held on December 31, 2020		Exercise price (IN THOUSANDS OF €)	Options vested until 2019	Options vested in 2020	Options to vest in 2021	Options to vest in 2022	Options to vest in 2023
A.A. Rosenberg	35,000	10,000	–	45,000		14.13	15,000				
						86.32	3,333	3,334	3,333		
						135.75		3,333	3,334	3,333	
						247.60			3,333	3,334	3,333
Total	**35,000**	**10,000**	**–**	**45,000**			**18,333**	**6,667**	**10,000**	**6,667**	**3,333**
James M. Daly	35,000	10,000	(10,000)	35,000		80.32	–	2,500	2,500		
						86.32	3,333	3,334	3,333		
						135.75		3,333	3,334	3,333	
						247.60			3,333	3,334	3,333
Total	**35,000**	**10,000**	**(10,000)**	**35,000**			**3,333**	**9,167**	**12,500**	**6,667**	**3,333**

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

NAME	Number of Stock options	Remaining term on December 31, 2020 (rounded up)
Peter K.M. Verhaeghe	5,560	2.5 years
	3,181	3 years
	4,854	4 years
	5,000	4 years
	10,000	5.5 years
	10,000	8 years
	10,000	9 years
	10,000	10 years
David L. Lacey	12,800	4 years
	10,000	5.5 years
	15,000	7 years
	10,000	8 years
	10,000	9 years
	10,000	10 years
Werner Lanthaler	10,000	3 years
	10,000	9 years
	10,000	10 years
J. Donald deBethizy	7,500	4.5 years
	10,000	5.5 years
	10,000	8 years
	10,000	9 years
	10,000	10 years
Pamela Klein	10,000	4.5 years
	10,000	5.5 years
	10,000	8 years
	10,000	9 years
	10,000	10 years
A.A. Rosenberg	15,000	6 years
	10,000	8 years
	10,000	9 years
	10,000	10 years
James M. Daly	5,000	7.5 years
	10,000	8 years
	10,000	9 years
	10,000	10 years

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

NAME	Number of Stock options	Exercise price
David Lacey	6.643	2,44
Don deBethizy	7.500	11,44
Jim Daley	10.000	80,82
Pam Klein	5.000	11,44
Peter Verhaeghe	5.990	3,95
Total	**35.133**	

As at the date of this Registration Document Werner Lanthaler holds 30.416 shares.

6.6.4 Long-Term Incentives Granted to Key Persons - Option Plan

On December 18, 2014, our board of directors adopted the Option Plan, which was approved by the shareholders at the General Meeting on May 13, 2015 and amended by the General Meeting on April 28, 2016 and November 25, 2019 and the board of directors on December 18, 2019 and November 5, 2020. The aim of the Option Plan is to encourage our executive management, directors and key outside consultants and advisors to acquire an economic and beneficial ownership interest in the growth and performance of the Company, to increase their incentive to contribute to our value and to attract and retain individuals who are key to our Company.

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

In connection with the Option Plan, our board of directors has also established an option allocation scheme. The option allocation scheme contains (i) the date on which options are granted each year, which shall be the same date each year and (ii) the number of options granted to each person or to each group of persons, which shall be based on objective criteria only.

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

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

Options granted pursuant to the Option Plan shall vest with respect to one third of the shares upon the first anniversary of the date of grant, with the remaining two thirds vesting in twenty-four equal monthly instalments with the option fully vesting upon the third anniversary of the date of grant, subject, in each case, to the optionee's continued status. Options are exercisable when vested, and in any case not after the option expiration date included in each individual option grant, which is (at the election of the optionee) either 5 years or 10 years from the date of grant.

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

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

6.6.5 Related Party Transactions

Since December 31, 2020, being the end of the last financial period for which audited financial statements have been published, we have not entered into any transactions with any related parties which are – as a single transaction or in their entirety – material to us.

In addition, in the period covered by the financial statements incorporated herein by reference, 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 paragraph 5.3.1 “Principal Shareholders” on page 170 and further, and the transactions we describe below.

Agreements with Our Executive Management
We have entered into a management agreement with Tim Van Hauwermeiren as our chief executive officer. The chief executive officer is our sole executive director. The key terms of his agreement are as follows:

	Tim Van Hauwermeiren
Fixed base compensation	€ 525,000
Short-term variable compensation	A target of 55% of fixed base compensation based on previously determined bonus targets established by the non-executive directors [1]
Pension contributions [2]	€ 22,609
Duration	Indefinite

(1) We have an established practice to provide the variable pay partially in the form of OTC options (which, for the avoidance of doubt, are not granted under the Option Plan). For those beneficiaries that opt to receive their bonus through over the counter (OTC) options rather than through a payment in cash.
(2) Amounts shown represent pension contributions paid during the year-ended December 31, 2020.

We may terminate Mr. Van Hauwermeiren’s services upon 18 months’ notice, or payment of 18 months’ pro-rated base compensation in lieu of notice. Mr. Van Hauwermeiren would be entitled to the same payment in lieu of notice in the event he terminates his services with us in circumstances in which it cannot reasonably be expected for him to continue providing services to us (and after our failure to remedy such conditions after being provided at least 14 days’ notice). Mr. Van Hauwermeiren would also be entitled to payment in lieu of notice in the event he terminated his services with us in certain cases of our failure to comply with obligations under applicable law or his agreement (and after our failure to remedy such non-compliance, if non-deliberate, after being provided at least 14 days’ notice). In these cases, there will be a full acceleration of the vesting of any outstanding stock options held by Mr. Van Hauwermeiren. There will be no notice period or payment in lieu of notice in certain cases of Mr. Van Hauwermeiren’s failure to comply with obligations under applicable law or his agreement. Mr. Van Hauwermeiren may be dismissed immediately as an executive director.

Eric Castaldi, our Chief Financial Officer, has an employment contract with our subsidiary, argenx BV, for an indefinite term. His employment contract may be terminated at any time by us, subject to a notice period and a severance payment of at least 12 months. The Company is currently recruiting a U.S.-based chief financial officer and has entered into a transition agreement with Mr. Castaldi.

Keith Woods, our Chief Operating Officer, has an employment contract with our subsidiary, argenx US Inc., for an indefinite term. His employment contract may be terminated at any time by us, subject to a notice period and a severance payment of at least 12 months.

Wim Parys, our Chief Medical Officer, has an employment contract with our subsidiary argenx BV, for an indefinite term. His employment contract may be terminated at any time by us, subject to a notice period and a severance payment of at least 12 months.

Hans de Haard, our Chief Scientific Officer, has an employment contract with our subsidiary, argenx BV, for an indefinite term. His employment contract may be terminated at any time by us, subject to a notice period and a severance payment of at least 12 months.

Arjen Lemmen, our VP Corporate Development & Strategy, has an employment contract with our subsidiary, argenx BV, for an indefinite term. His employment contract may be terminated at any time by us, subject to a notice period and a severance payment of at least 12 months.

Dirk Beeusaert, our General Counsel, has an employment contract with our subsidiary, argenx BV, for an indefinite term. His employment contract may be terminated at any time by us, subject to a notice period and a severance payment of at least 12 months.

Marc Schorpion, our Global Head of Human Resources, has an employment contract with our subsidiary, argenx B.V., for an indefinite term. His employment contract may be terminated at any time by us, subject to a notice period and a severance payment of at least 12 months.

Andria Wilk, our Global Head of Quality, has an employment contract with our subsidiary, argenx BV, for an indefinite term. Her employment contract may be terminated at any time by us, subject to a notice period and a severance payment of at least 12 months.

Indemnification Agreements
In connection with our initial U.S. public offering, we entered into indemnification agreements with each of our non-executive directors and each member of our executive management. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to non-executive directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Transactions with Related Companies
Agreement with FairJourney Biologics LDA - FairJourney Biologics LDA, or FairJourney, is a fee-for-service company focused on antibody discovery and engineering services. FairJourney was founded in 2012 and, as compensation for their support with the formation of FairJourney, our chief executive officer and executive director Tim Van Hauwermeiren acquired shares representing 5% of the equity securities of FairJourney, and our chief scientific officer, Hans de Haard, acquired shares representing 20% of the equity securities of FairJourney. In July 2012, we entered into a license and exclusive option agreement with FairJourney, pursuant to which we granted FairJourney a worldwide, non-exclusive license to our SIMPLE AntibodyTM Platform to develop, manufacture and commercialize SIMPLE Antibodies to certain targets selected by FairJourney. Under the terms of the agreement, once FairJourney has advanced a product candidate discovered under the agreement to near proof-of-concept stage, we have the option to acquire patent rights generated by FairJourney specific to such product candidate along with a non-exclusive license to additional FairJourney intellectual property useful for further development, manufacture, or commercialization of the product candidate. Upon exercising this option, we must pay FairJourney an option fee equal to two times the expenses incurred by FairJourney for advancing such product candidate through the option exercise date, and we are required to pay a specified royalty in the mid-single digits on any sub-licensing revenue received by us for such product candidate. Alternatively, if we elect not to exercise the option, FairJourney is required to pay us a specified royalty in the mid-single digits on any sub-licensing revenue received by FairJourney for such product candidate. In connection with the agreement, we acquired shares of FairJourney representing 15% of the fully-diluted equity securities of FairJourney at the time of issuance. In December 2017, the Company and executive director Tim Van Hauwermeiren sold their respective shareholding in FairJourney Biologics LDA, and thus FairJourney Biologics LDA is no longer a related company. In January 2020, the stake held by Prof. Hans de Haard in FairJourney was sold. This means that at the date of this Registration Document, FairJourney LDA no longer qualifies as related party.

6.7 Employees

As of December 31, 2020, we had 336 employees (excluding consultants). At each date shown below, we had the following number of employees, broken out by department and geography:

(IN THOUSANDS OF €)	2018	2019	2020	2021*
Function				
Research and development	75	118	193	208
Selling, general and administrative	30	70	143	154
Total	**105**	**188**	**336**	**362**
Geography				
Zwijnaarde, Belgium	94	145	213	225
Boston, USA	11	40	108	119
Tokyo, Japan	—	3	13	15
Breda, the Netherlands	—	—	—	—
Geneva, Switzerland	—	—	2	3
Total	**105**	**188**	**336**	**362**

* up to the date of this Registration Document.

Collective bargaining agreements, or CBAs, can be entered into in Belgium at the national, industry, or company levels. These CBAs are binding on both employers and employees. We have no trade union representation or CBAs at the company level, but we are subject to the national and industry level CBAs that relate to the chemical industry. The CBAs currently applicable to us relate to employment conditions such as wages, working time, job security, innovation and supplementary pensions. We have not had, and do not anticipate having, disputes on any of these subjects. CBAs may, however, change the employment conditions of our employees in the future and hence adversely affect our employment relationships.

6.8 Certain Relevant Provisions of Applicable Law and Our Articles of Association

6.8.1 Issue of Shares

The Articles of Association provide that shares may be issued or rights to subscribe for our shares may be granted pursuant to a resolution of the shareholders at the General Meeting, or alternatively, by our board of directors if so designated by the shareholders at the General Meeting. A resolution of the shareholders at the General Meeting to issue shares, to grant rights to subscribe for shares or to designate our board of directors as the corporate body of the company authorized to do so can only take place at the proposal of our board of directors with the consent of the majority of the non-executive directors. Shares may be issued or rights to subscribe for shares may be granted by resolution of our board of directors, if and insofar as our board of directors is designated to do so by the shareholders at the General Meeting. Designation by resolution of the shareholders at the General Meeting cannot be withdrawn unless determined otherwise at the time of designation. The scope and duration of our board of directors' authority to issue shares or grant rights to subscribe for shares (such as granting stock options or issuing convertible bonds) is determined by a resolution of the shareholders at the General Meeting and relates, at the most, to all unissued shares in the company's authorized capital at the relevant time. The duration of this authority may not exceed a period of five years. Designation of our board of directors as the body authorized to issue shares or grant rights to subscribe for shares may be extended by a resolution of the shareholders at the General Meeting for a period not exceeding five years in each case. The number of shares that may be issued is determined at the time of designation.

No shareholders' resolution or board of directors resolution is required to issue shares pursuant to the exercise of a previously granted right to subscribe for shares. A resolution of our board of directors to issue shares and to grant rights to subscribe for shares can only be taken with the consent of the majority of the non-executive directors.

On May 12, 2020, the shareholders at the General Meeting designated our board of directors as the corporate body competent to issue shares to a maximum of 4% of our outstanding share capital of the Company at the date of the general meeting, pursuant to, and within the limits of, the Option Plan and to limit or exclude pre-emptive rights of shareholders for such shares and option rights to subscribe for shares with the prior consent of the majority of the non-executive directors for a period of 18 months. On May 12, 2020, the shareholders at the General Meeting designated our board of directors as the corporate body competent to issue additional shares and grant rights to subscribe for shares to a maximum of 10% of the outstanding share capital of the Company at the date of the general meeting, and to limit or exclude pre-emptive rights of shareholders for such shares with the prior consent of the majority of the non-executive directors for a period of 18 months.

In addition, the shareholders at the General Meeting as the corporate body competent to issue additional shares and grant rights to subscribe for shares up to a maximum of 10% of the outstanding share capital of the Company at the data of the general meeting, for a period starting on May 12, 2020, and ending on December 31, 2020, for the purpose of a possible public offering of such shares and to limit or exclude pre-emptive rights of shareholders for such shares with the prior consent of the majority of the non-executive directors. While there is no current intention to benefit any specific person with this authorization to restrict the pre-emptive rights of the existing shareholders, when using this authorization the board will be able to restrict the pre-emptive rights in whole or in part, including for the benefit of specific persons. The board's ability to restrict the pre-emptive rights in whole or in part could be used by the board as a potential anti-takeover measure, although there is currently no likely scenario in which we expect that such ability would be used as an anti-takeover measure.

6.8.2 Public Offer

In accordance with Directive 2004/25/EC, each European Union member state should ensure the protection of minority shareholders by obliging any person that acquires a controlling interest in a listed company to make an offer to all the holders of that company's voting securities for all their holdings at an equitable price. The Directive 2004/25/EC applies to companies governed by the laws of a European Union member state of which voting securities are admitted to trading on a regulated market in one or more European Union member states. In accordance with Section 5:70 of the DFSA, any person—whether acting alone or in concert with others— who, directly or indirectly, acquires a controlling interest in such company will in principle be obliged to launch a mandatory public offer for all our outstanding shares. A controlling interest is deemed to exist if a (legal) person is able to exercise, alone or acting in concert, at least 30% of the voting rights in the General Meeting. In case of a mandatory public offer, the provisions regarding the offered consideration and the bid procedure will be governed by Belgian law pursuant to article 4§1, 3° of the Belgian law dated April 1, 2007 on public takeover bids, or the Takeover Law. Pursuant to article 53 of the Belgian Royal Decree of April 27, 2007 on public takeover bids, or the Takeover Royal Decree, a mandatory public offer on our shares must be launched at a price equal to the higher of (i) the highest price paid by the offeror or persons acting in concert with it for the acquisition of shares during the last 12 months and (ii) the weighted average trading prices during the last 30 days before the obligation to launch a mandatory public offer was triggered. The price can be in cash or in securities. However, if the securities that are offered as consideration are not liquid securities that are traded on a regulated market or if the offeror or persons acting in concert with it have acquired shares for cash in the last 12 months, a cash alternative has to be offered. Various protective measures are possible and permissible within the boundaries set by Dutch law and Dutch case law. We have not implemented specific measures with the aim of deterring takeover attempts. However, we have adopted several provisions that may have the effect of making a takeover of our Company more difficult or less attractive, including requirements that certain matters, including an amendment of our Articles of Association, may only be brought to our shareholders for a vote upon a proposal by our board of directors. No takeover bid has been instigated by third parties in respect of our equity during the previous financial year and the current financial year.

6.8.3 Amendment of Articles of Association

The shareholders at the General Meeting may resolve to amend the Articles of Association, at the proposal of our board of directors, with the consent of the majority of the non-executive directors. A resolution by the shareholders at the General Meeting to amend the Articles of Association requires a simple majority of the votes cast in a meeting in which at least half of our issued and outstanding capital is present or represented, or at least two-thirds of the votes cast, if less than half of our issued and outstanding capital is present or represented at that meeting.

Changing the rights of any of the shareholders will require the Articles of Association to be amended.

6.8.4 Squeeze Out Procedures

Pursuant to Section 92a, Book 2, Dutch Civil Code, a shareholder who for his own account holds at least 95% of our issued share capital may initiate proceedings against our minority shareholders jointly for the transfer of their shares to the claimant. The proceedings are held before the Dutch Enterprise Chamber of the Amsterdam Court of Appeal (Ondernemingskamer van het Gerechtshof te Amsterdam), or the Enterprise Chamber, and can be instituted by means of a writ of summons served upon each of the minority shareholders in accordance with the provisions of the Dutch Code of Civil Procedure (Wetboek van Burgerlijke Rechtsvordering). The Enterprise Chamber may grant the claim for squeeze out in relation to all minority shareholders and will determine the price to be paid for the shares, if necessary after appointment of one or three experts who will offer an opinion to the Enterprise Chamber on the value to be paid for the shares of the minority shareholders. Once the order to transfer becomes final before the Enterprise Chamber, the person acquiring the shares will give written notice of the date and place of payment and the price to the holders of the shares to be acquired whose addresses are known to him. Unless the addresses of all of them are known to the acquiring person, such person is required to publish the same in a daily newspaper with a national circulation. In addition, pursuant to Section 359c, Book 2 of the Dutch Civil Code, following a public offer, a holder of at least 95% of our issued share capital and voting rights has the right to require the minority shareholders to sell their shares to it. Any such request must be filed with the Enterprise Chamber within three months after the end of the acceptance period of the public offer. Conversely, pursuant to article 2:359d of the Dutch Civil Code each minority shareholder has the right to require the holder of at least 95% of our issued share capital and voting rights to purchase its shares in such case. The minority shareholder must file such claim with the Enterprise Chamber within three months after the end of the acceptance period of the public offer.

6.8.5 Shareholder Engagement

In June 2019, Directive 2017/828 of the European Parliament and of the Council of May 17, as regards the encouragement of long-term shareholder engagement, or the revised European Union Shareholder Rights Directive (SRD II), came into effect. The SRD II amends the Directive 2007/36/EC of the European Parliament and of the Council of July 11, 2007 on the exercise of certain rights of shareholders in listed companies, and aims at encouraging long-term engagement of shareholders of European listed companies. To achieve this long-term investment objective, the SRD II describes new obligations for European listed companies, leading to a greater transparency regarding (among other things) the investment strategy, the directors' remuneration, related party transactions and the voting process in general meetings. The SRD II also describes obligations for or concerns the shareholders themselves (by way of a right attributed to European listed companies to request information in order to identify their shareholders (excluding shareholders holding less than 0.5%) and a policy on shareholder engagement which should be established by institutional investors and asset managers) and proxy advisors. Although the Company considers shareholder engagement pivotal in its corporate governance practices, we do not believe any of the aforementioned legislation requires us to amend our policies and/or practices right now, but we will continue to review this.

6.8.6 Market Abuse Rules

As of July 3, 2016, setting aside previously applicable legislation in the European Union member states, Regulation (EU) No 596/2014 of the European Parliament and of the Council of April 16, 2014 on market abuse (market abuse regulation) and repealing Directive 2003/6/EC of the European Parliament and of the Council and Commission Directives 2003/124/EC, 2003/125/EC and 2004/72/EC, and the rules and regulations promulgated pursuant thereto, or MAR, provides for specific rules intended to prevent market abuse, such as prohibitions on insider dealing , disclosing inside information and tipping and market manipulation. The Company, the members of our board of directors and other insiders and persons performing or conducting transactions in the Company's financial instruments, as applicable, will be subject to the insider dealing prohibition, the prohibition on disclosing inside information and tipping and the prohibition on market manipulation.

Inside information is any information of a precise nature relating (directly or indirectly) to us, or to our shares or other financial instruments, which information has not been made public and which, if it were made public, would be likely to have a significant effect on the price of the shares or the other financial instruments or on the price of related derivative financial instruments.

Pursuant to the MAR, a person who possesses inside information is prohibited from using that information by acquiring or disposing of, for its own account or for the account of a third party, directly or indirectly, our shares and other financial instruments to which that information relates (which is considered to be insider dealing). The use of inside information by cancelling or amending an order concerning our shares or other financial instruments to which the information relates where the order was placed before the person concerned possessed the inside information, is also prohibited. In addition, a person is also prohibited to recommend another person to engage in insider dealing, or induce another person to engage in insider dealing, which arises where the person possesses inside information and (a) recommends, on the basis of that information, that another person acquire or dispose of our shares or other financial instruments to which that information relates, or induces that person to make such an acquisition or disposal or (b) recommends, on the basis of that information, that another person cancel or amend an order concerning our shares or other financial instruments to which that information relates, or induces that person to make such a cancellation or amendment.

