argenx SE
(a European public company with limited liability (Societas Europaea) incorporated under the laws of the Netherlands with its official seat in Rotterdam, the Netherlands)

This document constitutes a registration document (the ***Registration Document***) for the purposes of article 3 of directive 2003/71/EC of the European Parliament and of the Council of the European Union (as amended, including by Directive 2010/73/EU, the ***Prospectus Directive***) and has been prepared by argenx SE (the Company or argenx) in accordance with Chapter 5.1 of the Dutch Financial Supervision Act (*Wet op het financieel toezicht*) (the ***DFSA***). This Registration Document has been filed with and approved by the Dutch Authority for the Financial Markets (*Stichting Autoriteit Financiële Markten*) (the ***AFM***).

This Registration Document is to be read in conjunction with a securities note and summary, to be published at a later stage, and which will together with this Registration Document constitute a listing prospectus for the purposes of article 3 of the Prospectus Directive (the ***Prospectus***). The Prospectus will, upon approval thereof by the AFM, be notified by the AFM to the Belgian Financial Services and Markets Authority (the ***FSMA***) for passporting in accordance with article 18 of the Prospectus Directive.

Investing in the company's securities involves substantial risks and uncertainties. An investor is exposed to the risk to lose all or part of his investment. Before making any investment in the company's securities, an investor must read the entire document consisting of the summary, securities note and the Registration Document and in particular Part 1 "Risk Factors" of the Registration Document consisting of (i) Risks Related to Our Financial Position and Need for Additional Capital (from page 4 to 7 of the Registration Document), (ii) Risks Related to the Development and Clinical Testing of Our Product Candidates (from page 7 to 14 of the Registration Document), (iii) Risks Related to Commercialization of Our Product Candidates (from page 14 to 26 of the Registration Document), (iv) Risks Related to Our Business and Industry (from page 26 to 30 of the Registration Document), (v) Risks Related to Our Dependence on Third Parties (from page 30 to 33 of the Registration Document), (vi) Risks Related to Intellectual Property (from page 33 to 42 of the Registration Document), (vii) Risks Related to Our Organization and Operations (from page 42 to 46 of the Registration Document) and (viii) Risks related to securities in the Company (from page 46 to 55 of the Registration Document). Our main assets are intellectual property rights concerning technologies that have not led to the commercialization of any product. We have never been profitable and have never commercialized any products.

Registration Document, dated 26 March 2019.

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1 RISK FACTORS

Holders of Securities and prospective holders of Securities should carefully consider the risk factors set out below, together with the other information contained in this Registration Document and any subsequent Securities Note, before making an investment decision with respect to investing in the Company. All of these factors are contingencies which may or may not occur. We believe that the risks and uncertainties described below are all material risks and uncertainties relating to the Company and its subsidiaries. If additional risks and uncertainties not presently known to us or that are currently deemed to be immaterial, occur, this may also have a material adverse effect on our business, prospects, results of operation and financial condition. If any of those risks or uncertainties occurs, the price of the Securities may decline and holders of Securities and prospective holders of Securities could lose all or part of their investment.

In addition to carefully considering the Risk factors set out below, this entire Registration Document and any subsequent Securities Note(s), holders of Securities and prospective holders of Securities should also consult, before making an investment decision with respect to the Securities, their own financial, legal and tax advisors to carefully review the risks associated with an investment in the Securities and consider such an investment decision in light of their personal circumstances.

Risks Related to Our Financial Position and Need for Additional Capital

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

We are a clinical-stage biopharmaceutical company with a limited operating history. Since our inception, we have incurred significant operating losses. We incurred losses for the year and total comprehensive losses of €66.1 million and €28.1 million for the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, we had accumulated losses of €169.0 million. Our losses resulted principally from costs incurred in research and development, preclinical testing, clinical development of our product candidates as well as costs incurred for research programs and from general and administrative costs associated with our operations. In addition, we expect to continue to incur significant costs associated with our listings in the United States and in Europe. In the future, we intend to continue to conduct research and development, preclinical testing, clinical trials and regulatory compliance activities and we intend to establish a sales, marketing and distribution infrastructure. These expenses, together with anticipated general and administrative expenses, will result in incurring further significant losses for the next several years. Our losses, among other things, will continue to cause our working capital and shareholders' equity to decrease. We anticipate that our expenses will increase substantially if and as we:

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

Since our inception in 2008, we have invested most of our resources in developing our product candidates, building our intellectual property portfolio, developing our supply chain, conducting business planning, raising capital and providing general and administrative support for these operations. We do not currently have any approved products and have never generated any revenue from product sales. To date, we have funded our operations through public

and private placements of equity securities, upfront, milestone and expense reimbursement payments received from our collaborators, funding from governmental bodies and interest income from the investment of our cash, cash equivalents and financial assets.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, discovering and developing additional product candidates, obtaining regulatory approval for any product candidates that successfully complete clinical trials, establishing manufacturing and marketing capabilities and ultimately selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability.

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

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

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

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

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

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

We expect that the costs of development and commercialization will significantly increase due to the extended product development roadmap for cusatuzumab as part of our collaboration with Janssen Pharmaceuticals, Inc., or

Janssen. Although this collaboration agreement provides a joint decision process to approve the development plan as well as the budget, we will not control the actual amounts spent within such approved budget and we cannot control or guarantee that these funds are spent in the most efficient way.

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

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

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

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

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

Since our inception in 2008, we have invested most of our resources in developing our product candidates, building our intellectual property portfolio, developing our supply chain, conducting business planning, raising capital and providing general and administrative support for these operations. Our most advanced candidate, efgartigimod, completed a Phase 2 clinical trial for the treatment of MG and ITP. In September 2018, we launched our first Phase 3 clinical trial in MG. We also have a third ongoing Phase 2 clinical trial of efgartigimod for the treatment of PV and announced the analysis of efgartigimod in a fourth indication, CIDP. We also concluded a Phase 1 clinical trial of a subcutaneous formulation of efgartigimod for the treatment of chronic autoimmune diseases. We have not yet demonstrated an ability to obtain regulatory approvals, manufacture a commercial-scale product or conduct sales and marketing activities necessary for successful product commercialization. In addition, given our limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors in achieving our business objectives. If we are successful at completing the approval process for one of our product candidates, we may consider transitioning from our current research and development focus to focusing on commercializing our products. We may not be successful in such a transition or may incur greater costs than expected, which would materially adversely affect our business, prospects, financial condition and results of operation. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from quarter

to quarter and year to year due to a variety of factors, many of which are beyond our control. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or more experience developing and commercializing antibody-based drugs.

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

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

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

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

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

- delays in or failure to obtain regulatory approval to commence a trial, including as a result of circumstances beyond our control such as the partial shutdown of operations at U.S. governmental agencies involved in granting necessary approvals;
- delays in or failure to reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in or failure to obtain institutional review board, or IRB, or ethics committee approval at each site;
- delays in or failure to recruit suitable patients to participate in a trial;
- failure to have patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- adding new clinical trial sites;
- manufacturing sufficient quantities of product candidate for use in clinical trials;
- third-party actions claiming infringement by our product candidates in clinical trials and obtaining injunctions interfering with our progress;
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires;
- safety or tolerability concerns could cause us or our collaborators, as applicable, to suspend or terminate a trial if we or our collaborators find that the participants are being exposed to unacceptable health risks;
- changes in regulatory requirements, policies and guidelines;
- lower than anticipated retention rates of patients and volunteers in clinical trials;
- our third-party research contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- delays in establishing the appropriate dosage levels in clinical trials;
- the difficulty in certain countries in identifying the sub-populations that we are trying to treat in a particular trial, which may delay enrollment and reduce the power of a clinical trial to detect statistically significant results; and
- the quality or stability of the product candidate falling below acceptable standards.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted or ethics committees, by the Data Review Committee, or DRC, or Data Safety Monitoring Board, or DSMB, for such trial or by the EMA, the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or

trial site by the EMA, the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, including those relating to the class to which our product candidates belong, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates and impair our ability to commercialize our product candidates and may harm our business and results of operations.

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

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

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

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

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

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

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

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

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

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

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

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

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

The results of future clinical studies may show that our product candidates cause undesirable or unacceptable side effects or even death. In such an event, our trials could be suspended or terminated and the FDA, the EMA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these

occurrences may harm our business, financial condition and prospects significantly. Further, because all of our product candidates and preclinical programs, other than efgartigimod, are based on our SIMPLE Antibody™ platform, any adverse safety or efficacy findings related to any product candidate or preclinical program may adversely impact the viability of our other product candidates or preclinical programs.

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

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

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

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

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

Competition in the autoimmune field is intense and involves multiple monoclonal antibodies, other biologics and small molecules either already marketed or in development by many different companies including large pharmaceutical companies such as AbbVie Inc. (Humira/rheumatoid arthritis); Amgen Inc. (Enbrel/rheumatoid arthritis); Biogen, Inc. (Tysabri/multiple sclerosis); GlaxoSmithKline plc, or GSK, (Benlysta/lupus); F. Hoffman-La Roche AG,

or Roche, (Rituxan/often used off label); and Janssen (Remicade/rheumatoid arthritis and Stelara/psoriasis). In some cases, these competitors are also our collaborators. In addition, these and other pharmaceutical companies have monoclonal antibodies or other biologics in clinical development for the treatment of autoimmune diseases. In addition to the current standard of care, we are aware that Alexion Pharmaceuticals, Inc. is selling Soliris for the treatment of adult patients with generalized MG who are anti-acetylcholine receptor antibody positive and that GSK; Roche; Novartis AG; CSL Behring; Grifols, S.A.; BioMarin Pharmaceutical Inc.; Curavac, Millenium Pharmaceuticals, Inc., UCB S.A.; Ra Pharmaceuticals and Momenta Pharmaceuticals, among others, are developing drugs that may have utility for the treatment of MG. We are aware that Rigel Pharmaceuticals, Inc.; Dova Pharmaceuticals.; Bristol-Myers Squibb; Immunomedics; Protalex Inc. Principia Biopharma and others are developing drugs that may have utility for the treatment of ITP. We are aware that Roche is selling Rituxan for the treatment of moderate to severe PV and Principia; Alexion and others are developing drugs that may have utility for the treatment of PV. Furthermore, we are aware of competing products specifically targeting FcRn and being developed by UCB S.A.; Momenta, Inc.; Alexion; Immunovant and Affibody.

Competition in the leukemia and lymphoma space is intense, with many compounds in clinical trials by large multinational pharmaceutical companies and specialized biotech companies. Rituxan (Roche), Adcetris (Seattle Genetics, Inc. /Takeda Pharmaceutical Company Ltd), Darzalex (Janssen) and Poteligeo (Kyowa Hakko Kirin Co., Ltd.) are some examples of monoclonal antibodies approved for the treatment of Hodgkin's lymphoma, non-Hodgkin's lymphoma, multiple myeloma or other blood cancers. We are aware of AML drugs recently approved by the FDA, such as Daurismo (Pfizer), Mylotarg (Pfizer), Rydapt (Amgen), 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 ABBV-151 (formerly named ARGX-115) and a product candidate in development by Ionis Pharmaceuticals, Inc. may compete with ARGX-116, if they are approved.

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

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

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

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

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

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

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

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

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

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

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

- the FDA, the EMA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials, including the size of our clinical trials or the doses tested;

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

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

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

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

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

Our product candidates are classified as biologics in the United States and, therefore, can only be sold if we obtain a BLA from the FDA. The holder of a BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The holder of a BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing

process. Failure to comply with a BLA or any other ongoing regulatory obligation may result in suspension of approval to manufacture or distribute the relevant product, as well as fines or imprisonment for violations.

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

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

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

Risks Related to Commercialization of Our Product Candidates

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

Legislative processes in progress that may have a material impact on us

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

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

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

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

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

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

Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed repeal legislation, it has enacted laws that modify certain provisions of the ACA, such as removing or delaying penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance, delaying the implementation of certain ACA-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. On December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and 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. 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.

Proposed future legislative actions which may have a material impact on us

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These new laws may result in additional reductions in Medicare and other healthcare funding. For example, on August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.

2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including without limitation the Bipartisan Budget Act of 2015, will remain in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

Other administrative measures which may have a material impact on us

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

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

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

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

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

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

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

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

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

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

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

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

applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

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

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

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

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

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

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

worldwide annual turnover for certain comparatively minor offenses, or up to 20,000,000 Euros or up to 4% of our total worldwide annual turnover for more serious offenses. Given the new law, we face uncertainty as to the exact interpretation of the new requirements, and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the new law.

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

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

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

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

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

We may from time to time seek orphan drug designation in the United States or Europe for certain indications addressed by our product candidates. For example, in September 2017, the FDA granted orphan drug designation for the use of efgartigimod for the treatment of MG. Even if we are able to obtain orphan designation, we may not be the first to obtain marketing approval for such indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek

approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan drug is approved, the FDA or the EMA can subsequently approve the same drug with the same active moiety for the same condition if the FDA or the EMA concludes that the later drug is safer, more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

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

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

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

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

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

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

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

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

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

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

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

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

Our product candidates are at varying stages of development and we may never have a product that is commercially successful. To date, we have no product authorized for marketing. Our lead product candidates are in early stages of clinical development. Our lead product candidates will require further clinical investigation, regulatory review, significant marketing efforts and substantial investment before they can provide us with any revenues. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many other companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval for the marketing of their product. Due to the inherent risk in the development of pharmaceutical products, it is probable that not all or none of the product candidates in our portfolio will successfully complete development and be commercialized. We do not expect to be able to commercialize any

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

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

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

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

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

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;
- the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false, fictitious, or fraudulent or knowingly making, using, or causing to made or used a false record or statement to avoid, decrease, or conceal an obligation to pay money to the federal government;
- HIPAA, which created additional federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by HITECH, and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose obligations, including mandatory contractual terms,

with respect to safeguarding the privacy, security and transmission of individually identifiable health information without the appropriate authorization by entities subject to the law, such as healthcare providers, health plans and healthcare clearinghouses and their respective business associates;

- the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the Patient Protection and the ACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or CMS, within the U.S. Department of Health and Human Services, information related to payments and other transfers of value made by that entity to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

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

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

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

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

We do not have a sales or marketing infrastructure and have no experience in the sale or marketing of pharmaceutical products. To achieve commercial success for any approved product, we must develop or acquire a sales and marketing organization, outsource these functions to third parties or enter into collaboration arrangements with third parties.

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

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

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

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

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

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty. See also part 7 "Business" of this Registration Document.

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

Risks Related to Our Business and Industry

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

The international biopharmaceutical and medical technology industry is highly regulated by the FDA, the EMA and other comparable foreign authorities and by other national or supra-national regulatory authorities that impose substantial requirements covering nearly all aspects of our activities notably on research and development, manufacturing, preclinical tests, clinical trials, labeling, marketing, sales, storage, record keeping, promotion and pricing of

our product candidates. Such regulation is further subject to regular review by the FDA, the EMA and other comparable foreign authorities which may result in changes in applicable regulation. If we do not comply with one or more of these requirements in a timely manner, or at all, our product development could experience significant delays as a result of the FDA, the EMA or other comparable regulatory authorities recommending non-approval or restrictions on approval of a product candidate, leading to an inability to successfully commercialize any of our product candidates, which would materially harm our business. Any failure of any of our product candidates in clinical studies or to receive regulatory approval could have a material adverse effect on our business, results of operations and financial condition. If any of our product candidates fails to obtain approval on the basis of any applicable condensed regulatory approval process, this will prevent such product candidate from obtaining approval in a shortened time frame, or at all, resulting in increased expenses which would materially harm our business.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our business may be adversely affected as a result of computer system failures. We may suffer data leaks or become the target of cyber-attacks, as a result of which our financial assets, confidential information

and/or intellectual property may be materially negatively impacted. We may not be able to successfully protect our computer systems against unauthorized access by third parties.

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

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

Risks Related to Our Dependence on Third Parties

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

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

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

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

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

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

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

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

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

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

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

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

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

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

third parties for the production of our product candidates in accordance with relevant regulations (such as cGMP), which includes, among other things, quality control, quality assurance and the maintenance of records and documentation.

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

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

The manufacturing of all of our product candidates requires using cells which are stored in a cell bank. We have one master cell bank for each product manufactured in accordance with cGMP. Working cell banks have not yet been manufactured. Half of each master cell bank is stored at a separate site so that in case of a catastrophic event at one site we believe sufficient vials of the master cell banks are left at the alternative storage site to continue manufacturing. We believe sufficient working cell banks could be produced from the vials of the master cell bank stored at a given site to assure product supply for the future. However, it is possible that we could lose multiple cell banks and have our manufacturing significantly impacted by the need to replace these cell banks, which could materially adversely affect our business, prospects, financial condition and results of operations.

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

We have collaborated, and plan to continue to collaborate, with third parties on product candidates that we believe have promising utility in disease areas or patient populations that are better served by resources of larger biopharmaceutical companies. See "Collaborations" in Part 7 "Business" for a more detailed description of these collaborations. As part of some of these collaborations, our collaboration partners are responsible for providing us with financial information regarding specific projects, including funds spent, liabilities incurred and expected future costs, on which we rely for our own financial reporting. In the event that our collaboration partners fail to provide us with the necessary financial information within the agreed upon timeframes, or if such financial information proves partially inaccurate, this is likely to impact the accuracy of our own financial reporting. Any inaccuracy in our financial

reporting could cause investors to lose confidence in our financial reporting, which may negatively impact the price of our Securities.

Risks Related to Intellectual Property

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

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

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

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

a pending patent application. Even if patents do successfully issue and even if such patents cover our product candidates, third parties may initiate an opposition, interference, re-examination, post-grant review, *inter partes* review, nullification or derivation action in court or before patent offices, or similar proceedings challenging the validity, enforceability or scope of such patents, which may result in the patent claims being narrowed or invalidated. Our and our licensors', licensees' or collaboration partners' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology.

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

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

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

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

Intellectual property rights of third parties could adversely affect our ability to commercialize our product candidates, such that we could be required to litigate or obtain licenses from third parties in order to de-

velop or market our product candidates. Such litigation or licenses could be costly or not available on commercially reasonable terms.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We are a party to license agreements under which we are granted rights to intellectual property that are important to our business and we expect that we may need to enter into additional license agreements in the future. Existing license agreements impose, and we expect that future license agreements will impose, various development obligations, payment of royalties and fees based on achieving certain milestones, as well as other obligations. If we fail to comply with our obligations under these agreements, the licensor may have the right to terminate the license. The termination of any license agreements or failure to adequately protect such license agreements could prevent us from commercializing product candidates covered by the licensed intellectual property. Several of our existing license agreements are sublicenses from third parties which are not the original licensor of the intellectual property at issue. Under these agreements, we must rely on our licensor to comply with its obligations under the primary license agreements under which such third party obtained rights in the applicable intellectual property, where we may have no relationship with the original licensor of such rights. If the licensors fail to comply with their obligations under these upstream license agreements, the original third-party licensor may have the right to terminate the orig-

inal license, which may terminate the sublicense. If this were to occur, we would no longer have rights to the applicable intellectual property and, in the case of a sublicense, if we were not able to secure our own direct license with the owner of the relevant rights, which it may not be able to do at a reasonable cost or on reasonable terms, it may adversely affect our ability to continue to develop and commercialize the product candidates incorporating the relevant intellectual property.

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

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

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

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

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

- others may be able to make compounds that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- the patents of third parties may have an adverse effect on our business;
- we or our licensors or any current or future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or any future strategic partners might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- third parties performing manufacturing or testing for us using our products or technologies could use the intellectual property of others without obtaining a proper license;
- we may not develop additional technologies that are patentable; and
- the patents of others may have an adverse effect on our business. In particular, our product candidates may in the future be tested for new indications. If one of our product candidates would prove to be effective against a specific new indication, we may be confronted with existing patents covering such indication.

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

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

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

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

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

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

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

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

Failure to obtain or maintain trade secrets or confidential know-how trade protection could adversely affect our competitive position. Moreover, our competitors may independently develop substantially equivalent proprietary

information and may even apply for patent protection in respect of the same. If successful in obtaining such patent protection, our competitors could limit our use of our trade secrets or confidential know-how.