The Company is under an obligation to in principle make any inside information which directly concerns the Company public as soon as possible by means of a press release. However, the Company may, on its own responsibility, delay

disclosure of inside information if it can ensure the confidentiality of the information. Such delay is only permitted if (i) the immediate disclosure of the information is likely to prejudice the Company's legitimate interests and (ii) the delay of disclosure is not likely to mislead the public. When the Company delays the disclosure of inside information it may need to inform the Belgian Financial Services and Markets Authority thereof after the information is disclosed to the public and provide a written explanation of how the conditions for delay were met.

The Company is subject to Dutch law, Belgian law and MAR regarding the publication of inside information. Directors, other persons discharging managerial responsibilities and persons closely associated with them are covered by the MAR notification obligations. Directors and other persons discharging managerial responsibilities as well as persons closely associated with them, must notify the AFM of every transaction conducted on their own account relating to the shares or debt instruments of the Company, or to derivatives or other financial instruments linked to those shares or debt instruments. Non-compliance with these reporting obligations could lead to criminal penalties, administrative fines and cease-and-desist orders (and the publication thereof), imprisonment or other sanctions.

6.8.7 Transparency Directive

We are a European public company with limited liability (Societas Europaea or SE) incorporated and existing under the laws of the Netherlands. The Netherlands is our European Union home member state (lidstaat van herkomst) for the purposes of Directive 2004/109/EC of the European Parliament and of the Council of December 15, 2004 on the harmonization of transparency requirements in relation to information about issuers whose securities are admitted to trading on a regulated market and amending Directive 2001/34/EC and the rules and regulations promulgated pursuant thereto, as amended by various directives including 2013/50/EU, or the Transparency Directive, as a consequence of which we are subject to the DFSA in respect of certain ongoing transparency and disclosure obligations. In addition, as long as our shares are listed on Euronext Brussels and the ADSs on The Nasdaq Global Select Market, we are required to disclose any regulated information which has been disclosed pursuant to the DFSA as well in accordance with the Belgian Act of May 2, 2007, the Belgian Royal Decree of November 14, 2007 and Nasdaq listing rules. We must publish our annual accounts within four months after the end of each financial year and our half-yearly figures within two months after the end of the first six months of each financial year. Within five calendar days after adoption of our annual accounts, we must file our adopted annual accounts with the AFM. Pursuant to the DFSA, we will be required, among other things, to make public without delay any change in the rights attaching to our shares or any rights to subscribe our shares.

6.8.8 Dutch Financial Reporting Supervision Act

Pursuant to the Dutch Financial Reporting Supervision Act (Wet toezicht financiële verslaggeving), or the DFRSA, the AFM supervises the application of financial reporting standards by companies whose official seat is in the Netherlands and whose securities are listed on a regulated Dutch or foreign stock exchange. Pursuant to the DFRSA, the AFM has an independent right to (i) request an explanation from us regarding our application of the applicable financial reporting standards and (ii) recommend to us that we make available further explanations make these generally available and files these with the AFM. If we do not comply with such a request or recommendation, the AFM may request that the Enterprise Chamber orders us to (a) provide an explanation of the way we have applied the applicable financial reporting standards to our financial reports or (b) prepare our financial reports in accordance with the Enterprise Chamber's instructions.

6.8.9 Net Short Position

Pursuant to European Union regulation No 236/2012 and current ESMA guidance, each person holding a net short position attaining 0.1% of our issued share capital of must report it to the AFM. Each subsequent increase of this position by 0.1% will also have to be reported. Each net short position equal to 0.5% of our issued share capital and any subsequent increase of that position by 0.1% will be made public via the AFM short selling register. To calculate whether a natural person or legal person has a net short position, their short positions and long positions must be set off.

6.8.10 Substantial Holdings and Gross Short Position

Each person holding a substantial holding or gross short position in relation to our issued share capital or voting rights that reaches, exceeds or falls below one of the following thresholds: 3%, 5%, 10%, 15%, 20%, 25%, 30%, 40%, 50%, 60%, 75% and 95%, must immediately give written notice to the AFM.

If a person's substantial holding or gross short position reaches, exceeds or falls below one of the abovementioned thresholds as a result of a change in our issued share capital, such person is required to make a notification not later than on the fourth trading day after the AFM has published our notification in the public register of the AFM.

The AFM keeps a public register of the substantial holding and short selling notifications. Shareholders are advised to consult with their own legal advisors to determine whether any of the notification obligations apply to them.

7

General Information

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7 General Information

7.1 Persons Responsible for the Registration Document

argenx SE, with its statutory seat in Rotterdam and represented by its board of directors, is responsible for the preparation of this Registration Document and assumes responsibility for the information contained in this Registration Document.

7.2 Statement of the Entity Responsible for the Registration Document

argenx SE declares that to the best of its knowledge, the information contained in the Registration Document is in accordance with the facts and that the Registration Document makes no omission likely to affect its import.

Any information which has been sourced from third parties identified in this Registration Document as such, has been accurately reproduced and as far as we are aware and are able to ascertain from the information published by a third party, no facts have been omitted which would render the reproduced information inaccurate or misleading.

The information contained in this Registration Document is up to date as of the date hereof unless expressly stated otherwise. The publication and delivery of this Registration Document and any subsequent Securities Note and Summary at any time after the date hereof will not, under any circumstances, imply that there has been or will be no changes in our business or affairs or that the information contained herein is correct as of any time, subsequent to the date of this Registration Document.

The contents of this Registration Document should not be construed as providing legal, business, accounting or tax advice. Each prospective investor should consult its own legal, business, accounting and tax advisers prior to making a decision to invest in our shares.

7.3 Capitalized Terms

Unless otherwise stated, capitalized terms used in this Registration Document have the meaning set out in chapter 7 “Definitions and glossary” on page 240 and further.

7.4 Information Policy

7.4.1 Available Information

This Registration Document is available in English. The Registration Document is available, subject to certain conditions, on our website (www.argenx.com). The posting of the Registration Document on the internet does not constitute an offer to sell or a solicitation of an offer to buy any securities in our capital to or from any person. The electronic version of this Registration Document may not be copied, made available or printed for distribution. Except as set out in chapter 7 “Information Incorporated by Reference” on page 244, other information on our website (www.argenx.com) or any other website does not form part of or is in any way incorporated by reference into this Registration Document and has not been scrutinized or approved by the competent authority.

7.4.2 Further Information

During at least the twelve months following the date of this Registration Document, the following documents can be obtained free of charge, by electronic means, on our website (www.argenx.com):

- copies of our Articles of Association and Board By-laws; and
- our historical financial information, and the historical financial information for argenx and our subsidiary undertakings, for each of the three financial years preceding the date of this Registration Document.

As a listed company, we are required to also disclose inside information, information about the shareholder structure and certain other information to the public. In accordance with (i) article 17 of Regulation (EU) No 596/2014 of the European Parliament and of the Council of April 16, 2014 on market abuse (market abuse regulation) and repealing Directive 2003/6/EC of the European Parliament and of the Council and Commission Directives 2003/124/EC, 2003/125/EC and 2004/72/EC, and the rules and regulations promulgated pursuant thereto, or MAR, (ii) article 5:25m DFSA and (iii) Belgian Royal Decree of November 4, 2007 relating to the obligations of issuers of financial instruments admitted to trading on a Belgian regulated market (*Arrêté royal relatif aux obligations des émetteurs d’instruments financiers admis aux négociations sur un marché réglementé / Koninklijk besluit betreffende de verplichtingen van emittenten van financiële instrumenten die zijn toegelaten tot de verhandeling op een Belgische gereglementeerde markt*), such information and documentation will be made available through press releases made generally available in the Netherlands and Belgium as well as in the financial press in Belgium, our website, the communication channels of Euronext Brussels or a combination of these media.

As a result of the filing of a registration statement on Form F-1 with regard to ADSs representing the securities in our capital and the listing of the ADSs on the Nasdaq Global Select Market, we are subject to the informational requirements of the Exchange Act. Pursuant to the Exchange Act, we are required to file or furnish with the SEC, among other things, annual reports on Form 20-F and periodic reports on Form 6-K disclosing material information about us and other information that we are required to make public or distribute to shareholders in accordance with Dutch law and the rules of Euronext Brussels. Any such information that will be filed with the SEC, in addition to our information obligations under Dutch law, will be published on our website.

7.5 Information Sourced from Third Persons

To the extent we have used information sourced from third parties, this information has been accurately reproduced and as far as we are aware and are able to ascertain from information published by such parties, no facts have been omitted which would render the reproduced information inaccurate or misleading.

7.6 Notes on Presentation

In this Registration Document, references to we, us or our are to argenx SE together with its wholly owned subsidiary argenx BV and argenx IIP BV. All references to "USD", "dollars", "U.S. dollars", "$" and "cents" are to the lawful currency of the United States. All references to "euro", "Euro" "€" and "EUR" are to the currency introduced at the start of the third stage of the European economic and monetary union pursuant to the treaty establishing the European Community, as amended.

From January 2021 on, the Company will use the United States dollar as its functional currency.

7.6.1 Presentation of Financial Information

This Registration Document incorporates by reference our audited consolidated financial statements for the years ended December 31, 2020, 2019 and 2018 as contained within our annual reports for the years ended December 31, 2020, 2019 and 2018. Such financial information was prepared in accordance with International Financial Reporting Standards, as issued by the International Accounting Standards Board, and as adopted by the European Union, or IFRS. See chapter 7 "Information Incorporated by Reference" on page 244 for a comprehensive list of documents incorporated by reference in this Registration Document.

Unless otherwise specified, our financial information and analysis presented elsewhere in, or incorporated by reference into, this Registration Document is based on such consolidated financial statements. Unless otherwise specified, all our financial information included or incorporated by reference in this Registration Document has been stated in euros.

7.6.2 Rounding

Certain monetary amounts and other figures included in this Registration Document have been subject to rounding adjustments. Accordingly, any discrepancies in any tables between the totals and the sums of amounts listed are due to rounding.

7.6.3 Exchange Rate Information

Fluctuations in the exchange rate between the euro and the U.S. dollar will affect the U.S. dollar amounts received by owners of securities in our capital or ADSs on conversion of dividends, if any, paid in euro on the securities in our capital.

Before January 1, 2021, our functional currency was the euro, which is therefore the presentation currency throughout this Registration Document. As of January 1, 2021, the United States Dollar is our functional currency, meaning that the prices we charge and pay are primarily denominated in United States Dollar and reflected in our records as such.

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

	Year Ended December 31, 2016	Year Ended December 31, 2017	Year Ended December 31, 2018	Year Ended December 31, 2019	Year Ended December 31, 2020
High	1.1516	1.2041	1.2488	1.1524	1.2281
Low	1.0375	1.0416	1.1281	1.0905	1.0707
Rate at end of period	1.0552	1.2022	1.1456	1.1227	1.2271
Average rate per period	1.1072	1.1301	1.1817	1.1194	1.1474

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

	September, 2020	October, 2020	November, 2020	December, 2020	January, 2021	February, 2021
High	1.1987	1.1856	1.198	1.2281	1.2338	1.2225
Low	1.1634	1.1698	1.1652	1.1968	1.2064	1.1983
Rate at end of period	1.1708	1.1698	1.1980	1.2271	1.2136	1.2121

On March 16, 2021, the noon buying rate of the Federal Reserve Bank of New York for the euro was €1.00 = $1.1895.

7.7 Market and Industry Information

Market information (including market share, market position and industry data for our operating activities and those of our subsidiaries) or other statements presented in this Registration Document regarding our position relative to our competitors largely reflect the best estimates of our management. These estimates are based upon information obtained from customers, trade or business organizations and associations, other contacts within the industries in which we operate and, in some cases, upon published statistical data or information from independent third parties.

This Registration Document contains statistics, data and other information relating to markets, market sizes, market shares, market positions and other industry data pertaining to our business and markets.

Certain other statistical or market-related data has been estimated by management based on reliable third-party sources, where possible, including those referred to above or based on data generated in-house by us. Although management believes its estimates regarding markets, market sizes, market shares, market positions and other industry data to be reasonable, these estimates have not been verified by any independent sources (except where explicitly cited to such sources), and we cannot assure shareholders as to the accuracy of these estimates or that a third party using different

methods to assemble, analyze or compute market data would obtain the same results. Management's estimates are subject to risks and uncertainties and are subject to change based on various factors. We do not intend, and do not assume any obligation, to update the industry or market data set forth herein.

Industry publications or reports generally state that the information they contain has been obtained from sources believed to be reliable, but the accuracy and completeness of such information is not guaranteed. We have not independently verified and cannot give any assurance as to the accuracy of market data contained in this Registration Document that were extracted or derived from these industry publications or reports. Market data and statistics are inherently predictive and subject to uncertainty and not necessarily reflective of actual market conditions. Such statistics are based on market research, which itself is based on sampling and subjective judgments by both the researchers and the respondents, including judgments about what types of products and transactions should be included in the relevant market.

As a result, shareholders/investors should be aware that statistics, data, statements and other information relating to markets, market sizes, market shares, market positions and other industry data in this Registration Document and estimates and assumptions based on that information are necessarily subject to a high degree of uncertainty and risk due to the limitations described above and to a variety of other factors, including those described in chapter 1 "Risk Factors" on page 14 and further, and elsewhere in this Registration Document.

Independent Auditors

The audited consolidated financial statements as of and for the financial years ended December 31, 2020, 2019 and 2018 have been audited by our independent auditor, Deloitte, who rendered an unqualified audit report on these financial statements. The partner of Deloitte who signed the auditors' reports is a member of the Netherlands Institute of Chartered Accountants (*Koninklijke Nederlandse Beroepsorganisatie van Accountants*). The office of Deloitte is located at Wilhelminakade 1 3072AP Rotterdam, the Netherlands.

Statement Approval Competent Authority

This Registration Document has been approved by the AFM as competent authority under Regulation (EU) 2017/1129. The AFM only approves this Registration Document as meeting the standards of completeness, comprehensibility and consistency imposed by Regulation (EU) 2017/1129. Such approval should not be considered as an endorsement of the issuer that is the subject of this Registration Document.

This Registration Document may be used for the purposes of an offer to the public of securities or admission of securities to trading on a regulated market if completed by amendments, if applicable, and a securities note and summary approved in accordance with Regulation (EU) 2017/1129.

Caitlin

A determined nursing student deals with being diagnosed with MG as the COVID-19 pandemic swings into full force.

Caitlin was diagnosed with myasthenia gravis (MG) just as the United States was shutting down to curb the spread of the coronavirus. She had to manage her diagnosis while finishing nursing school and finding a job that would not put her at undue risk. Now a nurse in Virginia, Caitlin shares her learnings from her diagnosis journey and how she is taking life with MG day by day.

Patient Story

What happens when your whole life changes while the whole world is changing around you? In March 2020, Caitlin found out.

Caitlin was studying to be a nurse and living the life of so many early twenty-somethings finishing their college years.

On the last night of a spring break trip to Mexico with her girlfriends in early March, the group posed for a picture together. Despite having a good time, Caitlin struggled to smile. It felt forced and unnatural. Throughout dinner, her mind raced. She racked her brain for why she could be physically struggling to smile. The only diagnosis she could come up with was a mild stroke, but that didn't seem right.

On April 1, as if part of a not-funny April Fool's Day joke, Caitlin received her official diagnosis—she had myasthenia gravis. A neurologist who was also on the call said she needed to get to the hospital as a precaution.

Even as Caitlin starts to dream of the future again, she wants to stay in the present, taking each day as it comes.

"I think more in the short term now," she said. "I wake up each morning hoping for a good day."

When she is having a good day with MG, she takes advantage of it by staying active. On days when her myasthenia gravis symptoms are more pronounced, she rests and takes it easy. When she can't do something she wants to physically, she takes care of herself mentally. She has found that something as simple as enjoying the latest album by one of her favorite artists can help her on days when her MG is acting up.

When people hear Caitlin's story, they are often surprised at her temperament and that she doesn't seem angry or bitter.

Caitlin says this is an active choice. She says she chooses to put hope and inspiration into the world around her. She wants to give others the kind of encouragement and support that she received when she first posted about her myasthenia gravis diagnosis while sitting alone in a hospital room in the middle of a pandemic.

Definitions and Glossary

The following explanations are intended to assist the general reader to understand certain terms used in this Registration Document. The definitions set out below apply throughout this Registration Document, unless the context requires otherwise.

AbbVie	AbbVie S. Á. R. L.
ACA	the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010
ADCC	antibody dependent cell-mediated cytotoxicity
ADR	American Depositary Receipt
ADS	American Depositary Share
AFM	the Dutch Authority for the Financial Markets (Stichting Autoriteit Financiële Markten)
AIA	America Invents Act
AKS	the U.S. federal Anti-Kickback Statute
AML	acute myeloid leukemia
argenx	argenx SE
Articles of Association	our current articles of association
autoantibodies	self-directed antibodies
B-cell	B lymphocyte producing a specific antibody
BE	Belgium
Belgian BV	argenx BV
BioWa	BioWa, Inc
Bird Rock Bio	Bird Rock Bio, Inc.
BLA	Biologics License Application
Board By-Laws	the rules adopted by our board of directors that describe the procedure for holding meetings of the board of directors, for the decision-making by the board of directors and the board of directors' operating procedures
BPCIA	the U.S. Biologics Price Competition and Innovation Act
CBA	a collective bargaining agreement
cGMP	current good manufacturing practices
CH	Switzerland
CHMP	Committee for Medicinal Products for Human Use
Chugai	Chugai Pharmaceutical Co., Ltd.
CMOs	contract manufacturing organizations
CMS	Centers for Medicare & Medicaid
Code of Conduct	our Code of Business Conduct and Ethics
Company	argenx SE and its subsidiaries
CR	Complete remission
CRO	contract research organization
CTA	clinical trial authorization application
CTCL	cutaneous T-cell lymphoma
D	Germany
DCC	Dutch Civil Code
Deloitte	Deloitte Accountants B.V.
DFSA	Dutch Financial Supervision Act (Wet op het financieel toezicht)
DRC	Data Review Committee
DSMB	Data Safety Monitoring Board
Dutch Corporate Governance Code	the Dutch Corporate Governance Code dated December 8, 2016, which is in force as of the financial year starting on or after January 1, 2017
EEA	European Economic Area
EMA	European Medicines Authority
ENHANZE®	ENHANZE® Technology
Enterprise Chamber	the Dutch Enterprise Chamber of the Amsterdam Court of Appeal (Ondernemingskamer van het Gerechtshof te Amsterdam)
Euronext Brussels	the regulated market operated by Euronext Brussels SA/NV, a regulated market within the meaning of Directive 2014/65/EU of the European Parliament and of the Council of May 15 , 2014 on markets in financial instruments amending Council Directives 2004/39/EC, Directive 85/611/EEC, 93/6/EEC and Directive 2000/12/EC of the European Parliament and of the Council and repealing Council Directive 93/22/EEC (MiFID II)
Exchange Act	the U.S. Securities Exchange Act of 1934, as amended
F	France
FairJourney	FairJourney LDA
Fc	antibody region interacting with cell surface Fc receptors
FcRn	neonatal Fc receptor
FDA	U.S. Food and Drug Administration
FDCA	the U.S. Federal Food, Drug, and Cosmetic Act
GARP	glycoprotein A repetitions predominant
GCP	Good Clinical Practice
General Meeting	any general meeting of shareholders of argenx SE (i. e. any annual general meeting and any extraordinary general meeting)
GLP	Good Laboratory Practice
Group	argenx SE and each of its subsidiaries
GSK	GlaxoSmithKline plc
Hatch-Waxman Act	the U.S. Drug Price Competition and Patent Term Restoration Act of 1984
HGF	hepatocyte growth factor
HIPAA	the U.S. federal Health Insurance Portability and Accountability Act of 1996
HITECH	the Health Information Technology for Economic and Clinical Health Act of 2009
HTA	a health technology assessment
IFRS	International Financial Reporting Standards, as issued by the International Accounting Standards Board, and as adopted by the European Union
IgA	Immunoglobulin A
IgD	Immunoglobulin D
IgG	Immunoglobulin G
IgM	Immunoglobulin M
IIP	Immunology Innovation Program
IL-22	interleukin-22
IL-22R	interleukin-22 receptor
IMM	irreversible morbidity or mortality
IND	investigational new drug
IRB	institutional review board
ITP	immune thrombocytopenic purpura