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

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

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

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

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

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

Risks Related to Our Organization and Operations

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

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

The loss of key managers and senior scientists could delay our research and development activities. In addition, our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified management, scientific and medical personnel. Many other biotechnology and pharmaceutical companies and academic institutions that we compete against for qualified personnel have

greater financial and other resources, different risk profiles and a longer history in the industry than we do. Therefore, we might not be able to attract or retain these key persons on conditions that are economically acceptable. Furthermore, we will need to recruit new managers and qualified scientific, commercial, regulatory and financial personnel to develop our business if we expand into fields that will require additional skills. Our inability to attract and retain these key persons could prevent us from achieving our objectives and implementing our business strategy, which could have a material adverse effect on our business and prospects.

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

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

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

Since our inception in 2008, we have grown organically without any acquisitions. Should we in the future contemplate to acquire any complementary business, product candidates or technologies, our ability to integrate and manage acquired businesses, product candidates or technologies effectively will depend upon a number of factors including the size of the acquired business, the complexity of any product candidate or technology and the resulting difficulty of integrating the acquired business's operations, if any. Our relationship with current employees or employees of any acquired business may become impaired. We may also be subject to unexpected claims and liabilities arising from such acquisitions. These claims and liabilities could be costly to defend, could be material to our financial position and might exceed either the limitations of any applicable indemnification provisions or the financial resources of the indemnifying parties. There can also be no assurance that we will be able to assess ongoing profitability and identify all actual or potential liabilities of a business, product candidate or technology prior to its acquisition. If we acquire businesses, product candidates or technologies that result in assuming unforeseen liabilities in respect of which it has not obtained contractual protections or for which protection is not available, this could materially adversely affect our business, prospects, financial condition and results of operations.

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

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

- economic weakness, including inflation, or political instability in particular non-U.S. economies and markets;
- differing regulatory requirements for drug approvals;
- differing jurisdictions could present different issues for securing, maintaining or obtaining freedom to operate in such jurisdictions;
- potentially reduced protection for intellectual property rights;
- difficulties in compliance with different, complex and changing laws, regulations and court systems of multiple jurisdictions and compliance with a wide variety of foreign laws, treaties and regulations;
- changes in regulations and customs, tariffs and trade barriers;
- changes in currency exchange rates of the euro, U.S. dollar, British pound and Swiss francs and currency controls;
- changes in a specific country's or region's political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by governments;
- differing reimbursement regimes and price controls in certain international markets;
- negative consequences from changes in tax laws;

- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad, including, for example, the variable tax treatment in different jurisdictions of stock options granted under our share-based employee incentive plans;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- litigation or administrative actions resulting from claims against us by current or former employees or consultants individually or as part of class actions, including claims of wrongful terminations, discrimination, misclassification or other violations of labor law or other alleged conduct;
- litigation resulting from claims against us by third parties, including claims of breach of noncompete and confidentiality provisions of our employees' former employment agreements with such third parties;
- difficulties associated with staffing and managing international operations, including differing labor relations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

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

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

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

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

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

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

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

affected by fluctuations in foreign exchange rates between the euro and these other currencies, which may also have a significant impact on our reported results of operations and cash flows from period to period. Currently, we do not have any exchange rate hedging arrangements in place.

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

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

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

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

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

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

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

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

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

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

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

Furthermore, as explained in detail in chapter 8, we have effected a restructuring of our intellectual property rights involving a transfer of those rights from argenx SE to our Belgian subsidiary argenx BVBA. The restructuring resulted in a taxable amount for argenx SE of €2.4 million subject to Dutch corporate income tax and an elimination of its tax loss carry forwards for Dutch corporate income tax purposes in an amount of €77.5 million. The restructuring is expected to bring additional deductible costs to the Belgian BVBA for an amount of up to €80 million. However, whether we will be allowed to treat the amount of €80 million as a deductible cost for the Belgian BVBA depends on the outcome of a ruling procedure we have initiated and of which we do not control the outcome. We may not obtain the tax ruling from the Belgian ruling commission and we may not be allowed to treat the amount of €80 million as a deductible cost for the Belgian BVBA, which would lead to a loss of deductible costs. If the Company would become profitable in the future, and these deductible costs are not or no longer useable, we may face a higher tax burden as a result thereof, which would impact our operating results and financial condition for the relevant period.

Risks Related to Securities in the Company

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

The trading price of the Securities has fluctuated, and is likely to continue to fluctuate, substantially. The trading price of the Securities depends on a number of factors, including those described in this Part 1 "Risk Factors", many of which are beyond our control and may not be related to our operating performance. In addition, although the ADSs are listed on the Nasdaq Global Select Market and our ordinary shares are listed on Euronext Brussels, we cannot assure you that a trading market for those Securities will be maintained.

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

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

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

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

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

Fluctuations in exchange rates may increase the risk of holding our Securities.

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

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

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

In the event of an increase in our share capital, holders of our ordinary shares are generally entitled under Dutch law to full pre-emptive rights, unless these rights are excluded either by a resolution of the shareholders at the General Meeting, or by a resolution of the board of directors (if the board of directors has been designated by the shareholders at the General Meeting for this purpose). See Part 12 "Description of share capital and group structure—Pre-emptive rights" of this Registration Document. However, making pre-emptive rights available to holders of ordinary shares or ADSs representing ordinary shares also requires compliance with applicable securities laws in the jurisdictions where holders of those securities are located, which we may be unable or unwilling to do. In particular, holders of ordinary shares or ADSs located in the United States would not be able to participate in a pre-emptive rights offering unless we registered the securities to which the rights relate under the Securities Act or an exemption from the registration requirements of that Act is available. In addition, ADS holders would not be able to participate in a pre-emptive rights offering unless we made arrangements with the depositary to extend that offering to ADS holders, which we are not required to do.

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

We are a Dutch European public company with limited liability (Societas Europaea or SE). Our corporate affairs are, governed by our Articles of Association and by the laws governing companies incorporated in the Netherlands. The rights of shareholders and the responsibilities of members of our board of directors may be different from the rights and obligations of shareholders in companies governed by the laws of U.S. jurisdictions. In the performance of its duties, our board of directors is required by Dutch law to consider the interests of our company, our shareholders, our employees and other stakeholders, in all cases with due observation of the principles of reasonableness and fairness. It is possible that some of these parties will have interests that are different from, or in addition to, your interests as a shareholder. See Part 9 "Management" of this Registration Document.

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

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

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

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our board of directors on our internal control over financial reporting. We ceased to be an emerging growth company on December 31, 2018, and, as such, are now required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we are engaged in a process to document and evaluate our internal control over financial reporting, which is challenging and involves substantial accounting expenses. In this regard, we will need to continue to dedicate internal resources, including significant management time, potentially engage outside

consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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

We have a number of significant shareholders. For an overview of our current significant shareholders, please see "Principal Shareholders." At the date of this Registration Document, these significant shareholders and their affiliates, in the aggregate, own approximately 33.6% of our Securities.

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

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

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

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

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

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

As a Dutch European public company with limited liability (*Societas Europaea* or *SE*), we are subject to the Dutch Corporate Governance Code, or the DCGC. The DCGC contains both principles and best practice provisions for board of directors, management boards, supervisory boards, shareholders and general meetings of shareholders, financial reporting, auditors, disclosure, compliance and enforcement standards. The DCGC applies to all Dutch

companies listed on a regulated market, including Euronext Brussels. The principles and best practice provisions apply to our board of directors (in relation to role and composition, conflicts of interest and independency requirements, board committees and remuneration), shareholders and the General Meeting (for example, regarding anti-takeover protection and our obligations to provide information to our shareholders) and financial reporting (such as external auditor and internal audit requirements). We do not comply with all the best practice provisions of the DCGC. As a Dutch company, we are required to disclose in our annual report, filed in the Netherlands, whether we comply with the provisions of the DCGC. If we do not comply with the provisions of the DCGC (for example, because of a conflicting Nasdaq requirement or otherwise), we must list the reasons for any deviation from the DCGC in our annual report. Please refer to the section 'Corporate Governance Rules' under chapter 9 'Management' of this RD for a detailed discussion of the provisions of the DCGC with which we currently do not comply.

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

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

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

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

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

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

We report under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as a non-U.S. company with foreign private issuer status. Because we qualify as a foreign private issuer under the Exchange Act, we are exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including (i) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act; (ii) the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and (iii) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events. In addition, foreign private issuers are not required to file their annual report on Form 20-F until 120 days after the end of each fiscal year, while U.S. domestic issuers that are accelerated filers are required to file their annual report on Form 10-K within 75 days after the end of each fiscal year. Foreign private issuers are also exempt from the Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information. As a result of the above, you may not have the same protections afforded to shareholders of companies that are not foreign private issuers. However, we are subject to Dutch laws and regulations, and if we complete our possible redomiciliation, Belgian laws and regulations, with regard to such matters and intend to furnish quarterly unaudited financial information to the SEC on Form 6-K.

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

We qualify as a foreign private issuer. As a result, in accordance with the listing requirements of Nasdaq, we rely on home country governance requirements and certain exemptions thereunder rather than relying on the corporate governance requirements of Nasdaq. In accordance with Dutch law and generally accepted business practices, our Articles of Association do not provide quorum requirements generally applicable to General Meetings. To this extent, our practice varies from the requirement of Nasdaq Listing Rule 5620(c), which requires an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting stock. Although we must provide shareholders with an agenda and other relevant documents for the General Meeting, Dutch law does not have a regulatory regime for the solicitation of proxies and the solicitation of proxies is not a generally accepted business practice in the Netherlands, thus our practice will vary from the requirement of Nasdaq Listing Rule 5620(b). In addition, we have opted out of certain Dutch shareholder approval requirements for the issuance of securities in connection with certain events such as the acquisition of stock or assets of another company, the establishment of or amendments to equity-based compensation plans for employees, a change of control of us and certain private placements. To this extent, our practice varies from the requirements of Nasdaq Rule 5635, which generally requires an issuer to obtain shareholder approval for the issuance of securities in connection with such events. For an overview of our corporate governance principles, see Part 9 "Management". Accordingly, you may not have the same protections afforded to shareholders of companies that are subject to these Nasdaq requirements.

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

We are a foreign private issuer, and therefore we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers. We may no longer be a foreign private issuer as of June 30, 2019 (the end of our second fiscal quarter in the fiscal year after our initial U.S. public offering), which would require us to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers as of January 1, 2020 and would also trigger a 10-K filing for the year ended December 31, 2019. In order to maintain our current status as a foreign private issuer, either (a) a majority of our ordinary shares must be either directly or indirectly owned of record by non-residents of the United States or (b)(i) a majority of our executive officers or directors may not be U.S. citizens or residents, (ii) more than 50% of our assets cannot be located in the United States and (iii) our business must be administered

principally outside the United States. As of March 22, 2019[1], we believe at least 50% of our outstanding ordinary shares were held by U.S. residents (assuming that all our ordinary shares represented by ADSs were held by residents of the United States). If we lose this status, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC and Nasdaq rules. The regulatory and compliance costs to us under U.S. securities laws if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be significantly higher than the cost we would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities highly time consuming and costly. We also expect that if we were required to comply with the rules and regulations applicable to U.S. domestic issuers, it would make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our board of directors.

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

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

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

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

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

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in

[1] **Note:** to be confirmed at final filing date.

our financial and other public reporting, which would harm our business and the trading price of the Securities.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of the Securities.

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

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

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

In connection with the risk assessment process and the design and implementation of our updated internal control frameworks as of December 31, 2018, we identified material weaknesses relating to the effectiveness of risk assessment, design and implementation and operating effectiveness of control Activities, information and communication and monitoring activities as of December 31, 2018. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. The company com-

menced the risk assessment process and the design and implementation of updated internal control frameworks for activities related to argenx. These processes covered the following activities: revenues and accounts receivable, other income, expenditure and payables, the financial closing and reporting process and general information technology controls ("GITC"). The GITC deficiencies are related to the financial reporting system and the scope and conclusion of the service auditors' reports for the service organizations used by argenx's accounting software. These risk assessment activities were undertaken to establish control frameworks necessary to support the company. However, the risk assessment process and the design and implementation of these control frameworks were not completed as of December 31, 2018, and certain business process controls and GITCs were not implemented in a timely manner to operate with a sufficient number of instances or for a sufficient period of time to have effective monitoring activities as of December 31, 2018.

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

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

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

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

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

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

The trading market for the Securities will depend in part on the research and reports that securities or industry analysts publish about us or our business. If no or too few securities or industry analysts cover us, the trading price for the Securities would likely be negatively affected. If one or more of the analysts who cover us downgrade the Securities or publish inaccurate or unfavorable research about our business, the price of the Securities would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for the Securities could decrease, which might cause the price of the Securities and trading volume to decline.

We do not anticipate being treated as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes for the 2018 taxable year, but this conclusion is a factual determination that is made

annually and thus may be subject to change. If we were to qualify as a PFIC, this could result in adverse U.S. tax consequences to certain U.S. holders.

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

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

2 IMPORTANT INFORMATION

Responsibility Statements

We, represented by our board of directors, assume responsibility for the information contained in this Registration Document. We, represented by our board of directors, declare that, having taken all reasonable care to ensure that such is the case, the information contained in this Registration Document is, to the best of our knowledge and the knowledge of our directors, in accordance with the facts and contains no omission likely to affect its import. Any information 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, does not omit any facts 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 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 the our shares.

Capitalized Terms

Unless otherwise stated, capitalized terms used in this Registration Document have the meaning set out in Part 15 "Definitions and glossary" of this Registration Document.

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 Part 16 "Information incorporated by reference" of this Registration Document, other information on our website (www.argenx.com) or any other website should not be considered part of or in any way incorporated by reference into this Registration Document.

Further Information

During 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;
- all reports, letters, and other documents, historical financial information, valuations and statements prepared by any expert at our request any part of which is included or referred to in this Registration Document, if any; and
- our historical financial information, and the historical financial information for argenx SE 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 price sensitive 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.

Note on Presentation

In this Registration Document, references to we, us or our are to argenx SE together with its wholly owned subsidiary argenx BVBA and, as applicable, its former wholly owned subsidiaries. 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.

Presentation of Financial Information

This Registration Document incorporates by reference our audited consolidated financial statements as at and for the years ended December 31, 2017 and 2018 as contained within our annual reports for the years ended December 31, 2017 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 Part 16 "Information incorporated by reference" of this Registration Document 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.

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.

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.

U.S. Dollar

The euro is our functional currency and the currency in which we report our financial results. The following table sets forth, for each period indicated, the low and high exchange rates of U.S. dollars per euro, the exchange rate at the end of such period and the average of such exchange rates on the last day of each month during such period, based on the noon buying rate of the Federal Reserve Bank of New York for the euro. As used in this document, the term "noon buying rate" refers to the rate of exchange for the euro, expressed in U.S. dollars per euro, as certified by the Federal Reserve Bank of New York for customs purposes. The exchange rates set forth below 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,				
	2018	2017	2016	2015	2014
High	1.2488	1.2041	1.1516	1.2015	1.3927
Low	1.1281	1.0416	1.0375	1.0524	1.2101
Rate at end of period	1.1456	1.2022	1.0552	1.0859	1.2101
Average rate per period	1.1817	1.1301	1.1072	1.1096	1.3297

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 2018	October 2018	November 2018	December 2018	January 2019	February 2019
High	1.1773	1.1594	1.1459	1.1456	1.1524	1.1474
Low	1.1566	1.1332	1.1281	1.1300	1.1322	1.1268
Rate at end of period	1.1622	1.1332	1.1323	1.1456	1.1454	1.1379

On March 16, 2019, the noon buying rate of the Federal Reserve Bank of New York for the euro was €1.00 = $1.1326. Unless otherwise indicated, currency translations in this Registration Document reflect the March 22, 2019, exchange rate.

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 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 Part 1 "Risk factors" and elsewhere in this Registration Document.

Cautionary Note Regarding Forward-Looking Statements

This Registration Document, particularly in Part 6 "Management's discussion and analysis of financial condition and results of operations" and Part 7 "Business", 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. Forward-looking statements include, but are not limited to, statements about:

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

You should refer to 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, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

You should read this Registration Document and the documents that we reference in this Registration Document 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.

3 DIVIDEND POLICY

We have never paid or declared any cash dividends, 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.

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.

4 CAPITALIZATION AND INDEBTEDNESS

The table below sets forth our capitalization and indebtedness as of 31 December 2018 on an actual basis:

You should read this table together with our consolidated financial statements and related notes incorporated by reference in this Registration Document, as well as Part 5 "Selected consolidated financial data" and Part 6 "Management's discussion and analysis of financial condition and results of operations".

	At December 31, 2018 (audited)
Total current debt	**0**
Guaranteed	0
Secured	0
Unguaranteed/unsecured	0
Total non-current debt (excluding current portion of long-term debt)	**0**
Guaranteed	0
Secured	0
Unguaranteed/unsecured	0
Shareholders' equity	**538,395**
Share capital	3,597
Share premium	673,454
Accumulated losses	-169,603
Other reserves	30,947
Total	**538,395**
Cash	63,414
Cash equivalents	217,626
Trading securities	0
Liquidity	**281,040**
Current Financial Assets	**283,529**
Current bank debt	0
Current position of non-current debt	0
Other current financial debt	0
Net Current Financial Indebtedness	**0**
Non-current bank loans	0
Bonds issued	0
Other non-current loan	0
Non-Current Financial Indebtedness	**0**
Net Financial Indebtedness (Cash)	**-564,569**

5 SELECTED CONSOLIDATED FINANCIAL DATA

The following table sets forth our selected consolidated financial data for the periods indicated. The selected consolidated financial data as of and for the years ended December 31, 2017 and 2018 have been derived from our audited consolidated financial statements incorporated by reference in this Registration Document. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period. The information set forth below should be read in conjunction with Part 6 "Management's discussion and analysis of financial condition and results of operations" and with our consolidated financial statements and notes thereto incorporated by reference in this Registration Document. We present our financial data in euros and prepare our financial statements in accordance with IFRS.

	Year ended December 31,	
	2017	**2018**
Consolidated statement of profit and loss and other comprehensive income data:	**(In thousands, except share and per share data)**	
Revenue	36,415	21,482
Other operating income	4,841	7,749
Research and development expenses	(51,740)	(83,609)
Selling, general and administrative expenses	(12,226)	(27,471)
Operating loss	(22,932)	(81,849)
Financial income	1,250	3,694
Exchange gains (losses)	(5,797)	12,308
Loss before taxes	(27,479)	(65,847)
Income tax expense	(597)	(794)
Loss for the period and total comprehensive loss	(28,076)	(66,641)
Weighted average number of shares outstanding	24,609,536	33,419,356
Basic and diluted loss per share	(1.14)	(1.99)

	Year ended December 31,	
Consolidated statement of financial position data:	**2017**	**2018**
Cash, cash equivalents and current financial assets	359,774	564,569
Total assets	370,908	578,458
Deferred revenue (current and non-current)	10,070	2,161
Total liabilities	25,977	40,063
Share capital	3,217	3,597
Share premium	430,518	673,454
Total equity	344,931	538,395

6 MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

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

In September 2018, we launched our first Phase 3 trial for efgartigimod, our most advanced product candidate for the treatment of the rare autoimmune disease myasthenia gravis, or MG. The full data from the Phase 2 trial in myasthenia gravis were reported in April 2018. In addition, we recently completed a Phase 2 clinical trial for efgartigimod in immune thrombocytopenia, or ITP, where we reported for the second time a proof-of-concept of our lead product candidate with strong clinical improvement over placebo. In both Phase 2 studies, efgartigimod was observed to have a favorable tolerability profile consistent with that observed in our Phase 1 clinical trial. In September 2017, we initiated a Phase 2 clinical trial of efgartigimod for the treatment of a third rare autoimmune disease, pemphigus vulgaris, or PV. In June 2018, we reported interim data from the first cohort of this Phase 2 proof-of-concept clinical trial where rapid disease control was observed with a favorable tolerability profile. For efgartigimod, we are also developing a subcutaneous (SC) product formulation designed to enable administration potentially outside the hospital setting. In June 2018, we reported that at the same dose level the SC formulation was comparable across key measures, including half-life, pharmacodynamics and tolerability, to the intravenous (IV) formulation used in clinical studies to date.

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

We have a disciplined strategy to maximize the value of our pipeline whereby we plan to retain development and commercialization rights to those product candidates that we believe we can ultimately commercialize successfully on our own if they are approved. We plan to collaborate on product candidates that we believe have promising utility in disease areas or patient populations that are better served by the resources of larger biopharmaceutical companies. We have entered into collaborations with a number of biopharmaceutical companies, including our collaboration with Cilag GmbH International, an affiliate of Janssen. In January2019, we received a $300 million upfront payment and Johnson & Johnson Innovation Inc. (JJDC) made a €176.7 million equity investment in argenx. In addition, in August 2018, our collaborator AbbVie S.À.R.L, or AbbVie has exercised its exclusive option to license ARGX-115 (ABBV-151), a cancer immunotherapy-focused product candidate against the novel target glycoprotein A repetitions predominant, or GARP.