IVIg	intravenous IgG
Janssen	Janssen Pharmaceuticals, Inc.
J-MAA	Japanese Market Authorization Application
JOBS Act	the U.S. Jumpstart Our Business Startups Act of 2012
LEO Pharma	LEO Pharma A/S
Lonza	Lonza Sales AG
MAA	a marketing authorization application
MAR	Regulation (EU) No 596/2014 of the European Parliament and of the Council of April 16, 2014 on market abuse (market abuse regulation) and repealing Directive 2003/6/EC of the European Parliament and of the Council and Commission Directives 2003/124/EC, 2003/125/EC and 2004/72/EC, and the rules and regulations promulgated pursuant thereto
MDS	myelodysplastic syndrome
Member State	a member state of the EEA
MET	mesenchymal-epithelial transition factor
MFN	Most Favored Nation
MG	myasthenia gravis
MHLW	Minister of Health, Labour and Welfare
Minister	Minister of Health, Labour and Welfare
MMN	multifocal motor neuropathy
Nasdaq	the Nasdaq Stock Market
NHI	National Health Insurance
NHSA	National Healthcare Security Administration
NK	natural killer
NRDL	National Reimbursable Drug List
OIG	the Office of Inspector General
OOPD	the U.S. Office of Orphan Products Development
Option Plan	the employee stock option plan as adopted by our board of directors on December 18, 2014, which was approved by the shareholders at the General Meeting on May 13, 2015 and lastly amended by the General Meeting on November 25, 2019
PCT	Patent Cooperation Treaty
Pharmaceutical and Medical Device Act	the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals and Medical Devices
PHSA	the U.S. Public Health Service Act
PIP	pediatric investigation plan
PMDA	Pharmaceuticals and Medical Devices Agency (Japan)
Prospectus Regulation	Regulation (Eu) 2017/1129 Of The European Parliament And Of The Council of 14 June 2017 on the prospectus to be published when securities are offered to the pub-lic or admitted to trading on a regulated market, and repealing Directive 2003/71/EC
PRV	Priority Review Voucher
RDL	Reimburse Drug List
Registration Document	this universal registration document
REMS	risk evaluation and mitigation strategy
Roche	F. Hoffman-La Roche AG
RSUs	Restricted stock units
SE regulation	European Council Regulation (EC) No 2157/2001 of October 8, 2001 on the Statute for a European company (*Societas Europaea or SE*)
SEC	the U. S Securities and Exchange Commission
Section 404	Section 404 of the Sarbanes-Oxley Act of 2002

Securities	Shares or American Depositary Receipts to Shares in the share capital of argenx SE
Securities Act	the U.S. Securities Act of 1933, as amended
Shire	Shire AG (now known as Shire International GmbH)
Shire	Shire AG (now known as Shire International GmbH)
Sopartec	Sopartec S.A.
SRD II	Directive 2017/828 of the European Parliament and of the Council of May 17, as regards the encouragement of long-term shareholder engagement
Staten	Staten Biotechnology B.V.
Takeover Law	the Belgian law dated April 1, 2007 on public takeover bids
Takeover Royal Decree	the Belgian Royal Decree of April 27, 2007 on public takeover bids
T-cell	T lymphocyte protecting the body from infection
TCL	T-cell lymphoma
TGF-β	transforming growth factor beta
Transparency Directive	Directive 2004/109/EC of the European Parliament and of the Council of December 15, 2004 on the harmonization of transparency requirements in relation to information about issuers whose securities are admitted to trading on a regulated market and amending Directive 2001/34/EC and the rules and regulations promulgated pursuant thereto, as amended by various directives including 2013/50/EU
Tregs	T-cell population modulating the immune system
U.S.	the United States of America
UCL	Université Catholique de Louvain
UK	the United Kingdom
UoT	the University of Texas
USPTO	the United States Patent and Trademark Office
V-regions	antibody variable regions
we, us or our	argenx SE together with its wholly owned subsidiaries argenx IIP BV, argenx BV, argenx US Inc, argenx Japan K.K. and argenx Switzerland SA, and, as applicable, its former wholly owned subsidiaries
Zai Lab	Zai Lab Limited

Information Incorporated by Reference

Our consolidated financial statements as of and for the financial years ended December 31, 2020, 2019 and 2018 (including the independent auditor's reports thereupon) have been incorporated by reference in this Registration Document. We have incorporated certain documents into this Registration Document by reference. The parts of the documents incorporated herein by reference to which no specific reference has been made are either not relevant for investors or are covered elsewhere in this Registration Document.

The following table contains a cross-reference list to the relevant pages of our consolidated financial statements for the financial year ended December 31, 2020, which are incorporated by reference in this Registration Document:

Consolidated statement of financial position:	p. 251
Consolidated statement of profit and loss and other comprehensive income:	p. 253
Consolidated statement of cash flows:	p. 254
Consolidated statement of changes in equity:	p. 255
Notes to the consolidated financial statements for the year 2020:	p. 256

The following table contains a cross-reference list to the relevant pages of the financial statements of argenx SE for the financial year ended December 31, 2020, which are incorporated by reference in this Registration Document:

Company balance sheet on December 31, 2020:	p. 302
Company profit and loss account for the year ended December 31, 2020:	p. 303
Notes to the financial statements:	p. 304
Independent auditor's report on the financial statements:	p. 309

The following table contains a cross-reference list to the relevant pages of our annual report 2019 on which can be found our consolidated financial statements for the financial year ended December 31, 2019, which are incorporated by reference in this Registration Document:

Consolidated statement of financial position:	p. 251
Consolidated statement of profit and loss and other comprehensive income:	p. 253
Consolidated statement of cash flows:	p. 254
Consolidated statement of changes in equity:	p. 255
Notes to the consolidated financial statements for the year 2019:	p. 256

The following table contains a cross-reference list to the relevant pages of our annual report 2018 on which can be found our consolidated financial statements for the financial year ended December 31, 2018, which are incorporated by reference in this Registration Document:

Consolidated statement of financial position:	p. 251
Consolidated statement of profit and loss and other comprehensive income:	p. 253
Consolidated statement of cash flows:	p. 254
Consolidated statement of changes in equity:	p. 255
Notes to the consolidated financial statements for the year 2018:	p. 256

The full text of the Articles of Association and an unofficial English translation thereof are incorporated by reference in this Registration Document. Any information not listed in the tables above but included in the document incorporated by reference is given for information purpose only.

The documents incorporated by reference are available on our website (www.argenx.com), at the following locations:

Annual report 2018	https://www.argenx.com/sites/default/files/media-documents/argenx-annual-report-2018-final.pdf
Annual report 2019	https://www.argenx.com/sites/default/files/media-documents/argenx_Annual_Report_2019.pdf
Annual report 2020	https://www.argenx.com/sites/default/files/media-documents/argenx-annual-report-2020-final.pdf
Articles of association	https://www.argenx.com/sites/default/files/media-documents/argenx_SE_Articles_of_Association_Consolidated_Version-NL.pdf (NL) https://www.argenx.com/sites/default/files/media-documents/argenx_SE_Articles_of_Association_Consolidated_Translation-ENG.pdf (ENG)

Cross Reference Table for Annual Reporting Requirements

The following list of cross references identifies where each item required for us to disclose in our yearly financial report can be found in this Registration Document, as required by article 19 sub 2 of the Prospectus Regulation.

SOURCE OF REQUIREMENT	Topic		Location
Article 2:391 DCC, RJ 400, RJ 405	Report on the company's activities	2 3	To our Shareholders Business
	Corporate structure	5	General Description of the Company and its Share Capital
	Board of directors report	6	Corporate Governance
	Primary risks and uncertainties	1	Risk Factors
	Risk appetite & control	6.5	Risk Appetite & Control
	Analysis of financial condition and results	4	Management's Discussion and Analysis of Financial Condition and Results of Operations
	Information on research and developmentactivities	3.2 3.6 3.7	Our Product Candidates Collaboration Agreements License Agreements – General
	Forward looking paragraph	2.3	Outlook 2021
	Corporate governance code comply-or-explain	6.4	Dutch Corporate Governance Code, "Comply or Explain"
	Compensation statements and remuneration report	6.6	Compensation Statement and Remuneration Report
	Supervisory board report	6.1 6.2	Our Board of Directors Our Non-Executive Directors
RJ 430	Key figures, ratios etc.	4	Management's Discussion and Analysis of Financial Condition and Results of Operations
Article 2:392 DCC/RJ 410	Auditors opinion		Attached to the 2020 Financial Report included herein
	Articles of association on the distribution of profits	5.4.2	Articles of Association on Profits, distributions and losses
	List of subsidiaries	5.1.2	Group Structure
Article 10 Decree Takeover Directive (*besluit overnamerichtlijn*), Article 2:391 sub 5 DCC	Capital structure	5.2	General Description of the Share Capital
	Principal shareholders	5.3.1	Principal Shareholders
	Particular shareholder rights	5.3	Shareholdings and Voting Rights
	Procedure for appointment of board members	6.1.6	Composition, Appointment and Dismissal
	Procedure for amending the articles of association	6.8.3	Amendment of Articles of Association
	Authority of the board of irectors to issue shares	6.8.1	Issue of Shares

RJ = Guidelines on Annual Reporting (*Richtlijnen voor de Jaarverslaggeving*)

Management Confirmations

With due regard to best practice principle 1.4.3 of the Dutch Corporate Governance Code, we confirm that:

(i) This Registration Document provides sufficient insights into any failings in the effectiveness of the internal risk management and control systems, as is further substantiated in chapter 1 "Risk Factors" on page 14 and further, and section 6.5 "Risk appetite and control" on page 195 and further;

(ii) The risk- and control systems described herein, particularly in paragraph 6.5.5 "Financial risks and controls" on page 198 and further provide reasonable assurance that the financial reporting does not contain any material inaccuracies;

(iii) We confirm that 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. On the basis of the current state of affairs, it is justified that the financial reporting is prepared on a going concern basis; and

(iv) This report, particularly chapter 1 "Risk Factors" on page 14 and further states those material risks and uncertainties that are relevant to the expectation of our continuity for the period of twelve months after the preparation of this Registration Document. The aforementioned statement does not in any way limit the relevance or applicability of the Risk Factors set out in this Registration Document to the aforementioned period of 12 months.

/Signed on behalf of argenx SE/

Consolidated Financial Statements

AUDITED CONSOLIDATED FINANCIAL STATEMENTS AS OF AND FOR THE YEARS ENDED DECEMBER 31, 2020, 2019 AND 2018

Contents

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Responsibility Statement

We hereby certify that, to the best of our knowledge, the consolidated financial statements of argenx SE as of December 31, 2020, prepared in accordance with International Financial Reporting Standards (IFRS) as adopted by the European Union, and with the legal requirements applicable in The Netherlands, give a true and fair view of the assets, liabilities, financial position and profit or loss of the Company and the undertakings included in the consolidation taken as a whole, and that the management report includes a fair review of the development and performance of the business and the position of the Company and the undertakings included in the consolidation taken as a whole, together with a description of the principal risks and uncertainties that they face.

On behalf of the Board of Director
Tim Van Hauwermeiren
March 30, 2021

Consolidated Statements of Financial Position

Assets (IN THOUSANDS OF €)	NOTE	As of December 31, 2020	As of December 31, 2019	As of December 31, 2018
Current assets				
Cash and cash equivalents	12	991,609	331,282	281,040
Restricted cash — current		—	—	1,692
Research and development incentive receivables — current		377	261	301
Financial assets — current	11	635,359	1,004,539	283,529
Prepaid expenses		22,747	9,022	2,995
Inventories	9	20,532	—	—
Trade and other receivables	10	5,687	28,115	2,886
Total current assets		**1,676,311**	**1,373,219**	**572,443**
Non-current assets				
Other non-current assets	7	6,383	3,226	252
Research and development incentive receivables — non-current		16,840	8,566	4,883
Deferred tax asset	8	12,255	—	—
Property, plant and equipment	6	9,494	8,167	824
Intangible assets	5	136,410	40,161	56
Total non-current assets		**181,382**	**60,120**	**6,015**
Total assets		**1,857,693**	**1,433,339**	**578,458**

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

Consolidated Statements of Financial Position

Equity and Liabilities (IN THOUSANDS OF €)	NOTE	As of December 31, 2020	As of December 31, 2019	As of December 31, 2018
Equity	13			
Equity attributable to owners of the parent				
Share capital		4,757	4,276	3,597
Share premium		2,058,123	1,308,539	673,454
Accumulated losses		(861,491)	(332,568)	(169,603)
Other reserves		162,984	70,499	30,947
Total equity		**1,364,373**	**1,050,746**	**538,395**
Deferred tax liabilities		**1,212**	—	—
Non-current liabilities				
Provisions for employee benefits		128	64	7
Lease liabilities — non-current		5,035	4,540	—
Deferred revenue — non-current	16	219,248	218,032	—
Total non-current liabilities		224,411	222,636	7
Current liabilities				
Lease liabilities — current		2,833	1,974	—
Trade and other payables	15	224,262	85,301	37,072
Tax liabilities		2,850	344	823
Deferred revenue — current	16	37,754	72,338	2,161
Total current liabilities		**267,699**	**159,957**	**40,056**
Total liabilities		**492,110**	**382,593**	**40,063**
Total Equity and Liabilities		**1,857,695**	**1,433,339**	**578,458**

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

Consolidated Statements of Profit and Loss and Other Comprehensive Income

(IN THOUSANDS OF € EXCEPT FOR SHARES AND EPS)	NOTE	Year Ended December 31, 2020	Year Ended December 31, 2019	Year Ended December 31, 2018
Revenue	16	36,425	69,783	21,482
Other operating income	17	18,109	12,801	7,749
Total operating income		**54,534**	**82,584**	**29,231**
Research and development expenses	19	(325,479)	(197,665)	(83,609)
Selling, general and administrative expenses	20	(149,367)	(64,569)	(27,471)
Total operating expenses		**(474,846)**	**(262,234)**	**(111,080)**
Change in fair value on non-current financial assets	7	2,544	1,096	—
Operating loss		**(417,769)**	**(178,554)**	**(81,849)**
Financial income/(expense)	23	(1,414)	14,275	3,694
Exchange gains/(losses)	23	(106,956)	6,066	12,308
Loss before taxes		**(526,139)**	**(158,213)**	**(65,847)**
Income tax expense	24	(2,784)	(4,752)	(794)
Loss for the year and total comprehensive loss		**(528,923)**	**(162,965)**	**(66,641)**
Loss for the year and total comprehensive loss attributable to:				
Owners of the parent		(528,923)	(162,965)	(66,641)
Weighted average number of shares outstanding		45,410,442	38,619,121	33,419,356
Basic and diluted loss per share	25	(11.65)	(4.22)	(1.99)

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

Consolidated Statements of Cash Flows

(IN THOUSANDS OF €)	NOTE	Year Ended December 31, 2020	Year Ended December 31, 2019	Year Ended December 31, 2018
Cash flow (used in) / from operating activities				
Operating result		**(417,769)**	**(178,554)**	**(81,849)**
Adjustments for non-cash items				
Amortization of intangible assets		215	38	19
Depreciation of property, plant and equipment		3,214	2,128	474
Provisions for employee benefits		65	57	(18)
Expense recognized in respect of share-based payments		84,479	39,552	19,183
Fair value gains on non-current financial assets at fair value through profit or loss		(2,544)	(1,096)	—
		(332,340)	**(137,875)**	**(62,191)**
Movements in current assets/liabilities				
(Increase)/decrease in trade and other receivables		19,767	(22,965)	(44)
(Increase)/decrease in inventories		(20,532)	—	—
(Increase)/decrease in other current assets		(13,840)	(5,170)	(800)
Increase/(decrease) in trade and other payables		45,652	47,995	21,784
Increase/(decrease) in deferred revenue – current		(34,585)	62,106	(8,868)
Movements in non-current assets/liabilities				
(Increase)/decrease in other non-current assets		(8,888)	(5,560)	(1,720)
(Increase)/decrease in deferred revenue – non-current		1,216	200,533	(1,435)
Cash flows (used in)/from operating activities		**(343,550)**	**139,064**	**(53,274)**
Interest paid		(349)	(124)	—
Income taxes paid		(2,450)	(4,356)	(565)
Net cash flow (used in) / from operating activities		**(346,349)**	**134,584**	**(53,839)**
Purchase of intangible assets		(3,503)	(40,143)	(62)
Purchase of property, plant and equipment		(949)	(1,604)	(622)
(Increase)/decrease in financial assets – current		307,641	(708,060)	(108,229)
Interest received		7,061	5,469	1,371
Net cash flow (used in) / from investing activities		**310,250**	**(744,338)**	**(107,542)**
Principal elements of lease payments		(2,230)	(1,353)	—
Proceeds from issue of new shares, gross amount		731,546	678,936	255,721
Issue costs paid		(551)	(22,999)	(14,655)
Exchange gain from currency conversion on proceeds from issue of new shares		62	—	1,354
Proceeds from exercise of stock options		19,070	4,775	2,251
Net cash flow (used in) / from financing activities		**747,897**	**659,359**	**244,671**
Net increase (decrease) in cash & cash equivalents		**711,798**	**49,605**	**83,290**
Cash and cash equivalents at the beginning of the period		**331,282**	**281,040**	**190,867**
Exchange gains/(losses) on cash & cash equivalents		(51,471)	637	6,883
Cash and cash equivalents at the end of the period		**991,609**	**331,282**	**281,040**

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

Consolidated Statements of Changes in Equity

Attributable to owners of the parent (IN THOUSANDS OF €)	Share capital	Share premium	Accumulated losses	Other reserves	Total equity attributable to owners of the parent	**Total equity**
Balance at January 1, 2018	**3,216**	**430,518**	**(102,962)**	**11,764**	**342,536**	**342,536**
Total comprehensive loss of the period			(66,641)		(66,641)	(66,641)
Share-based payment				19,183	19,183	19,183
Issue of share capital	347	255,374			255,721	255,721
Transaction costs for equity issue		(14,655)			(14,655)	(14,655)
Exercise of stock options	34	2,217			2,251	2,251
Balance year ended December 31, 2018	**3,597**	**673,454**	**(169,603)**	**30,947**	**538,395**	**538,395**
Total comprehensive loss of the period			(162,965)		(162,965)	(162,965)
Share-based payment				39,552	39,552	39,552
Issue of share capital	637	678,299			678,936	678,936
Transaction costs for equity issue		(22,999)			(22,999)	(22,999)
Accounting treatment of the share subscription agreement		(24,948)			(24,948)	(24,948)
Exercise of stock options	42	4,733			4,775	4,775
Balance year ended December 31, 2019	**4,276**	**1,308,539**	**(332,568)**	**70,499**	**1,050,746**	**1,050,746**
Total comprehensive loss of the period			(528,923)		(528,923)	(528,923)
Income tax benefit from excess tax deductions related to share-based payments				8,006	8,006	8,006
Share-based payment				84,479	84,479	84,479
Issue of new shares	421	731,125			731,546	731,546
Transaction costs for equity issue		(551)			(551)	(551)
Exercise of stock options	60	19,010			19,070	19,070
Balance year ended December 31, 2020	**4,757**	**2,058,123**	**(861,491)**	**162,984**	**1,364,373**	**1,364,373**

Please refer to note 13 for more information on the share capital and movement in number of shares.
See also note 14 for more information on the share-based payments.

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

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 challenged 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), as adopted by the EU. The consolidated financial statements provide a general overview of the Company's activities and the results achieved. They present fairly the entity's financial position, its financial performance and cash flows, on a going concern basis.

The significant accounting policies applied in the preparation of the above consolidated financial statements are set out below. All amounts are presented in thousands of euro, unless otherwise indicated, rounded to the nearest € '000.

The consolidated financial statements have been approved for issue by the Company's Board of Directors (the Board) on March 30, 2021.

3.2 Adoption of New and Revised Standards

New standards and interpretations applicable for the annual period beginning on January 1, 2020
New standards and interpretations for the annual period beginning on January 1, 2020 did not have any material impact on our consolidated financial statements.

New standards and interpretations issued, but not yet applicable for the annual period beginning on January 1, 2020
We have not early adopted any other standard, interpretation, or amendment that has been issued but is not yet effective.

The following new standards and amendments to standards have been issued, but are not mandatory for the first time for the financial year beginning January 1, 2020 and have been endorsed by the European Union.

Amendments to IFRS 10 and IAS 28 – Sale or Contribution of Assets between an Investor and its Associate or Joint Venture
The amendments to IFRS 10 and IAS 28 deal with situations where there is a sale or contribution of assets between an investor and its associate or joint venture. Specifically, the amendments state that gains or losses resulting from the loss of control of a subsidiary that does not contain a business in a transaction with an associate or a joint venture that is accounted for using the equity method, are recognised in the parent's profit or loss only to the extent of the unrelated investors' interests in that associate or joint venture. Similarly, gains and losses resulting from the remeasurement of investments retained in any former subsidiary (that has become an associate or a joint venture that is accounted for using the equity method) to fair value are recognised in the former parent's profit or loss only to the extent of the unrelated investors' interests in the new associate or joint venture.