Since our inception in 2008, we have focused most of our financial resources and efforts towards developing our SIMPLE Antibody™ Platform and antibody engineering technologies, identifying potential product candidates, establishing process, development and manufacturing capabilities for our product candidates and advancing multiple discovery programs into the clinic. We have advanced six internally developed product candidates into clinical development—efgartigimod, cusatuzumab, ARGX-111, ARGX-109, ARGX-112 and ARGX-115 (ABBV-151) — two into the preclinical stage—ARGX-116 and ARGX-117—and currently have multiple programs in the discovery stages. Through December 31, 2018, we have raised an aggregate gross proceeds of €735.9 million, including (i) an aggregate of €46.0 million from the private placement of equity securities in 2008, 2009 and 2011, (ii) €41.8 million from our initial public offering on the Euronext Brussels in 2014, (iii) €46.0 million from the private placement of equity securities, primarily to U.S.-based institutional investors, in 2016, (iv) $114.7 million from our initial U.S. public offering on the Nasdaq Global Select Market in May 2017, (v) $265.5 million from our second U.S

public offering on the Nasdaq Global Select Market in December 2017 and (vi) $300.6 million from our third U.S public offering on the Nasdaq Global Select Market in September 2018. In addition, as of December 31, 2018, we have received upfront payments, milestone payments and research and development service fees from our collaborators totaling €88.2 million and have received €18.7 million in grants and incentives from governmental bodies. As of December 31, 2018, we had cash, cash equivalents and current financial assets of €564.6 million.

Since our inception, we have incurred significant operating losses. We do not currently have any approved products and have never generated any revenue from product sales. Our ability to generate revenue sufficient to achieve profitability will depend significantly upon the successful development and eventual commercialization of one or more of our product candidates, which may never occur. For the years ended December 31, 2018 and 2017, we incurred total comprehensive losses of €66.1 million and €28.1 million, respectively. As of December 31, 2018, we had accumulated losses of €169.6 million.

We expect our expenses to increase substantially in connection with our ongoing development activities related to our preclinical and clinical programs. In addition, we expect to continue to incur significant costs associated with operating as a public company in the United States. We anticipate that our expenses will increase substantially if and as we:

- execute the Phase 3 clinical trials of efgartigimod in MG and, potentially, ITP and PV;
- complete the Phase 2 clinical trials of efgartigimod in ITP and PV and launch a Phase 2 clinical trial in CIDP;
- complete the Phase 2 clinical trials of cusatuzumab in AML / high risk MDS;
- execute a Phase 2 clinical trial in ITP with the subcutaneous formulation of efgartigimod;
- jointly develop and commercialize cusatuzumab with Janssen as per the collaboration agreement signed in December 2018;
- continue the research and development of our other clinical- and preclinical-stage product candidates and discovery stage programs;
- seek to enhance our technology platform and discover and develop additional product candidates;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- potentially establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize any product candidates for which we may obtain regulatory approval;
- maintain, expand and protect our intellectual property portfolio, including litigation costs associated with defending against alleged patent infringement claims;
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts; and
- experience any delays or encounter any issues any of the above, including failed studies, ambiguous trial results, safety issues or other regulatory challenges.

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

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

Collaboration Agreements

We have a disciplined strategy to maximize the value of our pipeline whereby we plan to retain all development and commercialization rights to those product candidates that we believe we can ultimately commercialize successfully, if approved. We have partnered, and plan to continue to partner, product candidates that we believe have promising utility in disease areas or patient populations that are better served by resources of larger biopharmaceutical com-

panies. Below are summaries of our key collaborations. See "Collaborations" in Part 7 "Business" for a more detailed description of these agreements.

Janssen. In December 2018, we entered into a collaboration agreement with Cilag GmbH International, an affiliate of Janssen, to jointly develop and commercialize cusatuzumab. We have granted Janssen a license to the cusatuzumab program to develop, manufacture and commercialize products. For the U.S. the granted commercialization license is co-exclusive with argenx, while outside the U.S. the granted license is exclusive. Janssen and argenx will assume certain development obligations, and will be jointly responsible for all research, development and regulatory costs relating to the products.

Under the terms of the agreement, Janssen has paid argenx, $300 million in an upfront payment and JJDC has purchased €176.7 million ($200 million based on the exchange rate as of the date the agreement was signed) in newly issued shares, for a total of 1,766,899 shares representing 4.68% of our outstanding shares at a price of €100.02 per share ($113.17 based on the exchange rate in effect as of the date the agreement was signed) in January 2019. argenx will be eligible to receive potentially up to $1.3 billion in development, regulatory and sales milestones, in addition to tiered royalties, ranging from the low double digits to the high teens. Janssen will be responsible for commercialization worldwide. argenx retains the option to participate in commercialization efforts in the U.S., where the companies have agreed to share royalties on a 50/50 basis, and outside the U.S., Janssen will pay double-digit sales royalties to argenx (exact percentages not disclosed due to duties of confidentiality). The agreement stipulates customary standstill and lock-up provisions.

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

We granted AbbVie an exclusive option, for a specified period following completion of IND-enabling studies, to obtain a worldwide, exclusive license to the ARGX-115 (ABBV-151) program to develop and commercialize products. We received an upfront, non-refundable, non-creditable payment of $40.0 million (€35.1 million based on the exchange rate in effect as of the date the payment was received) from AbbVie for the exclusive option to license ARGX-115 (ABBV-151). During the course of the collaboration, we achieved two pre-defined preclinical milestones, each of which triggered a $10.0 million payment (€8.9 million based on the exchange rate in effect as of the date the first 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 and has now assumed certain development obligations, 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.

Bird Rock Bio. In October 2012, we entered into an exclusive license agreement with Bird Rock Bio, Inc. (formerly known as RuiYi, Inc. and Anaphore, Inc.), or Bird Rock Bio, under which we granted Bird Rock Bio an exclusive, worldwide, royalty bearing license to develop and commercialize ARGX 109. We received a non refundable, non creditable upfront payment from Bird Rock Bio of €0.5 million in cash plus shares of Bird Rock Bio stock, and we are eligible to receive additional development milestone payments of up to approximately € 10.0 million in cash and additional shares of Bird Rock Bio stock, regulatory milestone payments of up to €10.0 million in cash and commercial milestone payments of up to €12.0 million in cash. We are eligible to receive tiered royalties on Bird Rock Bio's commercial sales of ARGX 109 at percentages ranging from the low to high single digits and a tiered percentage of Bird Rock Bio's sublicensing income ranging from the mid teens to high twenties, subject to customary reductions. Bird Rock Bio and argenx have mutually agreed to terminate Bird Rock Bio's license agreement to develop and commercialize ARGX-109. Genor, a sublicensee of Bird Rock Bio, will continue to develop ARGX-109 for the Chinese market. Hence, we will not be entitled to receive some or all of the milestone or other payments under this exclusive license agreement with Bird Rock Bio.

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

We received a non-refundable, non-creditable upfront payment from LEO Pharma of €3.0 million in cash. In February 2016, June 2017 and April 2018, we achieved preclinical milestones under this collaboration for which we received milestone payments. LEO Pharma may exercise an option to obtain an exclusive, worldwide license to further develop and commercialize products. Following the exercise of the option, LEO Pharma would assume full responsibility for the continued development, manufacture and commercialization of such products, subject to certain diligence obligations. If LEO Pharma elects to exercise this option, it must pay us an option fee. We are also eligible to receive additional development, regulatory and commercial milestone payments in aggregate amounts of up to €11.5 million, €6.0 million and €102.5 million, respectively, as well as tiered royalties on product sales at percentages ranging from the low single digits to the low teens, subject to customary reductions.

Staten. In January 2015, we entered into a collaboration agreement with Staten Biotechnology B.V., or Staten, to develop and commercialize products in the area of dyslipidemia therapy. Under the collaboration agreement, the parties sought to discover and characterize antibodies against a human target with therapeutic relevance in the field of dyslipidemia and/or cardiovascular disease. The first research program under this agreement proceeded as planned and was extended to December 2017, with ARGX-116 identified as the initial product candidate. Staten exercised its exclusive option to license ARGX-116 in March 2017. Under the terms of the collaboration, the parties were and are jointly responsible for conducting research under a mutually agreed research plan, with Staten reimbursing us for all costs of carrying out our research responsibilities under each research program. Staten is also responsible for additional clinical development. In December 2018, Staten announced that it will collaborate with Novo Nordisk A/S to co-develop ARGX-116.

Shire. In February 2012, we entered into a collaboration agreement with Shire AG (now known as Shire International GmbH), or Shire, to discover, develop and commercialize novel human therapeutic antibodies against up to three targets to address diverse, rare and unmet diseases. Under the terms of the collaboration, for any target selected for study under the collaboration, the parties worked together to conduct research and development through discovery of antibodies with certain specificity for and functional activity against those targets.
In May 2014, we expanded the collaboration agreement to accommodate research and development of additional novel targets implicated in multiple disease areas. The initial three-year term of this expanded agreement expired on May 30, 2017, and Shire opted to extend the collaboration term for a further year until May 30, 2018, but no further beyond May 2018.

Through December 31, 2018, pursuant to the agreement Shire has paid us an aggregate total of (i) €3.4 million in upfront payments, (ii) €0.3 million in milestone payments and (iii) $12.6 million in research and development funding. In addition, Shire purchased €12.0 million of our ordinary shares in July 2014 by participating in our initial public offering on Euronext Brussels.

Basis of Presentation

Revenue

The Company generates revenue from collaborations and strategic alliances. The Company applies a five-step model to determine when, how and at what amount revenue is to be recognized depending on whether certain criteria are met.

1. Identify the contracts

In its current arrangements, the Company is licensing its Intellectual Property, providing research and development services and in the future, selling its products to collaborative entities. Revenue is generated through these arrangements via upfront payments, milestone payments based on development criteria, research and development service fees on an agreed full-time equivalent (FTE) basis and future sales based milestones and sales based royalties.