These amendments are not expected to have any material impact on our consolidated financial statements.

Amendments to IFRS 3 – Reference to the Conceptual Framework
The amendments update IFRS 3 so that it refers to the 2018 Conceptual Framework instead of the 1989 Framework. They also add to IFRS 3 a requirement that, for obligations within the scope of IAS 37, an acquirer applies IAS 37 to determine whether at the acquisition date a present obligation exists as a result of past events. For a levy that would be within the scope of IFRIC 21 Levies, the acquirer applies IFRIC 21 to determine whether the obligating event that gives rise to a liability to pay the levy has occurred by the acquisition date. Finally, the amendments add an explicit statement that an acquirer does not recognise contingent assets acquired in a business combination.

These amendments are not expected to have any material impact on our consolidated financial statements.

Amendments to IAS 16 – Property, Plant and Equipment—Proceeds before Intended Use
The amendments prohibit deducting from the cost of an item of property, plant and equipment any proceeds from selling items produced before that asset is available for use, i.e. proceeds while bringing the asset to the location and condition necessary for it to be capable of operating in the manner intended by management. Consequently, an entity recognises such sales proceeds and related costs in profit or loss. The entity measures the cost of those items in accordance with IAS 2 Inventories. The amendments also clarify the meaning of 'testing whether an asset is functioning properly'. IAS 16 now specifies this as assessing whether the technical and physical performance of the asset is such that it is capable of being used in the production or supply of goods or services, for rental to others, or for administrative purposes. If not presented separately in the statement of comprehensive income, the financial statements shall disclose the amounts of proceeds and cost included in profit or loss that relate to items produced that are not an output of the entity's ordinary activities, and which line item(s) in the statement of comprehensive income include(s) such proceeds and cost. The amendments are applied retrospectively, but only to items of property, plant and equipment that are brought to the location and condition necessary for them to be capable of operating in the manner intended by management on or after the beginning of the earliest period presented in the financial statements in which the entity first applies the amendments. The entity shall recognise the cumulative effect of initially applying the amendments as an adjustment to the opening balance of retained earnings (or other component of equity, as appropriate) at the beginning of that earliest period presented.

These amendments are not expected to have any material impact on our consolidated financial statements.

Amendments to IAS 37 – Onerous Contracts—Cost of Fulfilling a Contract
The amendments specify that the 'cost of fulfilling' a contract comprises the 'costs that relate directly to the contract'. Costs that relate directly to a contract consist of both the incremental costs of fulfilling that contract (examples would be direct labour or materials) and an allocation of other costs that relate directly to fulfilling contracts (an example would be the allocation of the depreciation charge for an item of property, plant and equipment used in fulfilling the contract). The amendments apply to contracts for which the entity has not yet fulfilled all its obligations at the beginning of the annual reporting period in which the entity first applies the amendments. Comparatives are not restated. Instead, the entity shall recognise the cumulative effect of initially applying the amendments as an adjustment to the opening balance of retained earnings or other component of equity, as appropriate, at the date of initial application.

These amendments are not expected to have any material impact on our consolidated financial statements.

3.3 Basis of Consolidation

The consolidated financial statements include the financial statements of the Company and entities controlled by the Company (its subsidiaries). Control is achieved when the Company;

- has power over the investee;
- is exposed, or has rights, to variable returns from its involvement with the investee; and
- has the ability to use its power to affect its returns.

The Company reassesses whether or not it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control listed above.

The results of the subsidiaries are included in the consolidated statement of profit and loss and other comprehensive income from the effective date of acquisition up to the date when control ceases to exist. When necessary, adjustments are made to the financial statements of subsidiaries to bring their accounting policies into line with those used by other members of the Group.

All inter-company transactions and unrealized gains on transactions between group companies are eliminated. Unrealised losses are also eliminated unless the transaction provides evidence of an impairment of the transferred asset.

3.4 Foreign Currency Transactions

3.4.1 Functional and Presentation Currency
Items included in the consolidated financial statements of each of our entities are valued using the currency of their economic environment in which the entity operates. The consolidated financial statements are presented in euro (€), which 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 statement of profit and loss and other comprehensive income. Non-monetary assets and liabilities denominated in foreign currencies are translated at the foreign exchange rate ruling at the date of the transaction.

3.4.3 Financial Statements of Foreign Entities
For foreign entities using a different functional currency than euro:

- assets and liabilities for each consolidated statements of financial position presented are translated at the closing rate at the date of that statement of financial position.
- income and expenses for each statement presenting profit or loss and other comprehensive income are translated at average exchange rates (unless this average is not a reasonable approximation of the cumulative effect of the rates prevailing on the transaction dates, in which case income and expenses are translated at the rate on the dates of the transactions).
- all resulting exchange differences are recognised in other comprehensive income.

3.5 Intangible Assets

3.5.1 Internally Generated Intangible Assets
Expenditure on research activities is recognized as an expense in the period in which it is incurred.

An internally-generated intangible asset arising from development (or from the development phase of an internal project) is recognized if, and only if, all of the following have been demonstrated:

- the technical feasibility of completing the intangible asset so that it will be available for use or sale;
- the intention to complete the intangible asset and use or sell it;
- the ability to use or sell the intangible asset;
- how the intangible asset will generate probable future economic benefits;
- the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and
- the ability to measure reliably the expenditure attributable to the intangible asset during its development.

The amount initially recognized for internally-generated intangible assets is the sum of the expenditure incurred from the date when the intangible asset first meets the recognition criteria listed above. Where no internally-generated intangible asset can be recognized, development expenditures are recognized in the consolidated statements of profit and loss and other comprehensive income in the period in which they are incurred.

Due to uncertainties inherent to the development and registration with the relevant healthcare authorities of its products, the Company estimates that the conditions for capitalization are not met until the regulatory procedures required by such healthcare authorities have been finalized. The Company currently does not own products that have been approved by the relevant healthcare authorities and this has resulted in all development costs being recognized as an expense in the period in which they are incurred.

3.5.2 Acquired In-Process R&D, Software and Databases and Other intangible assets
Intangible assets with finite useful lives that are acquired separately related to in-process research and development projects, software and databases and other intangible assets are carried at cost less accumulated amortization and accumulated impairment losses. Intangible assets with indefinite useful lives are carried at cost less accumulated impairment losses.

Payments for acquired in-process research and development projects obtained through in-licensing arrangements are capitalized as intangible assets provided that they are separately identifiable, controlled by the Company and expected to provide future economic benefits. As the probability criterion in IAS 38 is always considered to be satisfied for separately acquired research and development assets and the amount of the payments is determinable, upfront and mile-

stone payments to third parties for pharmaceutical products or compounds for which regulatory marketing approval has not yet been obtained are recognized as intangible assets.

Other intangible assets includes the Priority Review Voucher ("PRV") acquired in 2020 which the Company can use to obtain the priority review by the FDA for one of its future regulatory submissions or may sell or transfer to a third party. The PRV is measured at cost and reviewed for impairment when events or circumstances indicate that the carrying value may not be recoverable. At the time the Company commits using the PRV to accelerate the review of a drug application, the intangible asset will be amortized and derecognized upon filing of the related Biologic License Application.

3.5.3. Amortization of Intangible Assets

Intangible assets, which comprises of acquired in-process research and development, software and databases and other intangible assets, are amortized on a straight-line basis over the estimated useful life as from the time they are available for use, or when the underlying drug candidate is approved, generally on the following basis:

- Acquired In-Process R&D – the longer of the patent protection life and the useful life of the combined product
- Software and Databases – 3 – 5 years

The estimated useful life and amortization method are reviewed at the end of each reporting period, with the effect of any changes in estimate being accounted for on a prospective basis.

3.5.4 Derecognition of Intangible Assets

An intangible asset is derecognized either on disposal or when no future economic benefits are expected from its use. Gains or losses arising from derecognition of an intangible asset, measured as the difference between the net disposal proceeds, if any, and the carrying amount of the asset, are recognized in the consolidated statements of profit and loss and other comprehensive income when the asset is derecognized.

3.6 Property, plant and equipment

Items of property, plant and equipment held for use in the production or supply of goods or services, or for administrative purposes, are stated in the statement of financial position at their cost, less accumulated depreciation and impairment losses.

Depreciation is recognized as from acquisition date onwards (unless asset is not ready for use) so as to write off the cost or valuation of assets (other than freehold land and properties under construction) less their residual values over their useful lives, using the straight-line method. The estimated useful lives, residual values and depreciation method are reviewed at the end of each reporting period, with the effect of any changes in estimate accounted for on a prospective basis.

Unless revised due to specific changes in the estimated useful life, annual depreciation rates are as follows:

- Office and lab equipment: 3–5 years
- IT equipment: 3 years

An item of property, plant and equipment is derecognized upon disposal or when no future economic benefits are expected to arise from the continued use of the asset. Any gain or loss arising on the disposal or retirement of an item of property, plant and equipment is determined as the difference between the sales proceeds, if any, and the carrying amount of the asset and is recognized in the consolidated statement of profit or loss and other comprehensive income.

3.7 Inventories

Inventories are carried at cost or net realisable value, whichever is lowest. Cost is determined using the first-in, first-out method. Cost comprises of costs of purchase, costs of conversion and other costs incurred in bringing the inventories to their present location and condition.

If the expected sales price less completion costs to execute sales (net realizable value) is lower than the carrying amount, a write-down is recognised for the amount by which the carrying amount exceeds its net realisable value.

Included in inventory are products which could, besides commercial activities, be used in preclinical and clinical programs as well as in non-reimbursed Early Access Programs. These products are charged to research & development expenses or selling, general and administrative expenses, respectively, when dedicated to this channel.

We capitalize inventory costs associated with products prior to the regulatory approval of these products, or for inventory produced in new production facilities, when it is highly probable that the pre-approval inventories will be saleable. The determination to capitalize is based on the particular facts and circumstances relating to the expected regulatory approval of the product or production facility being considered. The assessment of whether or not the product is considered highly probable to be saleable is made on a quarterly basis and includes, but is not limited to, how far a particular product or facility has progressed along the approval process, any known safety or efficacy concern, potential labelling restrictions and other impediments.

Previously capitalized costs related to pre-launch inventories could be required to be written down upon a change in such judgement or due to a denial or delay of approval by regulatory bodies, a delay in commercialization or other potential factors, which will be recorded to research and development expenses.

3.8 Leases

As of January 1, 2019, the Company has changed its accounting policy for leases where the Company is the lessee.

3.8.1 Accounting Policy until December 31, 2018

Leases of property, plant and equipment where the Company, as lessee, had substantially all the risks and rewards of ownership were classified as finance leases. Finance leases were capitalised at the lease's inception at the fair value of the leased property or, if lower, the present value of the minimum lease payments. The corresponding rental obligations, net of finance charges, were included in other short-term and long-term payables. Each lease payment was allocated between the liability and finance cost. The finance cost was charged to the profit or loss over the lease period so as to produce a constant periodic rate of interest on the remaining balance of the liability for each period. The property, plant and equipment acquired under finance leases was depreciated over the asset's useful life or over the shorter of the asset's useful life and the lease term if there is no reasonable certainty that the Company will obtain ownership at the end of the lease term.

Leases in which a significant portion of the risks and rewards of ownership were not transferred to the Company as lessee were classified as operating leases. Operating lease payments were recognized as an expense on a straight-line basis over the lease term, except where another systematic basis was more representative of the time pattern in which economic benefits from the leased asset are consumed.

The Company has adopated IFRS 16 on January 1, 2019. The Company elected to apply the modified retrospective approach for the transition, which foresees that prior period figures remain as reported under the previous standard IAS 17, and the cumulative effect of applying IFRS 16 is recognized as an adjustment to the opening balance of equity as of the date of initial application (i.e., the beginning of the year 2019). On adoption of IFRS 16, the Company recognized lease liabilities in relation to leases which had previously been classified as 'operating leases' under IAS 17. These liabilities were measured at the present value of the remaining lease payments and discounted using the Company's incremental

borrowing rate as of January 1, 2019. The Company's weighted average incremental borrowing rate applied to these lease liabilities on January 1, 2019 was 1.32%.

The differences between our total operating lease commitments as reported in note 5.7 of our consolidated financial statements of December 31, 2018 and the total lease liabilities recognized in our statement of financial position as at January 1, 2019 are summarized below:

(IN THOUSANDS OF €)	
Operating lease commitments disclosed as at December 31, 2018	**3,004**
Less: discounting effect using the lessee's incremental borrowing rate of the date of initial application	(126)
Less: short-term leases recognized on a straight-line basis as expense	(88)
Lease liability recognized as at January 1, 2019	**2,790**
of which are:	
Current lease liabilities	1,078
Non-current lease liabilities	1,712

The cumulative effect of adopting IFRS 16 to the consolidated statements of financial position as of January 1, 2019 is as follows:

(IN THOUSANDS OF €)	
Property, plant and equipment (right-of-use assets)	2,790
Effect on total assets	**2,790**
Lease liabilities (current and non-current)	2,790
Effect on total equity and liabilities	**2,790**

The Company has elected not to reassess whether a contract is, or contains, a lease at the date of initial application. Instead, for contracts entered into before the transition date, the Company relied on its assessment made applying IAS 17 and IFRIC 4 Determining whether an Arrangement contains a Lease.

3.8.2 Accounting Policy as from January 1, 2019

As from January 1, 2019, the Company assesses whether a contract is or contains a lease, at inception of the contract. The Company recognises a right-of-use asset and a corresponding lease liability with respect to all lease arrangements in which it is the lessee, except for short-term leases (defined as leases with a lease term of 12 months or less) and leases of low value assets. For these leases, the Company recognises the lease payments as an operating expense on a straight-line basis over the term of the lease unless another systematic basis is more representative of the time pattern in which economic benefits from the leased assets are consumed.

The lease liability is initially measured at the present value of the lease payments that are not paid at the commencement date, discounted by using the rate implicit in the lease. If this rate cannot be readily determined, the lessee uses its incremental borrowing rate. The lease liability is subsequently measured by increasing the carrying amount to reflect interest on the lease liability (using the effective interest method) and by reducing the carrying amount to reflect the lease payments made. The lease liability is presented as a separate line in the consolidated statements of financial position.

The right-of-use assets comprise the initial measurement of the corresponding lease liability, lease payments made at or before the commencement day, less any lease incentives received and any initial direct costs. They are subsequently measured at cost less accumulated depreciation and impairment losses. Right-of-use assets are depreciated over the shorter period of lease term and useful life of the underlying asset. If a lease transfers ownership of the underlying asset or the cost of the right-of-use asset reflects that the Company expects to exercise a purchase option, the related right-of-use asset is depreciated over the useful life of the underlying asset. The right-of-use assets are presented in the consolidated statements of financial position under the caption "Property, plant and equipment".

3.9 Impairment of Assets

3.9.1 Financial Assets

The impairment loss of a financial asset measured at amortised cost is calculated based on the expected loss model.

For trade receivables, in the absence of a significant financing component, the allowance is measured at an amount equal to lifetime expected credit losses. Those are the expected credit losses that result from possible default events over the expected life of those trade receivables.

3.9.2 Property, Plant and Equipment and Intangible Assets

At the end of each reporting period, the Company reviews the carrying amounts of its tangible and intangible assets to determine whether there is any indication that those assets have suffered an impairment loss. If any such indication exists, the recoverable amount of the asset is estimated in order to determine the extent of the impairment loss, if any. Where it is not possible to estimate the recoverable amount of an individual asset, the Company estimates the recoverable amount of the cash-generating unit to which the asset belongs.

Intangible assets with indefinite useful lives and intangible assets not yet available for use are tested for impairment at least annually, and whenever there is an indication that the asset may be impaired.

If the recoverable amount of an asset or cash-generating unit is estimated to be less than its carrying amount, the carrying amount of the asset or cash-generating unit is reduced to its recoverable amount. An impairment loss is recognized immediately in the statement of profit or loss and other comprehensive income.

Where an impairment loss subsequently reverses, the carrying amount of the asset is increased to the revised estimate of its recoverable amount, but so that the increased carrying amount does not exceed the carrying amount that would have been determined had no impairment loss been recognized for the asset or cash-generating unit in prior years. A reversal of an impairment loss is recognized immediately in profit or loss.

3.10 Financial Instruments

Financial assets and financial liabilities are recognized in the consolidated statements of financial position when the Company becomes party to the contractual provisions of the instrument. The Company does not use currency derivatives to hedge planned future cash flows, nor does it make use of forward foreign exchange contracts. Additionally, the Company does not have financial debt at December 31, 2020.

3.10.1 Financial Assets

Financial assets are initially recognized either at fair value or at transaction price. All recognized financial assets are subsequently measured at either amortized cost or fair value under IFRS 9 on the basis of both the Company's model for managing the financial assets and the contractual cash flow characteristics of the financial asset.

- A financial asset that (i) is held within a business model whose objective is to collect the contractual cash flows and (ii) has contractual cash flows that are solely payments of principal and interest on the principal amount outstanding

is measured at amortized cost (net of any write down for impairment), unless the asset is designated at fair value through profit or loss (FVTPL) under the fair value option.
- A financial asset that (i) is held within a business model whose objective is achieved both by collecting contractual cash flows and selling financial assets and (ii) has contractual term that give rise on specified dates to cash flows that are solely payments of principal and interest on the principal outstanding, is measured at fair value through other comprehensive income (FVTOCI), unless the asset is designated at FVTPL under the fair value option.
- All other financial assets are measured at FVTPL.

A financial asset is classified as current when the cash flows expected to flow from the instrument mature within one year.

The Company derecognized a financial asset when the contractual rights to the cash flows from the asset expire, or the Company transfers the right to receive the contractual cash flows on the financial asset in a transaction in which substantially all the risks and rewards of ownership of the financial asset are transferred.

The Company classifies non-derivative financial assets into the following categories;
- financial asset at fair value through profit or loss (non-current financial assets, current financial assets and cash equivalents)
- financial assets at amortized cost (receivables and cash and cash equivalents)

Financial Assets at Fair Value through Profit or Loss
Financial assets are designated at fair value through profit or loss if the Company manages such investments and makes purchases and sales decisions based on their fair value in accordance with the Company's investment strategy. Attributable transaction costs are recognised in the consolidated statements of profit or loss and other comprehensive income as incurred. Financial assets at fair value through profit or loss are measured at fair value, and changes therein, which take into account any dividend income, are recognized in the consolidated statements of profit or loss and other comprehensive income.

3.10.1.1 Non-current Financial Assets
The Company holds investments in non-current financial assets, which based on IFRS 9, are designated as financial assets at fair value through profit or loss, which qualify for level 3 fair value measurement based on current market prices. If the market for a financial asset is not active (and for unlisted securities), the Company established fair value by using valuation techniques.

3.10.1.2 Current Financial Assets
Current financial assets include financial assets measured at fair value through profit or loss and comprise of money market funds and term accounts that have an initial maturity equal or less than 12 months, but exceeding 3 months.

3.10.1.3 Cash equivalents Measured at Fair Value through Profit or Loss
Cash equivalents measured at fair value through profit or loss may comprise of term accounts that have an initial maturity of equal or less than 3 months and money market funds that are readily convertible to cash and are subject to insignificant risk of changes in value. These financial assets are used by the Company in the management of the short-term commitments.

Financial Assets at Amortized Cost
3.10.1.4 Receivables
Trade and other receivables are designated as financial assets measured at amortized cost. They are initially measured either at fair value or at transaction price, in the absence of a significant financing component.

All receivables are subsequently measured at amortized cost, which generally corresponds to nominal value less expected credit loss provision.

Receivables mainly comprise trade and other receivables and current and non-current research and development incentive receivables. These research and development incentive receivables relate to refunds resulting from research and development incentives on research and development expenses in Belgium and are credited to the consolidated statements of profit or loss and other comprehensive income under the line "Other operating income" when the relevant expenditure has been incurred and there is a reasonable assurance that the research and development incentives are receivable.

3.10.1.5 Cash
Cash are financial assets measured at amortized cost and comprise of cash balances and savings accounts.

3.10.1.6 Cash Equivalents Measured at Amortized Costs
Cash equivalents measured at amortized cost comprise of term accounts that have an initial maturity of less than 3 months that are subject to an insignificant risk of changes in values. The financial assets are used by the Company in the management of short-term commitments.

Cash and cash equivalents exclude restricted cash, which is presented in the consolidated statements of financial position under the line "Restricted cash – current" and "Restricted cash -non-current".