2. Identify performance obligations

The Company has determined that there is one single performance obligation for certain arrangements in its material ongoing license and collaboration arrangements, that being the transfer of a license combined with performance of research and development services.

This is because we consider that the license has no stand-alone value without the Company being further involved in the research and development collaboration and that there is interdependence between the license and the research and development services to be provided. We estimate that the Company's activities during the collaboration are going to significantly add to Intellectual Property and thereby the value of the programs.

3. Determine the transaction price

We have analyzed the transaction prices of our material ongoing license and collaboration arrangements currently composed of upfront payments, milestone payments and research and development service fees being delivered. Sales based milestones and sales based royalties are part of certain of our arrangements but are not yet included in our revenues as our most advanced license and collaboration arrangement is still in the development phase.

4. Allocate the transaction price

In principle, an entity shall allocate the transaction price to each performance obligation identified in the contract on a relative stand-alone selling price. However, the transaction price of certain of our arrangements is allocated to a single performance obligation since the transfer of a license is considered to be combined with the performance of research and development services.

Therefore, research and development milestone payments are variable considerations that are entirely allocated to the single performance obligation.

5. Recognize revenue

Revenue from certain arrangements is recognized over time as the Company satisfies a single performance obligation. Our collaborative partner entities simultaneously receive the benefits provided by the Company's performance as the Company performs.

The Company recognizes upfront payments and milestone payments, allocated to a single performance obligation over the estimated service period based on a pattern that reflects the transfer of the services. The revenues recognized reflect the level of service during each period. In this case, the Company would use an input model that considers estimates of the percentage of total research and development service costs that are completed each period compared to the total estimated services costs (percentage of completion method).

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

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 acquisi-

tion or development of patents. This tax credit is a reduction of the corporate income taxes for Belgian statutory purposes and is transferrable to the next four accounting periods. These tax credits are paid to us in cash after five years to the extent they have not been offset against corporate taxes due.

Payroll Tax Rebates

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

Research and Development Expenses

Research and development expenses consist principally of:

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

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

	2017	2018
Research and development expenses (thousand euros)	51,740	83,609

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

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

- the scope, rate of progress and expense of our research and development activities;
- the successful enrollment in, and completion of clinical trials;
- the successful completion of preclinical studies necessary to support IND applications in the United States or similar applications in other countries;
- establishing and maintaining a continued acceptable safety profile for our product candidates;
- the terms, timing and receipt of regulatory approvals from applicable regulatory authorities;
- the expense of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- the ability to market, commercialize and achieve market acceptance for efgartigimod, cusatuzumab or any other product candidate that we may develop in the future, if approved; and

- our current and future collaborators continuing their collaborations with us.

Any of these variables with respect to the development of efgartigimod, cusatuzumab or any other product candidate that we may develop could result in a significant change in the costs and timing associated with, and the viability of, the development of such product candidates. For example, if the FDA, the EMA or other regulatory authority were to require us to conduct preclinical studies or clinical trials beyond those we currently anticipate will be required for the completion of clinical development or if we experience significant delays in enrolment in any clinical trials, we could be required to expend significant additional financial resources and time on the completion of our clinical development programs and the viability of the product candidate in question could be adversely affected.

Selling, General and Administrative Expenses

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

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

Financial Income (Expense)

Financial income reflects interest earned on the financial investments of our cash and cash equivalents and financial assets. Financial expense corresponds to interest expenses.

Exchange Gains (Losses)

Our exchange gains (losses) relate to (i) our transactions denominated in foreign currencies, mainly in U.S. dollars, Swiss francs and British pounds which generate exchange gains or losses and (ii) the translation at the reporting date of assets and liabilities denominated in foreign currencies into euros, which is our functional and presentation currency. For more information on currency exchange fluctuations on our business, please see "Item 11—Quantitative and Qualitative Disclosures about Market Risk—Foreign Exchange Risk." in our annual report for the period ended December 31, 2018 which is incorporated herein by reference. We have no derivative financial instruments to hedge interest rate and foreign currency risk.

Income Tax

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

Critical Accounting Policies and Significant Judgments and Estimates

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

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

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

Critical judgements in applying accounting policies

Revenue Recognition
Revenue from certain arrangements is recognized as the company satisfies a single performance obligation. The company recognizes upfront payments and milestone payments, allocated to a single performance obligation over the estimated service period based on a pattern that reflects the transfer of the services. The revenue recognized would reflect the level of service during each period. In this case, the company would use an input model that considers estimates of the percentage of total research and development service costs that are completed each period compared to the total estimated service costs (percentage of completion method). Research and development service fees are recognized as revenue when costs are incurred and agreed by the parties, as the company is acting as a principal in the scope of its stake in the research and development activities of its ongoing license and collaboration agreements.

Research and development cost accruals
Research and development costs are charged to expense as incurred and are typically made up of payroll costs, clinical and preclinical activities, drug development and manufacturing costs, including costs for clinical research organizations and investigative sites. Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as information provided by vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid expenses.

Critical accounting estimates

Going concern
The Company has incurred net losses since its inception and for the year ended December 31, 2018, its consolidated statement of profit and loss and other comprehensive income reflects a net loss, and its consolidated statement of financial position includes a loss carried forward. On March 26, 2019, the Board has reviewed and approved the consolidated financial statements and accounting policies. Taking into account the cash and cash equivalents and current financial asset position of €564.6 million on December 31, 2018, the Board is of the opinion that the Company is operating on a going concern basis.

Measurement of Share-Based Payments
We determine the costs of the share-based payment plan (i.e., our stock option plan) on the basis of the fair value of the equity instrument at grant date in accordance with IFRS 2. For the determination of the fair value we are using the Black Scholes pricing model. This requires the input into the valuation model of amounts that require judgment, like the estimated useful life of the stock options and the volatility of our stock (see also note 4.9 of our consolidated financial statements). Once calculated, the fair value of the stock options granted is recognized as an expense over the service period in our consolidated statement of comprehensive income and not re-measured subsequently.

In accordance with the terms of our stock option plan, as approved by our shareholders, our employees, certain of our consultants and our directors may be granted options to purchase ordinary shares at an exercise price per ordinary share equal to the average of the closing share prices of the last 30 calendar days preceding the date of the grant by the board of directors. Each stock option converts into one ordinary share upon exercise. No amounts are paid or payable by the beneficiary upon receipt of the option. The stock options carry neither rights to dividends nor voting rights. Stock options may be exercised at any time from the date of vesting to the date of their expiry.

The stock options generally vest as follows:

- one third of the stock options vest on the first anniversary of the grant date, and
- one twenty-fourth of the remaining two thirds of the stock options vest on the last day of each of the 24 months following the month of the first anniversary of the grant date.

In addition to the above, the stock options are subject to the terms and conditions of the argenx Employee Stock Option Plan.

On December 31, 2018, the total number of stock options outstanding was 3,536,651, compared to 2,862,216 on December 31, 2017. For the year ended December 31, 2018, no stock options had expired, a total of 319,671 stock options had been exercised and 46,369 stock options had been forfeited.

	Stock options granted in					
	June 2018			December 2018		
Number of options granted		178,900			861,575	
Average fair value of options	€	32.12		€	44.49	
Share price	€	72.00		€	82.20	
Exercise price	€	80.82		€	86.32	
Expected volatility		45.50	%		46.19	%
Average expected option life (in years)		7.36			10	(1)
Risk-free interest rate		0.72	%		0.77	%
Expected dividends		—	%		—	%

(1) The beneficiary can choose between a contractual term of five or ten years. The average expected option life for the December 2018 stock option grant is currently estimated at ten years. This estimate will be reassessed once the acceptance period of 60 days has passed and the beneficiaries will have made a choice between a contractual term of five or ten years. The total fair value of the grant would range from €27.7 million (100% of the stock options at an expected option life of five years) to €38.3 million (100% of the stock options at an expected option life of ten years).

	Stock options granted in					
	June 2017			December 2017		
Number of options granted		120,536			653,825	
Average fair value of options	€	7.90		€	37.10	
Share price	€	17.76		€	53.50	
Exercise price	€	18.41		€	21.17	
Expected volatility		36.60	%		36.14	%
Average expected option life (in years)		10			10	
Risk-free interest rate		0.61	%		0.53	%
Expected dividends		—	%		—	%

The grant date fair value of the options in the above table is estimated using the following assumptions:

- The expected volatility corresponds to the calculated annual volatility of our shares since our initial public offering on Euronext Brussels on July 10, 2014 until the date of grant of the options.
- The average expected option life is currently the contractual option term of 5 or 10 years.
- Risk-free interest rate equals the Belgium 10-Year Bond Yield at the date of grant.
- Expected dividends is considered 0% as we have no plan for distributing dividends and have no history of distributing dividends to shareholders.

The total share-based payment expense recognized in the consolidated statement of profit and loss and other comprehensive income was €19.2 million for the year ended December 31, 2018 and €4.3 million for the year ended December 31, 2017.

Recognition of Deferred Tax Assets and Liabilities

We are subject to income taxes in the Netherlands, in Belgium and in the United States. Significant judgment is required in determining the use of net loss carry-forwards and taxation of upfront and milestone payments for income tax purposes. There are many transactions and calculations for which the ultimate tax determination is uncertain. Where the final tax outcome of these matters is different from the amounts that were initially recorded, such differences will impact the current and deferred income tax assets and liabilities in the period in which such determination is made.

We had consolidated tax loss carry forwards of €117.1 million as of December 31, 2018 and €113.6 million as of December 31, 2017.

Deferred income tax assets are recognized for tax losses and other temporary differences to the extent that the realization of the related tax benefit through future taxable profits is probable. We recognize deferred tax assets arising from unused tax losses or tax credits only to the extent the relevant fiscal unity has sufficient taxable temporary differences or if there is convincing other evidence that sufficient taxable profit will be available against which the unused tax losses or unused tax credits can be utilized by the fiscal unity. Our judgment is that sufficient convincing other evidence is not available and therefore, a deferred tax asset is not recognized.