3.10.2 Financial Liabilities
Financial liabilities are initially measured at their transaction price. Subsequent to initial recognition, financial liabilities are measured at amortized cost.

Financial liabilities mainly comprise of trade and other liabilities.

Trade and other liabilities are comprised of liabilities that are due less than one year from the balance sheet date and are in general not interest bearing and settled on an ongoing basis during the financial year. They also include accrued expense related to the Company's research and development costs.

3.11 Shareholder's Equity

An equity instrument is any contract that evidences a residual interest in the assets of an entity after deducting all of its liabilities. Equity instruments issued by the Company are recognized at the proceeds received, net of direct issue costs.

The Company has never distributed any dividends to its shareholders. As of December 31, 2020, no profits were available for distribution.

3.12 Provisions

Provisions are recognized when the Company has a present obligation (legal or constructive) as a result of a past event, it is probable that an outflow of resources embodying economic benefits will be required to settle the obligations, and a reliable estimate can be made of the amount of the obligation.

The amount recognized as a provision is the best estimate of the consideration required to settle the present obligation at the end of the reporting period, taking into account the risks and uncertainties surrounding the obligation. When a provision is measured using the cash flows estimated to settle the present obligation, its carrying amount is the present value of those cash flows (where the effect of the time value of money is material).

3.13. Retirement Benefits

3.13.1 Defined contribution plans

Contributions to defined contribution pension plans are recognized as an expense in the consolidated statements of profit or loss and other comprehensive income as incurred.

3.13.2 Defined Benefit Plans

For defined retirement benefit plans, the cost of providing benefits is determined using the projected unit credit method, with actual valuations being carried out at the end of each annual reporting period. Remeasurement, comprising actuarial gains and losses, the effect of the changes to the asset ceiling (if applicable) and the return on plan assets (excluding interest), is reflected immediately in the consolidated statements of financial position with a charge or credit recognized in other comprehensive income in the period in which they occur. Remeasurement recognized in other comprehensive income is reflected immediately in retained earings and will not be reclassified to profit or loss. Past service cost is recognized in the consolidated statements of profit or loss and other comprehensive income in the period of a plan amendment. Net interest is calculated by applying the discount rate at the beginning of the period to the net defined benefit liability or asset.

Defined benefit costs are categorized as follows: service costs (including current service cost, past service cost, as well as gains and losses on curtailments and settlements), net interest expenses or income, and remeasurement.

The retirement benefit obligation recognized in the consolidated statements of financial position represents the actual deficit or surplus in the defined benefit plans. Any surplus resulting from this calculation is limited to the present value of any economic benefits available in the form of refunds from the plans or a reduction in future contribution to the plans. A liability for a termination benefit is recognized at the earlier of when we can no longer withdraw the offer of the termination benefit and when we recognize any related restructuring costs.

3.14 Short-term Employee Benefits

Short-term employee benefits include payables and accruals for salaries and bonuses to be paid to the employees of the Company. They are recognized as expenses for the period in which employees perform the corresponding services.

3.15 Share-based Payments

Equity-settled share-based payments to employees and others providing similar services are measured at the fair value of the equity instruments at the acceptance date.

The fair value determined at the acceptance date of the equity-settled share-based payments is expensed on a straight-line basis over the vesting period, based on the Company's estimate of equity instruments that will eventually vest, with a corresponding increase in equity. At the end of each reporting period, the Company revises its estimate of the number of equity instruments expected to vest. The impact of the revision of the original estimates, if any, is recognized in the consolidated statements of profit or loss and other comprehensive income such that the cumulative expense reflects the revised estimate, with a corresponding adjustment to the equity-settled share-based payment reserve.

3.16 Deferred Revenue

Current and non-current deferred revenue relates to cash received from collaboration & license agreements prior to completion of the earnings process. These payments are recognized as revenue over the estimated duration of the Company's involvement in the research and development programs provided for under the terms of the agreements.

3.17 Income Taxes

Income tax in the consolidated statements of profit or loss and other comprehensive income represents the sum of the current tax and deferred tax.

The current tax is based on taxable profit for the year. Taxable profit differs from profit as reported in the statement of profit and loss and other comprehensive income as it excludes items of income or expense that are taxable or deductible in other years and items that are never taxable or deductible. The Company's liability for current tax is calculated using tax rates that have been enacted or substantively enacted by the end of the reporting period.

Deferred tax is recognized on temporary differences between the carrying amounts of assets and liabilities in the consolidated financial statements and the corresponding tax basis used in the computation of taxable profit. Deferred tax assets are recognized to the extent that it is probable that future taxable profits will be available against which those deductible temporary differences can be utilized. The carrying amount of deferred tax assets is reviewed at the end of each reporting period and reduced to the extent that it is no longer probable that sufficient taxable profits will be available to allow all or part of the asset to be recovered. Deferred tax assets and liabilities are offset if there is a legally enforceable right to offset current tax liabilities and assets, and they relate to income taxes levied by the same tax authority on the same taxable entity, or on different taxable entities which intend either to settle current tax liabilities and assets on a net basis, or to realize the assets and settle the liabilities simultaneously.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply in the period in which the liability is settled or the asset realized, based on tax rates (and tax laws) that have been enacted or substantially enacted by the end of the reporting period.

3.18 Revenue and other Operating Income Recognition

3.18.1 Collaborations and License Agreements

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

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

1. Identify the contracts

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

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

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

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

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

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

For all our material ongoing collaboration and license agreements, the Company considers the performance obligations related to the transfer of the license as not distinct from the other promises to transfer goods and/or services; the Company utilizes judgement to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time. If over time, revenue is then recognized based on a pattern that best reflects the transfer of control of the service to the customer.

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

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

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

4. Allocate the transaction price
In principle, an entity shall allocate the transaction price to each performance obligation identified in the contract on a relative stand-alone selling price basis. As our ongoing license and collaboration arrangements only contain one single performance obligation, the transaction price is entirely allocated to this single performance obligation.

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

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

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

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

3.18.2 Grants, research and development incentives and payroll tax rebates
Because it carries out extensive research and development activities, the Company benefits from various grants, research and development incentives and payroll tax rebates from certain governmental agencies. These grants, research and development incentives and payroll tax rebates generally aim to partly reimburse approved expenditures incurred in research and development efforts of the Company and are credited to the consolidated statements of profit and loss and other comprehensive income, under the line "Other operating income", when the relevant expenditure has been incurred and there is reasonable assurance that the grants or research and development incentives are receivable.

3.19 Segment reporting

Segment results include revenue and expenses directly attributable to a segment and the relevant portion of revenue and expenses that can be allocated on a reasonable basis to a segment. Segment assets and liabilities comprise those operating assets and liabilities that are directly attributable to the segment or can be allocated to the segment on a reasonable basis. Segment assets and liabilities do not include income tax items.

The Company manages its activities and operates as one business unit which is reflected in its organizational structure and internal reporting. The Company does not distinguish in its internal reporting different segments, neither business nor geographical segments. The chief operating decision-maker is the Board of Directors.

4. Critical Accounting Judgements and Key Sources of Estimation Uncertainty

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

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

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

Critical estimates in applying accounting policies

Research and development cost accruals

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

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

5 Intangible assets

(IN THOUSANDS OF €)	Acquired In-Process R&D	Software & databases	Other Intangibles	Total
Cost				
On January 1, 2018	**—**	**99**	**—**	**99**
Additions	—	62	—	62
Disposals	—	(2)	—	(2)
On December 31, 2018	**—**	**159**	**—**	**159**
Additions	39,881	262	—	40,143
On December 31, 2019	**39,881**	**421**	**—**	**40,302**
Additions	13,236	2,503	80,725	96,464
On December 31, 2020	**53,117**	**2,924**	**80,725**	**136,766**
Amortization and impairment				
On January 1, 2018	**—**	**(86)**	**—**	**(86)**
Amortization	—	(19)	—	(19)
Disposals	—	2	—	2
On December 31, 2018	**—**	**(103)**	**—**	**(103)**
Amortization	—	(38)	—	(38)
On December 31, 2019	**—**	**(141)**	**—**	**(141)**
Amortization	—	(215)	—	(215)
On December 31, 2020	**—**	**(356)**	**—**	**(356)**
Carrying Amount				
On December 31, 2018	—	56	—	56
On December 31, 2019	39,881	280	—	40,161
On December 31, 2020	53,117	2,568	80,725	136,410

The Company performed an annual impairment review on the intangible assets not yet available for use. This review did not result in the recognition of an impairment charge.

As of December 31, 2020, there are no commitments to acquire additional intangible assets, except as set forth in note 29. No intangible assets are pledged as security for liabilities nor are there any intangible assets whose title is restricted.

6 Property, Plant and Equipment

(IN THOUSANDS OF €)	IT, office and lab equipment	Right-of-use assets Buildings	Right-of-use assets Vehicles	Leasehold improve-ments	Lease equipment[1]	**Total**
Cost						
On January 1, 2018	**2,389**	**—**	**—**	**—**	**—**	**2,389**
Additions	370	—	—	—	253	623
Disposals	(47)	—	—	—	—	(46)
On December 31, 2018	**2,712**	**—**	**—**	**—**	**253**	**2,965**
Adoption of IFRS 16	—	2,338	452	—	—	2,790
Additions	765	4,553	525	808	29	6,680
On December 31, 2019	**3,477**	**6,891**	**977**	**808**	**282**	**12,435**
Additions	597	2,718	875	352	—	4,542
Disposals	(90)	—	—	—	—	(90)
On December 31, 2020	**3,984**	**9,609**	**1,852**	**1,160**	**282**	**16,887**
Depreciation and impairment						
On January 1, 2018	**(1,713)**	**—**	**—**	**—**	**—**	**(1,713)**
Depreciation	(463)	—	—	—	(11)	(474)
Disposals	46	—	—	—	—	46
On December 31, 2018	**(2,130)**	**—**	**—**	**—**	**(11)**	**(2,141)**
Depreciation	(460)	(1,315)	(233)	(92)	(28)	(2,128)
On December 31, 2019	**(2,590)**	**(1,315)**	**(233)**	**(92)**	**(39)**	**(4,269)**
Depreciation	(468)	(1,981)	(386)	(351)	(28)	(3,214)
Disposals	90	—	—	—	—	90
On December 31, 2020	**(2,968)**	**(3,296)**	**(619)**	**(443)**	**(67)**	**(7,393)**
Carrying Amount						
On December 31, 2018	582	—	—	—	242	824
On December 31, 2019	887	5,576	744	716	243	8,167
On December 31, 2020	1,016	6,313	1,233	717	215	9,494

1The 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.

(IN THOUSANDS OF €)	Year Ended December 31, 2020	Year Ended December 31, 2019	Year Ended December 31, 2018
Restricted Cash - non-current	1,243	630	251
Non-current financial assets held at fair value through profit or loss	5,140	2,596	1
Total other non-current assets	**6,383**	**3,226**	**252**

Non-current restricted cash on December 31, 2020 was composed of mainly a deposit guarantee paid under the lease agreement for the laboratory and offices of the Company.

Non-current financial assets held at fair value through profit or loss is comprised of the profit share in AgomAb Therapeutics NV. In March 2019, the Company entered into a license agreement with AgomAb Therapeutics NV for the use of HGF-mimetic SIMPLE Antibodies™, developed under the Company's Innovative Access Program. In exchange for granting this license, the Company received a profit share in AgomAb Therapeutics NV.

In March 2019, AgomAb Therapeutics NV secured €21.0 million in a Series A financing round. The Company used the post-money valuation of this Series A financing round and the number of outstanding shares in determining the fair value of the profit sharing instrument and the revaluation of this instrument. This instrument is designated as financial asset held at fair value through profit or loss which qualify for level 3 fair value measurement currently based upon the Series A financing round valuation.

Fair value changes on non-current financial assets with fair value through profit of loss are recognized in the consolidated statements of profit and loss and other comprehensive income in line "Change in fair value on non-current financials assets".

The table below illustrates these non-current financials assets at fair value through profit or loss as of December 31, 2020, 2019 and 2018.

(IN THOUSANDS OF €)	Year Ended December 31, 2020	Year Ended December 31, 2019	Year Ended December 31, 2018
Cost at January 1	**1,499**	**—**	**—**
Acquisitions of the year	—	1,499	—
Cost at December 31	**1,499**	**1,499**	**—**
Fair value adjustments at January 1	**1,097**	**—**	**—**
Fair value adjustment of the year	2,544	1,097	—
Fair value adjustment at December 31	**3,641**	**1,097**	**—**
Net book value at December 31	**5,140**	**2,596**	**—**

8 Deferred Taxes

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

Year Ended December 31, 2020 (IN THOUSANDS OF €)	Assets	Liabilities	Net
Deferred tax assets / (liabilities)			
Accruals and allowances	**1,750**	—	1,750
Income tax benefit from excess tax deductions related to share-based payments	10,889	—	10,889
Property, plant and equipment	—	(136)	(136)
Intangible assets	—	(1,460)	(1,460)
Netting by taxable entity	(384)	384	—
Net deferred tax assets / (liabilities)	**12,255**	**(1,212)**	**11,043**

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

(IN THOUSANDS OF €)	Deferred tax assets	Deferred tax liabilities
Balance at January 1, 2020	—	—
Recognized in profit or loss	7,311	(1,212)
Recognized in equity	5,073	—
Effects of change in foreign exchange rate	(129)	—
Balance at December 31, 2020	**12,255**	**(1,212)**

9 Inventories

(IN THOUSANDS OF €)	Year Ended December 31, 2020	Year Ended December 31, 2019	Year Ended December 31, 2018
Raw materials and consumables	15,164	—	—
Inventories in process	5,368	—	—
Finished goods	—	—	—
Total inventories	**20,532**	—	—

On December 31, 2020, inventories amounted to €20.5 million and related to pre-launch efgartigimod-inventory, capitalized subsequent to the announcement of the topline data from the pivotal ADAPT trial of efgartigimod. As of December 31, 2020, no inventory write-downs were recorded.

10 Trade and Other Receivables

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

(IN THOUSANDS OF €)	Year Ended December 31, 2020	Year Ended December 31, 2019	Year Ended December 31, 2018
Trade receivable	234	22,580	214
Interest receivable	809	2,081	556
Other receivable	4,644	3,454	2,116
	5,687	**28,115**	**2,886**

The carrying amounts of trade and other receivables approximate their respective fair values.

Other receivables mainly included accrued income from subsidy projects and VAT receivables.

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

11 Financial Assets — Current

These current financial assets relate to term accounts with an initial maturity longer than 3 months but less than 12 months and money market funds that do not qualify as cash equivalents.

(IN THOUSANDS OF €)	Year Ended December 31, 2020	Year Ended December 31, 2019	Year Ended December 31, 2018
Money market funds	106,177	715,773	283,529
Term accounts	529,181	288,766	—
	635,359	**1,004,539**	**283,529**

On December 31, 2020, the current financial assets included $717.1 million held in USD, which could generate a foreign currency exchange gain or loss in our financial results in accordance with the fluctuations of the EUR/USD exchange rate as the Company's functional currency is EUR.

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

12 Cash and Cash Equivalents

(IN THOUSANDS OF €)	Year Ended December 31, 2020	Year Ended December 31, 2019	Year Ended December 31, 2018
Money market funds	699,447	—	—
Term accounts	50,001	227,551	217,451
Cash and bank balances	242,161	103,731	63,589
	991,609	331,282	281,040

Cash and cash equivalents may comprise of cash and bank balances, saving accounts, term accounts with an original maturity not exceeding 3 months and money market funds that are readily convertible to cash and are subject to an insignificant risk of changes in value.

Cash positions are invested with preferred financial partners, which are mostly considered to be high quality financial institutions with sound credit ratings to reduce credit risk.

On December 31, 2020, the cash and cash equivalents included $576.1 million held in USD, which could generate a foreign currency exchange gain or loss in our financial results in accordance with the fluctuations of the EUR/USD exchange rate as the Company's functional currency is EUR.

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

13 Share Capital and Share Premium

On December 31, 2020, the Company's share capital was represented by 47,571,283 shares. All shares were issued, fully paid up and of the same class. The table below summarizes our capital increases, as a result of offerings and the exercise of stock options under the Company's Employee Stock Option Plan

Roll forward of number of shares outstanding:

Number of shares outstanding on January 1, 2018	**32,180,641**
Exercise of stock options	319,671
U.S. third public offering on Nasdaq on September 18, 2018	3,475,000
Number of shares outstanding on December 31, 2018	**35,975,312**
Exercise of stock options	419,317
Share subscription from Johnson & Johnson Innovation Inc.	1,766,899
Global public offering on Euronext and Nasdaq on November 7, 2019	4,000,000
Over-allotment option exercised by underwriters on November 8, 2019	600,000
Number of shares outstanding on December 31, 2019	**42,761,528**
Exercise of stock options	602,463
Global public offering in Euronext and Nasdaq on May 28, 2020	3,658,515
Over-allotment option exercised by underwriters on May 29, 2020	548,777
Number of shares outstanding on December 31, 2020	**47,571,283**

On May 12, 2020 at the annual general meeting, the shareholders of the Company approved the authorization to the Board to issue:
- A maximum of 10% of the then-outstanding share capital for a period of 18 months
- A maximum of 10% of the then-outstanding share capital for a period till December 31, 2020

On December 31, 2020, an amount of €427,974.7, represented by 4,279,747 shares, still remained available under the authorized capital.

14 Share-based Payments

The Company has a stock options scheme for the employees of the Company and its subsidiaries. In accordance with the terms of the plan, as approved by shareholders, employees may be granted stock options to purchase ordinary shares at an exercise price as mentioned below per ordinary share.

The stock options are granted to employees, consultants or directors of the Company and its subsidiaries. The stock options have been granted free of charge. Each employee's stock option converts into one ordinary share of the Company upon exercise. The stock options carry neither rights to dividends nor voting rights. Stock options may be exercised at any time from the date of vesting to the date of their expiry.

The regular stock options granted vest, in principle, as follows:
- 1/3rd of the regular stock options granted will vest on the first anniversary of the granting of the stock options, and
- 1/24th of the remaining 2/3rd of regular stock options granted will vest on the last day of each of the 24 months following the month of the first anniversary of the granting of the stock options.

The sign-on stock options granted vest, in principle, as follows:
- 1/4rd of the stock options granted will vest on the first anniversary of the granting of the stock options, and
- 1/36th of the remaining 3/4th of the stock options granted will vest on the last day of each of the 36 months following the month of the first anniversary of the granting of the stock options.

In order to prefinance the taxes that are paid upon the grant of stock options, Belgian employees have the ability, in exchange for the taxes due upon the grant of the stock options, to transfer the economic benefits related to part of those stock options to a third party. As of December 31, 2020, the economic benefits of 126,982 stock options, for which accelerated vesting applies, were transferred to a third party.

No other conditions are attached to the stock options.

The following share-based payment arrangements were in existence during the current and prior years and which are exercisable at the end of each period presented:

Expiry date	Exercise price per stock options (in €)	Outstanding stock options on December 31, 2020	Outstanding stock options on December 31, 2019	Outstanding stock options on December 31, 2018
2020	3.95	—	7,210	18,200
2023	2.44	165,693	211,769	294,400
2024	2.44	100,086	102,696	144,703
2024	3.95	6,238	6,238	6,895
2024	7.17	294,167	335,067	407,061
2025	11.44	21,500	39,000	39,000
2025	10.34	950	3,000	3,000
2025	9.47	114,232	185,832	226,323
2026	11.38	45,000	45,000	50,415
2026	11.47	127,252	219,791	257,616
2026	14.13	176,426	258,746	315,102
2027	18.41	102,479	108,613	114,019
2027	21.17	460,701	565,798	628,292
2023	80.82	85,077	94,100	94,600
2028	80.82	49,532	73,100	75,450
2023	86.32	325,661	366,260	369,760
2028	86.32	381,317	402,714	491,815
2024	113.49	111,174	111,690	—
2029	113.49	163,410	299,560	—
2024	135.75	195,452	204,430	—
2029	135.75	692,914	717,455	—
2025	119.53	19,000	—	—
2030	119.53	123,700	—	—
2025	196.15	131,770	—	—
2030	196.15	325,150	—	—
2025	200.22	32,100	—	—
2030	200.22	175,200	—	—
2030	247.60	31,200	—	—
2025/2030 (1)	247.60	908,362	—	—
		5,365,743	**4,358,069**	**3,536,651**

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

	2020		2019		2018	
	Number of stock options	Weighted average exercise price	Number of stock options	Weighted average exercise price	Number of stock options	Weighted average exercise price
Outstanding at January 1	**4,358,069**	**63.75**	**3,536,651**	**33.42**	**2,862,216**	**11.54**
Granted	1,797,652	217.35	1,365,172	128.52	1,040,475	85.37
Exercised	(602,463)	31.67	(419,317)	11.35	(319,671)	7.02
Forfeited	(187,515)	139.34	(124,437)	88.92	(46,369)	30.44
Outstanding at December 31	**5,365,743**	**116.43**	**4,358,069**	**63.75**	**3,536,651**	**33.42**
Exercisable at December 31	**2,833,680**	**53.17**	**2,203,476**	**22.59**	**1,859,315**	**9.62**

The weighted average share price at the date of exercise of options exercised during the year ended December 31, 2020 was €207.43, compared to €110.99 during the year ended December 31, 2019 and €66.93 during the year ended December 31, 2018. The weighted average remaining contractual life of the stock options outstanding amounted to 7.08 years on December 31, 2020 compared to 7.27 years on December 31, 2019 and 7.82 years on December 31, 2018. The table below shows the weighted average remaining contractual life for each range of exercise price:

Exercise price (in €)	Outstanding on December 31, 2020	Weighted average remaining contractual life (in years)
2.44 - 3.95	272,017	3.08
7.17 - 9.47	408,399	4.24
10.34 - 14.13	371,128	5.62
18.41 - 21.17	563,180	6.87
80.82 - 86.32	841,587	5.46
113.49 - 135.75	1,305,650	7.64
196.15 - 247.60	1,603,782	9.29

The fair market value of the stock options has been determined based on the Black and Scholes model using the following unobservable assumptions:

- The expected volatility, determined on the basis of the implied volatility of the share price over the expected life of the option.
- The expected option life, calculated as the estimated duration until exercise, taking into account the specific features of the plans.