Results of Operation

Comparison of Years Ended December 31, 2018 and 2017

	Year ended December 31,				
	2018	2017	% Change		
	(In thousands)				
Revenue	€ 21,482	€ 36,415	(41)	%	
Other operating income	7,749	4,841	60	%	
Total operating income	**29,231**	**41,256**	**(29)**	**%**	
Research and development expenses	(83,609)	(51,740)	62	%	
Selling, general and administrative expenses	(27,471)	(12,448)	121	%	
Operating loss	**(81,849)**	**(22,932)**	**257**	**%**	
Financial income	3,694	1,250	195	%	
Exchange gains (losses)	12,308	(5,797)	(312)	%	
Loss before taxes	**€ (65,847)**	**€ (27,479)**	**140**	**%**	
Income tax expense	(794)	(597)	33	%	
Loss for the period and total comprehensive loss	**€ (66,641)**	**€ (28,076)**	**137**	**%**	
Weighted average number of shares outstanding	33,419,356	24,609,536			
Basic and diluted loss per share (in €)	(1.99)	(1.14)			

Revenue

	Year ended December 31,				
	2018	2017	% Change		
	(In thousands)				
Upfront payments	€ 8,635	€ 20,137	(57)	%	
Milestone payments	11,440	9,677	18	%	
Research and development service fees	1,407	6,601	(79)	%	
Total	€ 21,482	€ 36,415	(41)	%	

Our revenue decreased by €14.9 million for the year ended December 31, 2018 to €21.5 million, compared to €36.4 million for the year ended December 31, 2017, primarily related to a €11.5 million decrease in revenue recognized from upfront payments.

The decrease of €11.5 million in upfront payments for the year ended December 31, 2018 compared to the year ended December 31, 2017 was primarily due to the completion in 2018 of the preclinical activities under our collaborations with LEO Pharma and AbbVie.

The milestone payments recognized for the year ended December 31, 2018 and for the year ended December 31, 2017 related to payments received under the AbbVie and LEO Pharma collaborations. On January 1, 2018, the Company adopted IFRS 15, resulting in the reversal of €2.7 million of revenue related to milestone payments that

were previously recognized under IAS 18. We refer to note 5.1 of the consolidated financial statements for additional information on the impact of the adoption of IFRS 15.

Both the upfront payments and milestone payments are recognized as revenue over the estimated period of the Company's continuing involvement in the research and development activities provided for under the terms of these agreements.

The decrease of €5.2 million in research and development service fees for the year ended December 31, 2018 compared to the year ended December 31, 2017 is primarily linked with the completion of the preclinical activities under our collaboration agreements with LEO Pharma and Shire in the first half of the year.

Other Operating Income

	Year ended December 31,								
	2018			2017			% Change		
	(In thousands)								
Government grants		€	1,842		€	422		337	%
Research and development incentives			2,151			983		119	%
Payroll tax rebates			3,756			3,436		9	%
Total		€	7,749		€	4,841		60	%

Other operating income increased by €2.9 million for the year ended December 31, 2018 to €7.7 million, compared to €4.8 million for the year ended December 31, 2017. In April and September 2018, we received two new grants from The Flanders Innovation and Entrepreneurship Agency (VLAIO), which resulted in an increase of €1.4 million in government grant income in 2018. For the year ended December 31, 2018, we accrued research and development incentives income of €2.2 million, compared to €1.0 million for the year ended December 31, 2017, corresponding to Belgian research and development incentives with regard to incurred research and development expenses which will be paid to us in cash after a five-year period, if not offset against the taxable basis over the respective period. The increase in research and development incentives income is due to an extension of the scope which allows us to take more research and development expenses in consideration for the calculation of the incentive. We accounted for €3.8 million of payroll tax rebates in the year ended December 31, 2018, compared to €3.4 million in the year ended December 31, 2017, for employing certain research and development personnel.

For more information regarding governmental policies that could affect our operations, see Part 1 "Risk Factors".

Research and Development Expenses

	Year ended December 31,								
	2018			2017			% Change		
	(In thousands)								
Personnel expense		€	26,519		€	16,473		61	%
External research and development expenses			48,859			27,893		75	%
Materials and consumables			1,464			1,562		(6)	%
Depreciation and amortization			494			446		11	%
Other expenses			6,273			5,366		17	%
Total		€	83,609		€	51,740		62	%

Our research and development expenses totaled €83.6 million and €51.7 million for the years ended December 31, 2018 and 2017 respectively, primarily as a result of higher external research and development expenses and personnel expenses. The increase of €10.0 million in personnel expense for the year ended December 31, 2018 corresponded principally to (i) an increase of €7.1 million for share-based compensation expenses related to the grant of stock options to our research and development employees and (ii) increased costs associated with additional research and development personnel. We employed 75 employees in our research and development functions on December 31, 2018, compared to 58 employees on December 31, 2017.

Our external research and development expenses for the year ended December 31, 2018 totaled €48.9 million, compared to €27.9 million for the year ended December 31, 2017, reflecting higher clinical trial costs and manufacturing expenses related to the development of our product candidate portfolio. The table below provides additional detail on our external research and development expenses by program:

	Year ended December 31,			
	2018	2017	% Change	
	(In thousands)			
efgartigimod	€ 30,944	€ 12,382	150	%
cusatuzumab	9,289	3,144	195	%
Other programs	8,626	12,367	(30)	%
Total	€ 48,859	€ 27,893	75	%

External research and development expenses for our lead product candidate efgartigimod totaled €30.9 million for the year ended December 31, 2018, compared to €12.4 million for the year ended December 31, 2017. This increase of €18.5 million of external research and development expenses in 2018 corresponded primarily to increased manufacturing and clinical development activities in relation to the preparation for and initiation of two Phase 3 clinical trials in MG.

External research and development expenses for cusatuzumab totaled €9.3 million for the year ended on December 31, 2018 compared to €3.1 million for the year ended December 31, 2017. This increase of €6.2 million in 2018 resulted principally from increased manufacturing and clinical development activities in relation to the advancement of the Phase 1/2 clinical trial in patients with AML or high-risk MDS.

External research and development expenses on other programs decreased by €3.7 million to €8.6 million for the year ended December 31, 2018, compared to €12.4 million for the year ended December 31, 2017. This decrease was primarily due to the decreased external research and development expenses following the completion of the preclinical work under our collaboration agreements with LEO Pharma and AbbVie.

Selling, General and Administrative Expenses

	Year ended December 31,		
	2018	2017	% Change
		(In thousands)	
Personnel expense	€ 18,292	€ 6,745	171 %
Consulting fees	5,472	3,289	66 %
Supervisory board	1,088	621	75 %
Office costs	2,619	1,793	46 %
Total	€ 27,471	€ 12,448	121 %

Our selling, general and administrative expenses totaled €27.5 million and €12.4 million for the years ended December 31, 2018 and 2017, respectively. The increase of €15.1 million in our selling, general and administrative expenses for the year ended December 31, 2018 was principally due to:

- an increase of €11.5 million of personnel expenses resulting from (i) €8.0 million of increased costs of the share-based payment compensation plans related to the grant of stock options to our general and administrative employees, (ii) increased costs associated with additional employees recruited to strengthen our selling, general and administrative activities and from increases in our executive management's compensation.
- an increase of €2.2 million in consulting fees primarily related to costs for the preparation of a possible future commercialization of our lead product candidate efgartigimod.
- an increase of €0.5 million of our supervisory board expenses primarily due to increased costs for the share-based payment compensation plans related to the grant of stock options to the members of the board of directors.

On December 31, 2018, we employed 30 employees in our selling, general and administrative functions, compared to 15 employees on December 31, 2017.

Financial Income (Expense)

For the year ended December 31, 2018, financial income amounted to €3.7 million compared to €1.3 million for the year ended December 31, 2017. The increase of €2.4 million in 2018 related primarily to an increase in the interest received on our cash, cash equivalents and current financial assets.

Exchange Gains (Losses)

Exchange gains totaled €12.3 million for the year ended December 31, 2018. The increase was mainly attributable to unrealized exchange rate gains on our cash and current financial assets position in U.S. dollars due to the favorable fluctuation of the EUR/USD exchange rate in 2018.

Liquidity And Capital Resources

Sources of Funds

Since our inception in 2008, we have invested most of our resources to developing our product candidates, building our intellectual property portfolio, developing our supply chain, conducting business planning, raising capital and providing general and administrative support for these operations. We do not currently have any approved products and have never generated any revenue from product sales. To date, we have funded our operations through public and private placements of equity securities, upfront, milestone and expense reimbursement payments received from our collaborators, funding from governmental bodies and interest income from the investment of our cash, cash equivalents and financial assets. Through December 31, 2018, we have raised gross proceeds of €735.9 million from private and public offerings of equity securities, received €88.2 million in revenue from our collaborators, and €18.7 million in grants and incentives from governmental bodies.

Our cash flows may fluctuate and are difficult to forecast and will depend on many factors. On December 31, 2018, we had cash, cash equivalents and current financial assets of €564.6 million, compared to €359.8 million on December 31, 2017.

We have no ongoing material financing commitments, such as lines of credit or guarantees, that are expected to affect our liquidity over the next five years, other than operating leases.

For more information as to the risks associated with our future funding needs, see Part 1 "Risk Factors" of this Registration Document.

For more information as to our financial instruments, please see “Note 6—Financial instruments and financial risk management—Overview of financial instruments” in our consolidated financial statements which are appended to our annual report for the period ended December 31, 2018 and which are incorporated herein by reference.

Cash Flows

Comparison for the Years Ended December 31, 2018 and 2017

The table below summarizes our cash flows for the years ended December 31, 2018 and 2017.

	Year ended December 31,		
	2018	2017	Variance
	(In thousands)		
Cash and cash equivalents at beginning of the period	**€ 190,867**	**€ 89,897**	**€ 100,970**
Net cash flows (used in) / from operating activities	(53,839)	(36,546)	(17,293)
Net cash flows (used in) / from investing activities	(107,542)	(162,052)	54,510
Net cash flows (used in) / from financing activities	244,671	305,365	(60,694)
Effect of exchange rate differences on cash and cash equivalents	6,883	(5,797)	12,680
Cash and cash equivalents at end of the period	**€ 281,040**	**€ 190,867**	**€ 90,173**

Net Cash Used in Operating Activities

Net cash outflow from our operating activities increased by €17.3 million to a net outflow of €53.8 million for the year ended December 31, 2018, compared to a net outflow of €36.5 million for the year ended December 31, 2017. The increased cash used in operating activities for the years ended December 31, 2018 and December 31, 2017 resulted primarily from increased research and development expenses in relation to the manufacturing and clinical development activities of efgartigimod and cusatuzumab and the advancement of other preclinical and discovery-stage product candidates.