Below is an overview of the parameters used in relation to the determination of the fair value of the grants during 2020:

Stock options granted in	April 2020	June 2020	October 2020	December 2020
Number of options granted	142,700	550,090	196,500	908,362
Fair value of options (in €)	62.31 - 120.63	68001 - 105.65	74.24 - 127.68	119.26 - 124.67
Share price (in €)	126.50 - 205.60	183.20 - 229.20	209.00 - 239.20	247.4
Exercise price (in €)	119.53	196.15	200.22	247.6
Expected volatility	44.44 - 64.77 %	43.46 - 52.19 %	44.17 - 52.71 %	53.00 - 53.51 %
Expected option life (in years)	4 - 6.68	4 - 6.68	4 - 6.68	6.15 - 6.68[1]
Risk-free interest rate	(0.32) - (0.18) %	(0.43) - (0.28) %	(0.51) - (0.34) %	(0.42) - (0.40) %
Expected dividends	—	—	—	—

1In December 2020, the Company granted a total of 908,362 stock options. The beneficiary can choose between a contractual term of five or ten years. The expected option life ranges between 6.15 and 6.68 years. This estimate will be reassessed once the acceptance period of 60 days has passed and the beneficiaries will have made a choice between a contractual term of five or ten years. The total fair value of the grant would range from €84.5 million (100% of the stock options with a contractual term of five years) to €110.3 million (100% of the stock options with a conctractual term of ten years).

Below is an overview of the parameters used in relation to the determination of the fair value of grants during 2019:

Stock options granted in	June 2019	November 2019	December 2019
Number of options granted	423,487	19,800	921,885
Average fair value of options (in €)	63.45	57.69	41.40 - 66.39
Share price (in €)	123.20	126.40	130,1 - 150,7
Exercise price (in €)	113.49	113.49	135,75
Expected volatility	45.25 %	44.14 %	43,80 - 44,11 %
Average expected option life (in years)	8.59	6.50	4 - 6.5
Risk-free interest rate	0.07 %	(0.05) %	(0,57) - (0,24) %
Expected dividends	—	—	—

Below is an overview of the parameter used in relation to the determination of the fair value of grants during 2018:

Stock options granted in	June 2018	December 2018
Number of options granted	178,900	861,575
Fair value of options (in €)	32.12	39.85
Share price (in €)	72.00	82.20
Exercise price (in €)	80.82	86.32
Expected volatility	45.50 %	46.19 %
Average expected option life (in years)	7.36	7.83
Risk-free interest rate	0.72 %	0.77 %
Expected dividends	—	—

The total share-based payment expense recognized in the consolidated statement of comprehensive income totaled €84.5 million for the year ended December 31, 2020, compared to €39.6 for the year ended December 31, 2019 and €19.2 million for the year ended December 31, 2018.

15 Trade and Other Payables

(IN THOUSANDS OF €)	Year Ended December 31, 2020	Year Ended December 31, 2019	Year Ended December 31, 2018
Trade payables	168,140	58,429	24,152
Short-term employee benefits	56,122	26,872	12,920
	224,262	**85,301**	**37,072**

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

As of December 31, 2020, the trade payables include accruals amounting to €52.6 million related to accruals from clinical manufacturing organizations for the manufacturing of drug products and from clinical research organisations.

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

16 Revenue

The following table summarizes details of revenues for the year ended December 31, 2020, 2019 and 2018 by collaboration agreement and by category of revenue: upfront payments, milestone payments and research and development service fees.

(IN THOUSANDS OF €)	Year Ended December 31, 2020	Year Ended December 31, 2019	Year Ended December 31, 2018
Upfront payments	**30,348**	**22,360**	**8,635**
Janssen	29,818	20,056	—
AbbVie	497	761	8,455
Agomab	—	1,499	—
Other	33	44	180
Milestone payments	**3,021**	**28,085**	**11,440**
Janssen	2,333	1,569	—
AbbVie	671	26,494	10,510
Other	17	22	930
Research and development service fees	**3,056**	**19,338**	**1,407**
Janssen	2,807	18,968	—
Other	249	370	1,407
Total revenue	**36,425**	**69,783**	**21,482**

For the years ended December 31, 2020, 2019 and 2018, the majority of the revenue was generated under the agreements with Janssen and AbbVie, each as described below.

The table below summarizes the changes in deferred revenue – current and deferred revenue -non-current for the year ended December 31, 2020, 2019 and 2018.

(IN THOUSANDS OF €)	Janssen	AbbVie	Other	**Total**
On January 1, 2018	—	**12,376**	**344**	**12,720**
Received				
Milestone	—	8,633	883	9,516
Revenue recognition	—			
Upfront	—	(8,455)	(180)	(8,635)
Milestone	—	(10,510)	(930)	(11,440)
On December 31, 2018	—	**2,045**	**116**	**2,161**
Received				
Upfront	288,060			288,060
Milestone	22,535	26,560		49,095
Revenue recognition				
Upfront	(20,056)	(761)	(44)	(20,861)
Milestone	(1,569)	(26,494)	(22)	(28,085)
On December 31, 2019	**288,971**	**1,350**	**50**	**290,371**
Received				
Milestone	—	—	—	—
Revenue recognition				
Upfront	(29,818)	(497)	(33)	(30,348)
Milestone	(2,333)	(671)	(17)	(3,021)
On December 31, 2020	**256,819**	**182**	**0**	**257,001**

Below are summaries of the key collaborations.

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

The Company granted AbbVie an exclusive option, for a specified period following completion of IND enabling studies, to obtain a worldwide, exclusive license to the ARGX-115 (ABBV-151) program to develop and commercialize products. The Company received an upfront, nonrefundable, non-creditable payment of $40 million (€35.1 million as of the date the payment was received) from AbbVie for the exclusive option to license ARGX-115 (ABBV-151). The Company achieved two preclinical milestones, each of which triggered a $10.0 million payment (€8.9 million based on the exchange rate in effect as of the date the first milestone payment was received, and €8.7 million based on the exchange rate in effect as of the date the second milestone payment was received).

In August 2018, AbbVie exercised its option and has assumed certain development obligations, being solely responsible for all research, development and regulatory costs relating to ARGX-115 based products. In March 2019, the Company achieved the first development milestone upon initiation of a first-in-human clinical trial, triggering a $30.0 million payment. Subject to the continuing progress of ARGX-115 (ABBV-151) by AbbVie, the Company is eligible to receive development, regulatory and commercial milestone payments in aggregate amounts of up to $110 million, $190 million and $325 million, respectively, as well as tiered royalties on sales at percentages ranging from the mid-single digits to the lower teens, subject to customary reductions.

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

With regard to its collaboration with AbbVie, the Company concluded as follows:

- There is one single performance obligation under IFRS 15, that being the transfer of a license combined with performance of research and development activities. The Company concluded that the license is not distinct in the context of the contract.
- The transaction price of these two agreements is currently composed of a fixed part, that being an upfront license fee, and a variable part, being milestone payments and cost reimbursements of research and development activities delivered. Milestone payments are only included in the transaction price to the extent it is highly probable that a significant reversal in the amount of cumulative revenue recognition will not occur when the uncertainty associate with the variable consideration is subsequently resolved. We estimate the amount to be included in the transaction price upon achievement of the milestone event. Sales-based milestones and sales-based royalties are a part of the Company's arrangements but are not yet included in its revenues.
- The transaction price has been allocated to the single performance obligation and revenues have been recognized over the estimated service period based on a pattern that reflects the transfer of the license and progress to complete satisfaction of the research and development activities. This is because we considered that there is a transformational relationship between the license and the research and development activities to be delivered.
- The Company has chosen an input model to measure the satisfaction of the single performance obligation that considers percentage of costs incurred for these programs that are completed each period (percentage of completion method).
- Cost reimbursements received are recognized in revenues when costs are incurred and agreed by the parties, as the Company is acting as a principal in the scope of its stake of the research and development activities of its ongoing license and collaboration agreements.

Janssen
In December 2018, the Company entered into a collaboration agreement with Cilag GmbH International, an affiliate of Janssen, to jointly develop and commercialize cusatuzumab. The Company has granted Janssen a license to the cusatuzumab program to develop, manufacture and commercialize products. For the U.S., the granted commercialization license is co-exclusive with argenx, while outside the U.S., the granted license is exclusive. Janssen and argenx will assume certain development obligations, and will be jointly responsible for all research, development and regulatory costs relating to the products. argenx will be eligible to receive potentially up to $1.3 billion in development, regulatory and sales milestones, in addition to tiered royalties, ranging from the low double digits to the high teens. Janssen will be responsible for commercialization worldwide. argenx retains the option to participate in commercialization efforts in the US, where the companies have agreed to share royalties on a 50/50 basis, and outside the U.S., Janssen will pay sales royalties ranging from the low double digits to the high teens to argenx.

Under the terms of the agreement, Janssen committed to an upfront payment of $500 million consisting of a license payment of $300 million and a $200 million equity investment in the Company by subscribing to 1,766,899 new shares at a price of €100.02 per share, including an issuance premium. The agreement became effective in January 2019 following expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act. In December 2019, the Company achieved the first development milestone, triggering a $25.0 million payment.

With regard to this collaboration with Janssen, the Company concluded as follows:

- There is one single performance obligation under IFRS 15, that being the transfer of a license combined with performance of research and development activities. The Company concluded that the license is not distinct in the context of the contract.
- The Company concluded that the share premium that Janssen paid above the closing price on the day of entering into the investment agreement (being December 2, 2018) was paid because of the existing obligations to deliver development services under the terms of the collaboration agreement, and is therefore to be considered to be part of the overall consideration received.

- The transaction price of these two agreements is currently composed of a fixed part, that being an upfront license fee, and a variable part, being milestone payments and cost reimbursements of research and development activities delivered. Milestone payments are only included in the transaction price to the extent it is highly probable that a significant reversal in the amount of cumulative revenue recognition will not occur when the uncertainty associate with the variable consideration is subsequently resolved. We estimate the amount to be included in the transaction price upon achievement of the milestone event. Sales-based milestones and sales-based royalties are a part of the Company's arrangements but are not yet included in its revenues.
- The transaction price has been allocated to the single performance obligation and revenues have been recognized over the estimated service period based on a pattern that reflects the transfer of the license and progress to complete satisfaction of the research and development activities. This is because we considered that there is a transformational relationship between the license and the research and development activities to be delivered.
- The Company has chosen an input model to measure the satisfaction of the single performance obligation that considers percentage of costs incurred for these programs that are completed each period (percentage of completion method).
- Cost reimbursements received are recognized in revenues when costs are incurred and agreed by the parties, as the Company is acting as a principal in the scope of its stake of the research and development activities of its ongoing license and collaboration agreements.

17 Other Operating Income

(IN THOUSANDS OF €)	Year Ended December 31, 2020	Year Ended December 31, 2019	Year Ended December 31, 2018
Grants	1,226	2,289	1,842
Research and development incentives	8,875	4,818	2,151
Payroll tax rebates	8,008	5,694	3,756
	18,109	**12,801**	**7,749**

17.1 Grants

The grant income is related to grants received from the Flanders Innovation and Entrepreneurship Agency. No conditions related to the above government grants were unfulfilled, nor were there any material contingencies related thereon at the date of the approval of these consolidated financial statements.

17.2 Research and development incentives

The Company has accounted for a tax receivable of €8.9 million in the year ended December 31, 2020, compared to €4.8 and €2.2 million in the year ended December 31, 2019 and December 31, 2018, respectively, following a research and development tax incentive scheme in Belgium according to which the incentive will be refunded after a five year period, if not offset against the current tax payable over the period.

17.3 Payroll tax rebates

The Company accounted for €8.0 million payroll tax rebates in the year ended December 31, 2020, compared to €5.7 and €3.8 million in the year ended December 31, 2019 and December 31, 2018, respectively, as a reduction in withholding income taxes for its highly qualified personnel employed in its research and development department.

18 Segment Reporting

The Company operates from the Netherlands, Belgium, the United States of America and Japan. Revenues are generated by external customers with their main registered office geographically located as shown in the table below. In prior periods this has been presented based on the geographical location of the contracting entity.

Revenue from external customers (IN THOUSANDS OF €)	Year Ended December 31, 2020	Year Ended December 31, 2019	Year Ended December 31, 2018
Denmark	299	436	1,136
Belgium	—	1,499	—
United States	36,126	67,848	18,964
Other	—	—	1,382
Total	**36,425**	**69,783**	**21,482**

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

Non-current assets (IN THOUSANDS OF €)	Year Ended December 31, 2020	Year Ended December 31, 2019	Year Ended December 31, 2018
Netherlands	1	1	1
Belgium	163,224	56,777	5,967
United States	3,872	3,058	47
Japan	2,030	284	—
Total	**169,127**	**60,120**	**6,015**

19 Research and Development Expenses

(IN THOUSANDS OF €)	Year Ended December 31, 2020	Year Ended December 31, 2019	Year Ended December 31, 2018
Personnel expense	75,121	45,733	26,519
External research and development expenses	228,438	137,050	48,859
Materials and consumables	3,099	2,027	1,464
Depreciation and amortization	2,472	1,641	494
Other expenses	16,349	11,214	6,273
	325,479	**197,665**	**83,609**

20 Selling, General and Administrative Expenses

(IN THOUSANDS OF €)	Year Ended December 31, 2020	Year Ended December 31, 2019	Year Ended December 31, 2018
Personnel expense	94,251	40,082	18,292
Consulting fees	42,459	16,343	5,472
Supervisory board	4,243	2,792	1,088
Other Expenses	8,414	5,352	2,619
	149,367	**64,569**	**27,471**

21 Personnel Expenses

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

(IN THOUSANDS OF €)	Year Ended December 31, 2020	Year Ended December 31, 2019	Year Ended December 31, 2018
Short-term employee benefits—Salaries	65,516	32,866	18,617
Short-term employee benefits—Social Security	7,848	3,555	2,213
Post-employment benefits	1,072	748	441
Termination benefits	849	644	96
Share-based payment	80,644	37,208	18,527
Employer social security contributions stock options	13,443	10,794	4,918
	169,372	**85,815**	**44,812**

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

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

Average Number of FTE	Year Ended December 31, 2020	Year Ended December 31, 2019	Year Ended ecember 31, 2018
Research and development	213.0	121.6	76.1
Selling, general and administrative	119.5	56.3	27.6
	332.5	**177.9**	**103.7**

22 Leases

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

(IN THOUSANDS OF €)	Year Ended December 31, 2020	Year Ended December 31, 2019
Right-of-use assets		
Buildings	6,313	5,576
Vehicles	1,233	744
Equipment	215	243
	7,760	**6,563**
Lease liabilities		
Current	2,833	1,974
Non-current	5,035	4,540
	7,868	**6,514**

Additions to the right-of-use assets amounted to €3.6 million for the year ended December 31, 2020.

The table below shows a maturity analysis of the lease liabilities as on December 31, 2020:

(IN THOUSANDS OF €)	Less than 1 year	1-3 years	3-5years	More than 5 years	Total contractual cash flows	Carrying amount
Lease liabilities	3,043	4,085	1,171	—	8,299	7,868

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

(IN THOUSANDS OF €)	Year Ended December 31, 2020	Year Ended December 31, 2019	Year Ended December 31, 2018
Depreciation charges			
Buildings	1,981	1,315	—
Vehicles	386	233	—
Equipment	28	28	11
	2,395	**1,576**	**11**
Interest expense (included in finance cost)	176	105	—
Expense relating to short-term leases	231	123	—
Expense relating to leases of low-value assets that are not shown above as short-term leases	5	5	—

The total cash outflow for leases in 2020 was €2.6 million.

The Company did not enter into any lease agreement with variable lease payments or residual value guarantees. The Company has leases that include extension options. These options provide flexibility in managing the leased assets and align with the Company's business needs. The Company exercises judgement in deciding whether it is reasonably certain that the extension options will be exercised.

23 Financial Result and Exchange Gains/(losses)

(IN THOUSANDS OF €)	Year Ended December 31, 2020	Year Ended December 31, 2019	Year Ended December 31, 2018
Interest income	4,517	7,874	1,371
Net gain on current financial assets held at fair value through profit or loss and cash equivalents	1,173	6,525	2,323
Financial income	**5,690**	**14,399**	**3,694**
Net loss on current financial assets held at fair value through profit or loss and cash equivalents	(6,755)	—	—
Other financial expense	(349)	(124)	—
Financial expense	**(7,104)**	**(124)**	**—**
Realized exchange gains/(losses)	(400)	(338)	1,355
Unrealized exchange gains/(losses)	(106,556)	6,404	10,953
Exchange gains/(losses)	**(106,956)**	**6,066**	**12,308**

The exchange losses of €107.0 million for the year ended December 31, 2020 were primarily attributable to unrealized exchange rate gains on our cash and cash equivalents and current financial assets position in USD due to the unfavorable fluctuation of the USD exchange rate over the period.

24 Income Tax Expense

The income tax expense for the year can be reconciled to the accounting loss as follows:

(IN THOUSANDS OF €)	Year Ended December 31, 2020	Year Ended December 31, 2019	Year Ended December 31, 2018
Loss before taxes	526,139	158,213	65,847
Income tax calculated at 25%	131,535	39,553	16,462
Effect of expenses deductible in determining taxable results	(11,478)	(7,701)	(3,934)
Effect of stock issue expenses that are not deductible in determining taxable results	11,775	5,750	3,716
Effect of concessions	6,804	572	430
Effect of tax losses carried forward not recognized	(100,771)	(11,670)	(5,511)
Effect of different tax rates in jurisdictions in which the company operates	(168)	(52)	(15)
Deferred tax asset other than loss carryforwards not recognized	(39,516)	(27,341)	(11,968)
(Underprovided)/overprovided in prior years	(857)	(3,876)	
Other	(108)	13	26
Income tax expense recognized in the consolidated statement of profit and loss	**(2,784)**	**(4,752)**	**(794)**

The tax rate used for the 2020, 2019 and 2018 reconciliations above is the corporate income tax rate of 25% payable by corporate entities in the Netherlands.

The unrecognized deferred tax asset on deductible temporary differences and unused tax losses amounts to €141.9 million on December 31, 2020, compared to €40.0 million on December 31, 2019. Deferred tax have been measured using the effective rate that will apply in Belgium and the Netherlands (25%). The Company has unused tax losses carried forward for an amount of € 567.8 million on December 31, 2020, compared to €160 million on December 31, 2019, of which €1.4 and €7.2 million will expire in 2028 and 2029, respectively. This, combined with other temporary differences, resulted in a net deferred tax asset position. Due to the uncertainty surrounding the Company's ability to realize taxable profits in the near future, the Company did not recognize any deferred tax assets, with the exception of those further detailed in note 10.

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

(IN THOUSANDS OF €)	Year Ended December 31, 2020	Year Ended December 31, 2019	Year Ended December 31, 2018
Current year	6,871	4,752	794
Income tax prior years	1,547	—	—
Current tax expense	**8,418**	**4,752**	**794**
Originating and reversal of temporary differences	(5,634)	—	—
Deferred tax expense / (income)	**(5,634)**	**—**	**—**
Total tax expense	**2,784**	**4,752**	**794**

25 Loss per Share

(IN THOUSANDS OF €)	Year Ended December 31, 2020	Year Ended December 31, 2019	Year Ended December 31, 2018
Loss of the year	(528,923)	(162,965)	(66,641)
Weighted average number of shares outstanding	45,410,442	38,619,121	33,419,356
Basic and diluted loss per share (in €)	**(11.65)**	**(4.22)**	**(1.99)**

Earnings/losses per ordinary share are calculated by dividing the loss for the period by the weighted average number of ordinary shares during the year.

As the Company reported a net loss in 2020, 2019 and 2018, stock options have an anti-dilutive effect rather than a dilutive effect. As such, there is no difference between basic and diluted earnings/losses per ordinary share.

26 Financial Risk Management

The financial risks are managed centrally. The Company coordinates the access to national and international financial markets and considers and manages continuously the financial risks concerning the Company's activities. These relate to the financial markets risk, credit risk, liquidity risk and currency risk. There are no other important risks, such as interest rate risk on borrowings, as the Company has no financial debt. The Company does not buy or trade financial instruments for speculative purposes.

Categories of financial assets and liabilities:

	Measurement category	Carrying amount		
(IN THOUSANDS OF €)		Year Ended December 31, 2020	Year Ended December 31, 2019	Year Ended December 31, 2018
Financial assets — non-current	FVTPL	5,140	2,596	1
Research and development incentive receivables — non-current	Amortised cost	16,840	8,566	4,883
Restricted cash — non-current	Amortised cost	1,243	630	251
Trade and other receivables	Amortised cost	5,687	28,115	2,886
Financial assets—current	FVTPL	635,359	1,004,539	283,529
Research and development incentive receivables — current	Amortised cost	377	261	301
Restricted cash — current	Amortised cost	—	—	1,692
Cash and bank balances	Amortised cost	242,161	103,731	63,589
Cash equivalents	FVTPL	699,447	—	—
Cash equivalents	Amortised cost	50,001	227,551	217,451
Trade and other payables	Amortised cost	224,262	85,301	37,072

The carrying amounts of trade and other payables are considered to be the same as their fair values, due to their short-term nature.

Financial assets held at fair value through profit or loss
Financial assets held at fair value through profit or loss consisted of equity instruments of listed and nonlisted 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 the liabilities. These instruments are classified as financial assets held at fair value through profit or loss which qualify for

- Level 1 fair value measurement with respect to current financial assets and cash equivalents based upon the closing price (net asset value) of such securities at each reporting date.
- Level 3 fair value measurement with respect to non-current financial assets.

The market price of these financial instruments might face fluctuations and might be affected by a variety of factors, such as the global economic situation. Current financial assets and cash equivalents include collective investment funds nominated in € and $ of which the underlying investments include bonds and other international debt securities. Based on the average credit rating of the underlying instruments, amongst others, these investments are either classified as current financial assets or cash equivalents.

The maximum exposure to credit risk is the carrying amount at reporting date.

The Company carried the following assets at fair value on December 31, 2020, 2019 and 2018 respectively:

	As of December 31, 2020		
(IN THOUSANDS OF €)	Level 1	Level 2	Level 3
Non-current financial assets	—	—	5,140
Current financial assets	635,359	—	—
Cash Equivalents	699,447	—	—
Assets carried at fair value	**1,334,806**	**—**	**5,140**

	As of December 31, 2019		
(IN THOUSANDS OF €)	Level 1	Level 2	Level 3
Non-current financial assets	—	—	2,596
Current financial assets	1,004,539	—	—
Assets carried at fair value	**1,004,539**	**—**	**2,596**

	As of December 31, 2018		
(IN THOUSANDS OF €)	Level 1	Level 2	Level 3
Non-current financial assets	—	—	1
Current financial assets	283,529	—	—
Assets carried at fair value	**283,529**	**—**	**1**

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

In March 2019, the Company entered into a license agreement with AgomAb Therapeutics NV for the use of HGF-mimetic SIMPLE Antibodies™, developed under the Company's Innovative Access Program. In exchange for granting this license, the Company received a profit share in AgomAb Therapeutics NV. The profit share has been designated as a non-current financial asset held at fair value through profit or loss. Since AgomAb Therapeutics NV is a private company, the valuation of the profit share is based on level 3 assumptions.

Capital risk
The Company manages its capital to ensure that it will be able to continue as a going concern. The capital structure of the Company consists of equity attributed to the holders of equity instruments of the Company, such as capital, reserves and accumulated losses as mentioned in the consolidated statement of changes in equity. The Company makes the necessary adjustments in the light of changes in the economic circumstances, risks associated to the different assets and the projected cash needs of the current and projected research activities. On December 31, 2020, cash and cash equivalents amounted to €991.6 million and total capital amounted to €2,062.9 million. The current cash situation and the anticipated cash generation are the most important parameters in assessing the capital structure. The Company's objective is to maintain the capital structure at a level to be able to finance its activities for at least twelve months. Cash income from existing and new partnerships is taken into account and, if needed and possible, the Company can issue new shares or enter into financing agreements.

Credit risk
Credit risk refers to the risk that a counterparty will default on its contractual obligations resulting in financial loss to the Company. The Company has adopted a policy of only dealing with creditworthy counterparties and obtaining sufficient collateral, where appropriate, as a means of mitigating the risk of financial loss from defaults. Concentrations in credit risk are determined based on an analysis of counterparties and their importance on the overall outstanding contractual obligations at year end.

The Company has a limited number of license and collaboration partners and therefore has a significant concentration of credit risk. However, it has policies in place to ensure that credit exposure is kept to a minimum and significant concentrations of credit exposure are only granted for short periods of time to high credit quality collaboration partners.

The Company applied the IFRS 9 simplified approach to measuring expected credit losses which uses a lifetime expected loss allowance for all receivables. To measure the expected credit losses, receivables have been grouped based on credit risk characteristics and the days past due. The provision for expected credit losses was not significant given that there have been no credit losses over the last three years and the high quality nature of our customers.

Cash and cash equivalents and current financial assets are invested with several highly reputable banks and financial institutions. The Company holds its cash and cash equivalents mainly with different banks which are independently rated with a minimum rating of 'A-'. The Company also holds short term investment funds in the form of money market funds with a recommended investment horizon of 6 months or shorter but with a low historical volatility. These money market funds are highly liquid investments, can be readily convertible into a known amount of cash. Since they are a basket of funds there is no individual credit risk involved. The average credit rating of the underlying instruments for the investment funds is "BBB-" or higher.

Liquidity risk
The Company manages liquidity risk by maintaining adequate reserves, by continuously monitoring forecast and actual cash flows, and by matching the maturity profiles of financial assets and liabilities.

The Company's main sources of cash inflows are obtained through capital increases and collaboration agreements. This cash is invested in savings accounts, term accounts and short term investment funds in the form of money market funds. These money market funds represent the majority of the Company's available sources of liquidity however since all of these are immediately tradable and convertible in cash they have a limited impact on the liquidity risk.

Interest rate risk
The only variable interest-bearing financial instruments are cash and cash equivalents and current financial investments. Changes in interest rates may cause variations in interest income and expense resulting from short-term interest-bearing assts. Management does not expect the short-term interest rates to decrease significantly in the immediate foreseeable future, which limits the interest exposure on our cash and cash equivalents and current financial investments.

For the year ended December 31, 2020, if applicable interest rates would increase/decrease by 25 basis points, this would have a positive/negative impact of €1.5 million (compared to €2.0 million for the year ended December 31, 2019 and €0.3 million for the year ended December 31, 2018).

Foreign exchange risk
The Company undertakes transactions denominated in foreign currencies; consequently, exposures to exchange rate fluctuations arise. The Company is mainly exposed to the U.S. Dollar, Japanse yen, British pound and Swiss franc. To limit this risk, the Company attempts to align incoming and outgoing cash flows in currencies other than EUR.

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

(IN THOUSANDS OF €)	As of December 31, 2020	As of December 31, 2019	As of December 31, 2018
USD	1,053,803	821,916	312,831
JPY	215	488	—
GBP	39	4	2
CHF	94	1	4

On December 31, 2020, if the USD/EUR exchange rate would have increased/decreased by 10%, this would have had a negative/positive impact of €95.80 million, compared to €74.72 million and €28.44 million on December 31, 2019 and December 31, 2018, respectively. On December 31, 2020, if the exchange rate for other currencies would have increased/decreased by 10% , this would have had no significant impact.

27 Related Party Transactions

27.1 Relationship and Transactions with Subsidiaries

See note 31 for an overview of the consolidated companies of the group, which are all wholly-owned subsidiaries of argenx SE.

Balances and transactions between the Company and its subsidiaries, which are related parties of the Company, have been eliminated on consolidation and are not disclosed in this note.

27.2 Relationship and Transactions with Key Personnel

The Company's key management personnel consists of the members of the management team and the members of the board of directors.

Remuneration of key management personnel
On December 31, 2020, the executive committee consisted of 9 members: Chief Executive Officer, Chief Operating Officer, Chief Financial Officer, Chief Scientific Officer, General Counsel, Chief Medical Officer, Vice President Corporate Development and Strategy, Global Head of Quality Assurance and Global Head of Human Resources. They provide their services on a full-time basis.

On December 31, 2020, the board of directors consisted of 8 members: Peter Verhaeghe, Don deBethizy, Pamela M. Klein, David L. Lacey, Werner Lanthaler, A.A. Rosenberg, James M. Daly and Tim Van Hauwermeiren.

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

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

(IN THOUSANDS OF €, EXCEPT FOR THE NUMBER OF STOCK OPTIONS)	Year Ended December 31, 2020	Year Ended December 31, 2019	Year Ended December 31, 2018
Remuneration of key management personnel			
Short-term benefits for executive team members as a group			
Gross salary	2,842	2,527	2,505
Variable pay	1,322	975	1,078
Employer social security	659	813	528
Other short term benefits	137	122	125
Termination Benefits	337	470	—
Post-employment benefits for executive team members as a group	141	144	153
Cost of stock options granted in the year for executive team members as a group	37,493	21,847	13,363
Employer social security cost related to stock options	9,811	9,160	2,793
Total benefits for key management personnel	**52,742**	**36,058**	**20,544**
Numbers of stock options granted in the year			
Executive team as a group	334,900	405,000	460,700
Remuneration of non-executive directors			
Board fees and other short-term benefits for directors	355	378	355
Cost of stock options granted in the year for non-executive directors	8,384	4,330	3,271
Total benefits for non-executive board members	**8,739**	**4,708**	**3,626**
Numbers of stock options granted in the year			
Non-executive directors	70,000	70,000	85,000

Other
No loans, quasi-loans or other guarantees were given by the Company or any of its subsidiaries to members of the board of directors or the executive team. We have not entered into transactions with our key management personnel, other than as described above with respect to remuneration arrangements relating to the exercise of their mandates as members of the executive team and the board of directors.

28 Contingencies

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

29 Commitments

At balance sheet date, there were no commitments signed for the acquisition of property, plant and equipment. In January 2021, the Company entered into a binding lease commitment related to the envisioned relocation to a newly built office in Zwijnaarde, Belgium. Included in the binding lease commitment is a rent free period for 6 months following the completion of the building. The total future cash outflows related to this lease are as follows:

(IN THOUSANDS OF €)	Less than 1 year	1-3 years	3-5years	More than 5 years	Total contractual cash flows
Lease commitments not commenced	—	282	3,382	13,247	16,912

In February 2019, and as amended in September 2020, the Company entered into a global collaboration and license agreement with Halozyme Therapeutics, Inc. Under the terms of the agreement, the Company will pay $12.5 million per target for future target nominations and potential future payments of up to $160.0 million per selected target subject to achievement of specified development, regulatory and sales-based milestones and up to $40.0 million subject to the achievement of additional, specified sales-based milestones. This amount represents the maximum amount that would be paid if all milestones would be achieved but excludes variable royalty payments based on unit sales. In 2019, the Company exercised the option to nominate an additional target (triggering a $10.0 million development milestone payment) and initiated a Phase 1 clinical trial using Halozyme's proprietary ENHANZE® drug delivery technology (triggering a $5.0 million development milestone payment). In 2020, the Company initiated a Phase 3 clinical trial using Halozyme's proprietary ENHANZE® drug delivery technology (triggering a $15.0 million development milestone payment).

The Company's manufacturing commitments with Lonza, its drug substance manufacturing contractor, relate to the ongoing execution of the biologic license application (BLA) services for efgartigimod and its manufacturing activities related to the potential future commercialisation. In December 2018, the Company signed its first commercial supply agreement with Lonza related to the reservation of commercial drug substance supply capacity for efgartigimod. In the aggregate, the Company has outstanding commitments for efgartigimod under the first commercial supply agreement of €114.0 million.

30 Audit fees

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

(IN THOUSANDS OF €)	Year Ended December 31, 2020	Year Ended December 31, 2019	Year Ended December 31, 2018
Audit fees [1]	808	730	648
Audit-related fees	165	159	143
Tax and other services [2]	—	—	—
Total	**973**	**889**	**791**

(1) Audit services performed by Deloitte Accountants B.V. as the external auditor referred to in Section 1 of the Dutch Accounting Firms Oversight Act (Wta) as well as by the Deloitte network.
(2) Tax and other services performed by the Deloitte network.

31 Overview of Consolidation Scope

The parent company argenx SE is domiciled in the Netherlands. The Company, argenx SE, has two subsidiaries, argenx BV and argenx IIP BV, based in Belgium. argenx BV has three subsidiary, argenx US, Inc., based in the United States of America, argenx Japan KK, based in Japan and argenx Switzerland SA, based in Switzerland. Details of the Company's consolidated entities at the end of the reporting period are as follows:

NAME	Registration number	Country	Participation	Main activity
argenx SE	COC 24435214	The Netherlands	100.00 %	Holding company
argenx BV	0818292196	Belgium	100.00 %	Biotechnical research on drugs and pharma processes
argenx IIP BV	0751809485	Belgium	100.00 %	Biotechnical research on drugs and pharma processes
argenx US, Inc.	36-4880497	USA	100.00 %	Pharmaceuticals and pharmacy supplies merchant wholesalers
argenx Switzerland, SA	CH-660.3.799.020-7	Switzerland	100.00 %	Pharmaceuticals and pharmacy supplies merchant wholesalers
argenx Japan KK	0104-01-145183	Japan	100.00 %	Pharmaceuticals and pharmacy supplies merchant wholesalers

32 Events After the Balance Sheet Date

On January 6, 2021, argenx and Zai Lab announced a Strategic Collaboration for efgartigimod in Greater China, expected to allow the Company to more rapidly advance new potential indications into clinical development each year and grants Zai Lab the exclusive rights to develop and commercialize efgartigimod in Greater China. Zai Lab will recruit Chinese patients to argenx's registrational trials for the development of efgartigimod and will allow argenx to accelerate efgartigimod development by initiating multiple Phase 2 proof-of-concept trials in new autoimmune indications.

Under the terms of the agreement, the Company will receive up to $175 million in collaboration payments, comprised of a $75 million upfront payment in the form of 568,182 newly issued Zai Lab shares calculated at a price of $132 per share, $75 million as guaranteed non-creditable, non-refundable payment, and an additional $25 million milestone payment upon approval of efgartigimod in the U.S. The Company is also eligible to receive tiered royalties (mid-teen to low twenties on a percentage basis) based on annual net sales of efgartigimod in Greater China.

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

On February 5, 2021, argenx SE announced the closing of their global offering of 3,125,000 of its ordinary shares through a global offering which consisted of (i) a public offering of 1,608,000 ADSs in the U.S. and certain other countries outside the European Economic Area (EEA) at a price of $320.00 per ADS, before underwriting discounts and commissions, and offering expenses; and (ii) a concurrent private placement of 1,517,000 ordinary shares in the European Economic Area at a price of €265.69 per share, before underwriting discounts and commissions, and offering expenses. On February 4, 2021, the underwriters of the offering exercised their over-allotment option to purchase 468,750 additional ADSs in full. As a result, the Company received €954.8 million in gross proceeds from the offering, decreased by €46.8 million of underwriter discounts and commissions, and offering expenses, of which €46.5 million is expected to be deducted from equity. The total net cash proceeds from the offering amounted to €908.0 million.

9

Company Financial Statements

FOR ARGENX SE - FOR THE YEAR ENDED DECEMBER 31, 2020

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Signatures of Executive and Non-Executive Directors

In accordance with article 2:101 of the Dutch Civil Code, the annual accounts were signed by all executive and non-executive directors on March 30, 2021.

Company Financial Statements for argenx SE

For argenx SE.
For the year ended December 31, 2020.

Company Balance Sheet on December 31, 2020 argenx SE

Assets (IN THOUSANDS OF €)	NOTE	As of December 31, 2020	As of December 31, 2019
Non-current Assets			
Financial Fixed Assets	2		
Investments in Group Companies		1,251,797	935,185
Other financial assets		1	1
Total Financial Fixed assets		1,251,798	935,186
Total Non-Current Assets		1,251,798	935,186
Current assets			
Receivables	3	5,016	522
Financial assets — current	4	4,425	20,571
Cash in banks	5	96,157	97,206
Total Current Assets		**105,598**	**118,299**
Total Assets		**1,357,396**	**1,053,485**

Equity and liabilities (IN THOUSANDS OF €)	NOTE	As of December 31, 2020	As of December 31, 2019
Equity	**6**		
Share Capital		4,757	4,276
Share Premium		2,058,122	1,308,539
Accumulated losses		(861,491)	(332,568)
Reserve for Share-Based payments		154,977	70,499
Total Equity		**1,356,365**	**1,050,746**
Current liabilities	7		
Accounts Payable		0	372
Intercompany payables		534	472
Taxes payable		0	598
Accrued expenses		497	1.297
Total Liabilities		**1,031**	**2,739**
Total Equity & Liabilities		**1,357,396**	**1,053,485**

Company Profit and Loss Account for the Year Ended December 31, 2020 argenx SE

(IN THOUSANDS OF €)	NOTE	Year ended December 31, 2020	Year ended December 31, 2019
G&A Expenses		**(11,152)**	**(7,452)**
Total operating expenses		**(11,152)**	**(7,452)**
Operating result		**(11,152)**	**(7,452)**
Financial income and expense	8	(1,424)	3,087
Share in result of subsidiaries	9	(516,258)	(158,608)
Result before taxation		**(528,834)**	**(162,972)**
Taxation on result of ordinary activities		(89)	7
Result after taxation		**(528,923)**	**(162,965)**

Notes to The Company Financial Statements of argenx SE

1 Accounting Information and Policies

Basis of Preparation
The company financial statements of argenx SE (hereafter: the company) have been prepared in accordance with Part 9, Book 2 of the Dutch Civil Code. In accordance with article 362 sub8, Book 2 of the Dutch Civil Code, the company's financial statements are prepared based on the accounting principles of recognition, measurement and determination of profit, as applied in the consolidated IFRS financial statements.

Summary of Significant Accounting Policies
In case no other policies are mentioned, refer to the accounting policies as described in the summary of significant accounting policies in the consolidated IFRS financial statements. For an appropriate interpretation, the company financial statements of argenx SE should be read in conjunction with the consolidated IFRS financial statements.

Participating interests in group companies
Participating interests in group companies are valued using the equity method, applying the IFRS accounting policies endorsed by the European Union. Following the adoption of IFRS 9 by the group, and our interpretation of the Dutch Accounting Standard 100.107A, the company shall, upon identification of a credit loss on an intercompany loan and/or receivable, eliminate the carrying amount of the intercompany loan and/or receivable for the value of the identified credit loss.

Result of participating interests
The share in the result of participating interests consists of the share of the Company in the result of these participating interests. In so far as gains or losses on transactions involving the transfer of assets and liabilities between the Company and its participating interests or between participating interests themselves can be considered unrealized, they have not been recognized.

All amounts are presented in thousands of euro, unless stated otherwise. The balance sheet and income statement references have been included. These refer to the notes.

Correction of an immaterial error
Subsequent to the issuance of the company's financial statements for the year ended December 31, 2019, the company determined that the costs related to the capital increase in the subsidiary argenx BV should not have been presented as "Capital increase argenx BV", but should have been presented as "Receivable on group companies" instead. Management evaluated the materiality of the error from a quantitative and qualitative perspective and concluded that this adjustment was not material to the company's previously issued financial statements. The company has elected to revise the historical financial information presented herein in the company's schedule of movement in financial fixed assets, as presented in note 2, to reflect the correction of this error for the prior period presented and to conform to current year's presentation. Since the revisions were not material, no amendments to previously filed reports were required. The revision had the effect of increasing "Receivable on group companies" and decreasing "Capital increase argenx BV" with €23.0 million as of December 31, 2019.

2. Financial Fixed Assets

The Company has two Belgian subsidiaries, argenx BV and argenx IIP BV, which carry out the research and development activities of the Group. argenx IIP BV was incorporated through a partial demerger of argenx BV in 2020.argenx BV has three subsidiaries, argenx US Inc. (United States), argenx Japan KK (Japan), and argenx Switzerland SA (Switzerland). The financial fixed assets consist of the 100% participations in argenx BV and argenx IIP BV, both registered at Industriepark 7, Zwijnaarde, Belgium.

The movement in financial fixed assets is as follows:

(IN THOUSANDS OF €)	At December 31, 2020	At December 31, 2019
Investments in Group Companies		
Opening Balance	907,174	378,532
Share of loss of investments	(516,258)	(158,608)
Share-based payment expenses of investments	79,714	36,613
Capital increase argenx BV	730,336	650,637
Partial demerger argenx BV	(8,657)	0
Incorporation argenx IIP BV	8,657	0
Capital increase argenx IIP BV	50,000	0
Closing balance	**1,250,966**	**907,174**
Receivable/(payable) on Group companies	831	28,011
Investments in Group companies	**1,251,797**	**935,185**
Other financial assets		
Opening Balance	1	1
Balance as at year-end	**1**	**1**
Total financial fixed assets	**1,251,798**	**935,186**

3 Receivables

(IN THOUSANDS OF €)	At December 31, 2020	At December 31, 2019
Interest receivable	0	25
Other receivables	411	487
Prepaid expenses	4,604	10
Total Receivables	**5,016**	**522**

Receivables fall due in less than one year. The fair value of the receivables approximates the nominal value, due to their short-term character.

4 Financial Assets

(IN THOUSANDS OF €)	At December 31, 2020	At December 31, 2019
Money market funds	4,425	8,999
Term account	0	11,572
Total Financial asssets	**4,425**	**20,571**

5 Cash and Cash Equivalents

(IN THOUSANDS OF €)	At December 31, 2020	At December 31, 2019
Term deposits	56,105	76,354
Current bank accounts	40,053	20,852
Total Cash in banks	**96,157**	**97,206**

6 Equity

For the details on Equity we refer to note 13 of the consolidated IFRS financial statements.
For the details on Share Based Payments we refer to note 14 of the consolidated IFRS financial statements.
The company holds no legal reserves as part of the equity.

7 Current Liabilities

(IN THOUSANDS OF €)	At December 31, 2020	At December 31, 2019
Accounts payable	0	372
Intercompany payables	534	472
Taxes payable	0	598
Accrued expenses	497	1,297
Total Current Liabilities	**1,031**	**2,739**

All current liabilities fall due in less than one year. The fair value of the current liabilities approximates the nominal value, due to their short-term character.

8 Financial Result and Exchange Gains/(Losses)

(IN THOUSANDS OF €)	Year ended December 31, 2020	Year ended December 31, 2019
Interest income on bank deposits	125	1,263
Net gains on investments at FVTPL	0	0
Fees collected from ADS holders	352	357
Interest on I/C current account	0	0
Financial income	**477**	**1,620**
Net losses on investments at FVTPL	(471)	0
Interest expense	(76)	0
Other financial expenses	(24)	(27)
Financial expenses	**(570)**	**(5)**
Exchange gains/(losses)	**(1,330)**	**1,494**
Financial income and expense	**(1,424)**	**3,110**

9 Share in Result of Subsidiaries

(IN THOUSANDS OF €)	Year ended December 31, 2020	Year ended December 31, 2019
argenx BV	(500,818)	(158,608)
argenx IIP BV	(15,440)	0
	(516,258)	**(158,608)**

10 Other Disclosures

CONTINGENT LIABILITIES
The contingent liabilities of the Company consist of a rental agreement for office space at DocWork Breda for an amount of KEUR 6 per annum. The lease can be terminated annually.

RELATED-PARTY TRANSACTIONS
All legal entities that can be controlled, jointly controlled or significantly influenced are considered as a related party. Also, entities which can control the company are considered a related party. In addition, directors, other key management of argenx SE and close relatives are regarded as related parties. Other than the intercompany cross-charges, there were no related party transactions.

REMUNERATION
See note 27 of the notes to the consolidated IFRS financial statements.

INFORMATION RELATING TO EMPLOYEES
During the year 2020, the Company had an average of 0.2 FTE (2019: 0.2 FTE).

AUDITOR'S FEES
See note 30 of the notes to the consolidated IFRS financial statements.

PROPOSAL FOR APPROPRIATION OF THE RESULT
The Company reported a net loss of €528.9 million for the year ended on December 31, 2020. The Board of Directors proposes to carry forward the net loss of the year 2020 to the accumulated losses. Anticipating the approval of the financial statements by the shareholders at the annual general meeting of shareholders, this proposal has already been reflected in the 2020 financial statements.

EVENTS AFTER THE BALANCE SHEET DATE
For the events after balance sheet date, we refer to note 32 of the consolidated IFRS financial statements.

Breda, March 30, 2021
The Director
Tim Van Hauwermeiren, CEO

Other Information

Provision in the Articles of Association Governing the Appropriation of Results

1. The company shall have a policy on reserves and dividends which shall be determined and may be amended by the board of directors. The adoption and thereafter each material change of the policy on reserves and dividends shall be discussed at the general meeting under a separate agenda item.

2. From the profits, shown in the annual accounts, as adopted, the board of directors shall determine which part shall be reserved. Any profits remaining thereafter shall be at the disposal of the general meeting. The board of directors shall make a proposal for that purpose. A proposal to pay a dividend shall be dealt with as a separate agenda item at the general meeting.

3. Distribution of dividends on the shares shall be made in proportion to the nominal value of each share.

4. Distributions may be made only insofar as the company's equity exceeds the amount of the paid in and called up part of the issued capital, increased by the reserves which must be kept by virtue of the law.

5. If a loss was suffered during any one year, the board of directors may resolve to offset such loss by writing it off against a reserve which the company is not required to keep by virtue of the law.

6. The distribution of profits shall be made after the adoption of the annual accounts, from which it appears that the same is permitted.

7. The board of directors may, subject to due observance of the policy of the company on reserves and dividends, resolve to make an interim distribution, provided the requirement of paragraph 4 of this article has been complied with, as shown by interim accounts. Such interim accounts shall show the financial position of the company not earlier than on the first day of the third month before the month in which the resolution to make the interim distribution is announced. Such interim accounts shall be signed by all members of the board of directors. If the signature of one or more of them is missing, this shall be stated and reasons for this omission shall be given. The interim accounts shall be deposited in the offices of the trade register within eight days after the day on which the resolution to make the interim distribution has been announced.

8. At the proposal of the board of directors, the general meeting may resolve to make a distribution on shares wholly or partly not in cash but in shares.

9. The board of directors may, subject to due observance of the policy of the company on reserves and dividends, resolve that distributions to holders of shares shall be made out of one or more reserves.

10. A claim of a shareholder for payment of a distribution shall be barred after five years have elapsed.

Independent Auditor's Report

To the Shareholders and the Board of Directors of argenx SE

Report on the Audit of the Financial Statements for the year ended December 31, 2020 included in the Annual Report

Our opinion
We have audited the accompanying financial statements for the year ended December 31, 2020 of argenx SE, based in Breda, the Netherlands. The financial statements include the consolidated financial statements and the company financial statements.

In our opinion:

- The accompanying consolidated financial statements give a true and fair view of the financial position of argenx SE as at December 31, 2020, and of its result and its cash flows for the year ended December 31, 2020 in accordance with International Financial Reporting Standards as adopted by the European Union (EU-IFRS) and with Part 9 of Book 2 of the Dutch Civil Code.
- The accompanying company financial statements give a true and fair view of the financial position of argenx SE as at December 31, 2020, and of its result for the year ended December 31, 2020 in accordance with Part 9 of Book 2 of the Dutch Civil Code.

The consolidated financial statements comprise:

1. The consolidated statement of financial positionas at December 31, 2020.
2. The following statements for the year ended December 31, 2020: the consolidated statement of profit and loss and other comprehensive income, cash flows and changes in equity.
3. The notes comprising a summary of the significant accounting policies and other explanatory information.

The company financial statements comprise:

1. The company balance sheet as at December 31, 2020.
2. The company profit and loss account for the year ended December 31, 2020.
3. The notes comprising a summary of the accounting policies and other explanatory information.

Basis for our opinion
We conducted our audit in accordance with Dutch law, including the Dutch Standards on Auditing. Our responsibilities under those standards are further described in the "Our responsibilities for the audit of the financial statements" section of our report.

We are independent of argenx SE in accordance with the EU Regulation on specific requirements regarding statutory audit of public-interest entities, the Wet toezicht accountantsorganisaties (Wta, Audit firms supervision act), the Verordening inzake de onafhankelijkheid van accountants bij assurance-opdrachten (ViO, Code of Ethics for Professional Accountants, a regulation with respect to independence) and other relevant independence regulations in the Netherlands. Furthermore, we have complied with the Verordening gedrags-en beroepsregels accountants (VGBA, Dutch Code of Ethics).

We believe the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Materiality
Based on our professional judgement we determined the materiality for the financial statements as a whole at €14,400,000. The materiality is based on 3% of Operating expenses. We have also taken into account misstatements and/or possible misstatements that in our opinion are material for the users of the financial statements for qualitative reasons.

We agreed with the Board of Directors that misstatements in excess of €720,000, which are identified during the audit, would be reported to them, as well as smaller misstatements that in our view must be reported on qualitative grounds.

Scope of the group audit
argenx SE is at the head of a group of entities. The financial information of this group is included in the consolidated financial statements of argenx SE.

Because we are ultimately responsible for the opinion, we are also responsible for directing, supervising and performing the group audit. In this respect we have determined the nature and extent of the audit procedures to be carried out for group entities. The audit procedures on all group entities have been performed by the group engagement team. By performing these procedures,we have been able to obtain sufficient and appropriate audit evidence about the group's financial information to provide an opinion about the consolidated financial statements.

Scope of fraud and non-compliance with laws and regulations within our audit
In accordance with the Dutch Standards on Auditing, we are responsible for obtaining reasonable assurance that the financial statements taken as a whole are free from material misstatements, whether due to fraud or error. Non-compliance with laws and regulations may result in fines, litigation or other consequences for the company that may have a material effect on the financial statements.

Consideration of fraud
In identifying potential risks of material misstatement due to fraud, we obtained an understanding of the company and its environment, including the entity's internal controls. We evaluated the company's fraud risk assessment and made inquiries with management, those charged with governance and with others within the company, including but not limited to, VP Global Compliance, Global Head of QA and Senior Internals Controls Manager. We evaluated several fraud risk factors to consider whether those factors indicated a risk of material misstatement due to fraud. We involved our forensic specialists in our risk assessment and in determining the audit response.

Following these procedures, and the presumed risks under the prevailing auditing standards, we considered the fraud risks in relation to management override of controls, including evaluating whether there was evidence of bias by the Executive Board, the executive leadership team and other members of management, which may represent a risk of material misstatement due to fraud.

As part of our audit procedures to respond to these fraud risks, we evaluated the design and implementation and, where considered appropriate, tested the operating effectiveness of the internal controls relevant to mitigate these risks. We performed substantive audit procedures, including detailed testing of journal entries, evaluating the accounting estimates for bias (including retrospective reviews of prior year's estimates), review of the supporting documentation in relation to post-closing adjustments. We also incorporated elements of unpredictability in our audit. The procedures described are in line with the applicable auditing standards and are not primarily designed to detect fraud.

Our procedures to address fraud risks did notresult in a Key Audit Matter.

Consideration of compliance with laws and regulations
We assessed the laws and regulations relevant to the company through discussion with the legal counsel, reading minutes and reports of internal audit. We involved our forensic specialists in this evaluation.

As a result of our risk assessment procedures, and while realizing that the effects from non-compliance could considerably vary, we considered laws and regulations, adherence to (corporate) tax law and financial reporting regulations, the requirements under the International Financial Reporting Standards as adopted by the European Union (EU-IFRS) and Part 9 of Book 2 of the Dutch Civil Code with a direct effect on the financial statements as an integrated part of our audit procedures, to the extent material for the related financial statements. We obtained sufficient appropriate audit evidence regarding provisions of those laws and regulations generally recognized to have a direct effect on the financial statements.

Apart from these, the company is subject to other laws and regulations where the consequences of non-compliance could have a material effect on amounts and/or disclosures in the financial statements, for instance, through imposing fines or litigation. Given the nature of the company's business and the complexity of laws and regulations, there is a risk of non-compliance with the requirements of such laws and regulations. In addition, we considered major laws and regulations applicable to listed companies.

Our procedures are more limited with respect to these laws and regulations that do not have a direct effect on the determination of the amounts and disclosures in the financial statements. Compliance with these laws and regulations may be fundamental to the operating aspects of the business, to argenx's ability to continue its business, or to avoid material penalties (e.g., compliance with the terms of operating licenses and permits or compliance with environmental regulations) and therefore non-compliance with such laws and regulations may have a material effect on the financial statements. Our responsibility is limited to undertaking specified audit procedures to help identify non-compliance with those laws and regulations that may have a material effect onthe financial statements. Our procedures are limited to (i) inquiry of management, the Supervisory Board, the Executive Board and others within the company as to whether the company is in compliance with such laws and regulations and (ii) inspecting correspondence, if any, with the relevant licensing or regulatory authorities to help identify non-compliance with those laws and regulations that may have a material effect on the financial statements.

Naturally, we remained alert to indications of (suspected) non-compliance throughout the audit.

Finally, we obtained written representations that all known instances of (suspected) fraud or non-compliance with laws and regulations have been disclosed to us.

Because of the characteristics of fraud, particularly when it involves sophisticated and carefully organized schemes to conceal it, such as forgery, intentional omissions, misrepresentation and collusion, an unavoidable risk remains that we may not detect all fraud during our audit.

Our key audit matters
Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the financial statements. We have communicated the key audit matters to the Board of Directors. The key audit matters are not a comprehensive reflection of all matters discussed.

These matters were addressed in the context of our audit of the financial statements as a whole and in forming our opinion thereon, and we do not provide a separate opinion on these

Trade and Other Payables –research and development cost accruals —Refer to Note 15 to the Financial Statements

DESCRIPTION	OUR RESPONSE
The company recognizes costs of EUR 52.6million, as specified in Note 15 to the financial statements, incurred for clinical trial activities as research and development expenses based on evaluation of its vendors' progress toward completion of specific tasks. Vendors' progress during 2020 may be impacted by the effects of the Covid-19 pandemic when compared to original planning. Payment timing may differ significantly from the period in which the costs are recognized as expense, resulting in research and development cost accruals recognized within Trade and Other Payables in the Statement of Financial Position. Quantification of the research progress and the translation of the progress to the research and development cost accruals requires judgment, because the progress is not directly observable. In estimating the vendors' progress toward completion of specific tasks, the company therefore uses data such as patient enrollment, clinical site activations and vendor information of actual costs incurred. This data is obtained through reports from or discussions with company personnel and outside service providers as to the progress or state of completion of trials, or the completion of services. Costs are expensed over the service period the services are provided. Costs for services provided that have not yet been paid are recognized as accruals. Research and development cost accruals also directly impact the revenue recognized from collaboration agreements, given the company records revenue based on the percentage of completion method, whereby research and development cost accruals are used as key input value. We identified the research and development cost accruals as a critical audit matter due to the number of ongoing clinical trial activities and the subjectivity involved in estimating research and development cost accruals and as auditing the research and development cost accruals involves judgement in evaluating the progress of the research and development activities relative to the costs incurred.	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 clinicaltrials, including the monthly review meetings between the finance department and clinical research personnel. • We read selected research and collaboration agreements, as well as amendments thereto, to evaluate whether the progress of the clinical trials reflects all relevant contractual elements. • We considered publicly available information (such as press releases and investor presentations) and board of directors' materials regarding the status of clinical trial activities and compared this informationto the judgements applied in recording the accruals and prepaid expenses. • For a selection of contracts, we compared the amount of accruals at the end of the prior period to current year activity and evaluated the accuracy of the company's estimation methodology. • We performed confirmation procedures related to the progress of the projects for significant vendors to test the research and development cost input calculations. • We made selections of specific amounts recognized as research and development expense as well as those recognized as accrued expenses and performed the following procedures: - Evaluated management's estimate of the vendor's progress based on inquiries with company clinical operations personnel, specifically taking into account potential impact on the vendor's progress as a result of the Covid-19 pandemic. - Reconciled the related statement of work, purchase order, or other supporting documentation to management's estimate (such as communications between the company and vendors). **OBSERVATIONS** The scope and nature of the audit procedures we performed was sufficient and appropriate to address the risks of material misstatement related to the research and development cost accruals.

Compared to prior year we have not included the key audit matter related to Revenue and Deferred Revenue, as this key audit matter addressed the initial accounting treatment of the Cilag GmbH International global collaboration and license agreement.

Report on the other information included in the Annual Report

In addition to the financial statements and our auditor's report thereon,the annual report contains other information that consists of:

- The Business section.
- The Corporate Governance section, including the Remuneration Report.
- Other Information as required by Part 9 of Book 2 of the Dutch Civil Code.

Based on the following procedures performed, we conclude that the other information:

- Is consistent with the financial statements and does not contain material misstatements.
- Contains the information as required by Part 9 of Book 2 of the Dutch Civil Code.

We have read the other information. Based on our knowledge and understanding obtained through our audit of the financial statements or otherwise, we have considered whether the other information contains material misstatements.

By performing these procedures, we comply with the requirements of Part 9 of Book 2 of the Dutch Civil Code and the Dutch Standard 720. The scope of the procedures performed is substantially less than the scope of those performed in our audit of the financial statements.

Management is responsible for the preparation of the other information, including the Management Board's Report in accordance with Part 9 of Book 2 of the Dutch Civil Code, and the other information as required by Part 9 of Book 2 of the Dutch Civil Code.

Report on the other legal and regulatory requirements

Engagement
We were engaged by the Board of Directors as auditor of argenx SE on May 13, 2015, as of the audit for the year 2015 and have operated as statutory auditor ever since that financial year.

No prohibited non-audit services
We have not provided prohibited non-audit services as referred to in Article 5(1) of the EU Regulation on specific requirements regarding statutory audit of public-interest entities.

Description of responsibilities regarding the Financial Statements

Responsibilities of management and the Board of Directors for the financial statements
Management is responsible for the preparation and fair presentation of the financial statements in accordance with EU-IFRS and Part 9 of Book 2 of the Dutch Civil Code. Furthermore, management is responsible for such internal control as management determines is necessary to enable the preparation of the financial statements that are free from material misstatement, whether due to fraud or error.

As part of the preparation of the financial statements, management is responsible for assessing the company's ability to continue as a going concern. Based on the financial reporting frameworks mentioned, management should prepare the financial statements using the going concern basis of accounting unless management either intends to liquidate the company or to cease operations, or has no realistic alternative but to do so.

Management should disclose events and circumstances that may cast significant doubt on the company's ability to continue as a going concern in the financial statements.

The Board of Directors is responsible for overseeing the company's financial reporting process.

Our responsibilities for the audit of the financial statements
Our objective is to plan and perform the audit assignment in a manner that allows us to obtain sufficient and appropriate audit evidence for our opinion.

Our audit has been performed with a high, but not absolute, level of assurance, which means we may not detect all material errors and fraud during our audit.

Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

The materiality affects the nature, timing and extent of our audit procedures and the evaluation of the effect of identified misstatements on our opinion. We have exercised professional judgement and have maintained professional skepticism throughout the audit, in accordance with Dutch Standards on Auditing, ethical requirements and independence requirements. Our audit included e.g.:

- Identifying and assessing the risks of material misstatement of the financial statements, whether due to fraud or error, designing and performing audit procedures responsive to those risks, and obtaining audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtaining an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.
- Evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.
- Concluding on the appropriateness of management's use of the going concern basis of accounting, and based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the company to cease to continue as a going concern.
- Evaluating the overall presentation, structure and content of the financial statements, including the disclosures.
- Evaluating whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

We communicate with the Board of Directors regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant findings in internal control that we identified during our audit. In this respect we also submit an additional report to the audit committee in accordance with Article 11 of the EU Regulation on specific requirements regarding statutory audit of public-interest entities. The information included in this additional report is consistent with our audit opinion in this auditor's report.

We provide the Board of Directors with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated with the Board of Directors, we determine the key audit matters: those matters that were of most significance in the audit of the financial statements. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, not communicating the matter is in the public interest.

Rotterdam, March 30, 2021

Deloitte Accountants
P.J. Seegers

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