Net Cash Used in Investing Activities

Investing activities consist primarily of the acquisition of current financial assets, purchase of laboratory equipment and interest received from the placements of our cash and cash equivalents and current financial assets. Cash flow used in investing activities represented a net outflow of €107.5 million for the year ended December 31, 2018, compared to a net outflow of €162.1 million for the year ended December 31, 2017. The net outflow for the year ended December 31, 2018 related to (i) the investment of €114.6 million in current financial assets, including money market funds and U.S. dollar term deposit accounts, (ii) the purchase of €0.7 million of office, information technology and laboratory equipment, and less (iii) €3.7 million interest received from the placements of our cash, cash equivalents and current financial assets. The net outflow for the year ended December 31, 2017 related to (i) the acquisition of €162.1 million of current financial assets, including money market funds and a U.S. dollar term deposit account, (ii) the purchase of €0.3 million of office, information technology and laboratory equipment, and less (iii) €0.4 million interest received from the placements of our cash, cash equivalents and current financial assets.

Net Cash Provided by Financing Activities

Financing activities consist of net proceeds from our private placements and public offerings of our securities and exercise of stock options. The net cash inflow from financing activities was €244.7 million for the year ended December 31, 2018, compared to a net cash inflow of €305.4 million for the year ended December 31, 2017. The net cash inflow for the year ended December 31, 2018 was attributed to (i) €241.1 million net cash proceeds of our follow-on U.S. public offering of ADSs on the Nasdaq Global Select Market in September 2018 (based on the exchange rate in effect of the date the proceeds were received) and (ii) €2.3 million proceeds received from the exercise of stock options in 2018. The net cash inflow for the year ended December 31, 2017 was attributed to (i) €93.2 million net cash proceeds from our initial U.S. public offering of ADSs on the Nasdaq Global Select Market in May 2017 (based on the exchange rate in effect of the date the proceeds were received), (ii) €211.5 million net cash proceeds of our follow on offering of ADSs on the Nasdaq Global Select Market in December 2017 (based on the exchange rate in effect of the date the proceeds were received) and (iii) €0.7 million proceeds received from the exercise of stock options in 2017.

Operating and Capital Expenditure Requirements

We have never achieved profitability and, as of December 31, 2018, we had accumulated losses of €169.0 million. We expect to continue to incur significant operating losses for the foreseeable future as we continue our research and development efforts and seek to obtain regulatory approval and commercialization of our product candidates.

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

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

For more information as to the risks associated with our future funding needs, see Part 1 "Risk Factors" of this Registration Document.

No significant change

There has been no significant change in our financial or trading position between 31 December 2018 and the date of this Registration Document.

7 BUSINESS

Overview

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

In September 2018, we launched our first Phase 3 trial for efgartigimod (ARGX-113), our most advanced product candidate for the treatment of the rare autoimmune disease myasthenia gravis, or MG. The full data from the Phase 2 trial in myasthenia gravis were reported in April 2018. In addition, we recently completed a Phase 2 clinical trial for efgartigimod in immune thrombocytopenia, or ITP, where we reported for the second time a proof-of-concept of our lead product candidate with strong clinical improvement over placebo. In both Phase 2 studies, efgartigimod was observed to have a favorable tolerability profile consistent with that observed in our Phase 1 clinical trial. In September 2017, we initiated a Phase 2 clinical trial of efgartigimod for the treatment of a third rare autoimmune disease, pemphigus vulgaris, or PV. In June 2018, we reported interim data from the first cohort of this Phase 2 proof-of-concept clinical trial where rapid disease control was observed with a favorable tolerability profile. For efgartigimod, we are also developing a subcutaneous (SC) product formulation designed to enable administration potentially outside the hospital setting. In June 2018, we reported that at the same dose level the SC formulation was comparable across key measures, including half-life, pharmacodynamics and tolerability, to the intravenous (IV) formulation used in clinical studies to date.

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

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

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

- ***Our proprietary SIMPLE Antibody™ Platform*** sources antibody V-regions from the immune system of outbred llamas, each of which has a different genetic background. The V-region is responsible for targeting a specific antibody to an antigen, which is a substance that induces an immune response, and is different for every type of antibody. The llama produces highly diverse panels of antibodies with a high human homology, or similarity, in their V-regions when immunized with targets of human disease. By contrast, most antibody platforms start with antibodies generated in inbred mice or synthetic antibody library systems, approaches that we believe are limited by insufficient antibody repertoires and limited diversity, respectively. Our SIMPLE Antibody™ Platform allows us to access and explore a broad target universe,

including novel and complex targets, while minimizing the long timelines associated with generating antibody candidates using traditional methods.

- ***Our Fc engineering technologies***—NHance®, ABDEG™ and POTELLIGENT®—focus on engineering the Fc region of antibodies in order to augment their intrinsic therapeutic properties. These technologies are designed to enable us to expand the therapeutic index of our product candidates, which is the ratio between toxic and therapeutic dose, by modifying their half-life, tissue penetration, rate of disease target clearance and potency.

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

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

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

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

We believe that our clinical expertise and execution capabilities position us well to advance our product pipeline and enter into collaborations designed to maximize the value of our portfolio. We have assembled a team of over 130 employees and consultants with experience across the spectrum of antibody drug discovery and development and business development. Members of our board of directors, management team and key personnel have extensive experience in the life sciences industry and have previously served at companies including Alexion Pharmaceutical, Inc.; Cambridge Antibody Technology Group Plc; Celgene Corporation; Galapagos NV; Glax-

oSmithKline plc; Janssen; Micromet, Inc.; Nicox S.A.; The Procter & Gamble Company; Quintiles IMS Holdings, Inc; Shire Plc (now part of Takeda Pharmaceutical Company Limited) and Unilever N.V.

Our Competitive Strengths

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

- ***Phase 3 lead product candidate with clinical proof-of-concept in MG and ITP; pipeline-in-a-product opportunity with an ongoing Phase 3 clinical trial and Phase 2 clinical trials in two additional indications.*** We launched a Phase 3 clinical trial in MG for our lead product candidate, efgartigimod, in September 2018. We announced full data from the Phase 2 clinical trial in ITP in December 2018. We expect to prepare for Phase 3 clinical development in this indication in the second half of 2019, subject to discussions at an end-of-Phase 2 meeting with the FDA, EMA and the Japanese Pharmaceuticals and Medical Devices Agency, or PMDA, which we intend to schedule in the first half of 2019. We reported interim data of the additional Phase 2 clinical trial of efgartigimod in PV in June 2018 and announced the planned launch of an additional Phase 2 clinical trial in CIDP during the second half of 2019. MG, ITP, PV and CIDP are four rare, severe autoimmune diseases in which there is high unmet medical need. Each indication is characterized by high levels of pathogenic immunoglobulin G, or IgG, antibodies, and we designed efgartigimod to reduce IgG antibody levels. All patients in the treatment arm of our Phase 2 clinical trial in MG showed a rapid and deep reduction of their total IgG levels and disease improvement was found to correlate with reduction in pathogenic IgG levels. The treated ITP patients in the Phase 2 clinical trial showed a correlation between IgG reduction, platelet counts increase and reduction of bleeding events. In addition, interim data from the treated PV patients showed a rapid disease control in 4 out of 6 patients. As such, we believe efgartigimod is a pipeline-in-a-product opportunity for us in these three, and potentially other, indications. In a Phase 1 clinical trial of efgartigimod with healthy volunteers, we observed a reduction of circulating IgG antibody levels of 50% to 85%. We believe that a reduction of pathogenic IgG antibody levels, which are a subset of circulating IgG antibodies in people with autoimmune disease, of at least 30% would be clinically meaningful. We expect to launch a Phase 2 trial with the subcutaneous formulation and start the third cohort of the Phase 2 clinical trial in PV in the first half of 2019. By the second half of 2019, we expect to launch a Phase 2 clinical trial in our fourth indication CIDP. Depending on the outcome of the discussions with regulatory agencies, we intend to enter into Phase 3 clinical development in ITP.

- ***Productive discovery capabilities that fuel a deep pipeline of clinical and preclinical product candidates.*** We are advancing a deep pipeline of both clinical- and preclinical-stage product candidates for the treatment of severe autoimmune diseases and cancer. Leveraging our technology suite and clinical expertise, we have advanced six product candidates into clinical development—efgartigimod, cusatuzumab, ARGX-111, ARGX-109, ARGX-112 and ARGX-115 (ABBV-151); two into the preclinical stage—ARGX-116 and ARGX-117; and we currently have multiple programs in the discovery stage. Our second lead product candidate, cusatuzumab, was being investigated in Phase 1/2 clinical trials, and we reported proof-of-concept results from these trials in December 2018. We believe this level of productivity affords us a breadth of options with regard to independently advancing or partnering our pipeline assets.

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

- ***The ability to use our Fc engineering technologies to modulate immune response.*** We employ technologies—NHance®, ABDEG™ and POTELLIGENT®—that focus on engineering the Fc region of anti-

bodies in order to augment their intrinsic therapeutic properties. These technologies are designed to expand the therapeutic index of our product candidates by modifying their half-life, tissue penetration, rate of disease target clearance and potency.

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

Our Strategy

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

- ***Rapidly advance efgartigimod to regulatory approval in MG and through clinical proof-of-concept in three additional indications.*** We are currently developing our lead product candidate, efgartigimod for the treatment of patients with MG, ITP and PV and plan for a fourth indication CIDP. We chose these indications based on the biological rationale of targeting the neonatal Fc receptor, or FcRn, thereby reducing the pathogenic IgG antibody levels that drive all of these disease states. We launched a Phase 3 clinical trial in MG for efgartigimod, in September 2018, aiming for a first approval in MG. We announced full data from the Phase 2 clinical trial in ITP in December 2018. We expect to prepare for Phase 3 clinical development in this indication in the second half of 2019, subject to discussions at an end-of-Phase 2 meeting with the FDA, which we intend to schedule in the first quarter of 2019. We reported interim data of the additional Phase 2 clinical trials of efgartigimod in PV in June 2018 and announced the launch of an additional Phase 2 clinical trial in CIDP. In the first half of 2019, we expect to launch a Phase 2 with the subcutaneous formulation and start the third cohort of the Phase 2 clinical trial in PV. During the second half of 2019, we will launch a Phase 2 clinical trial in our fourth indication CIDP. Depending on the outcome of the discussions with regulatory agencies, we intend to enter into Phase 3 clinical development in ITP or more of these indications.

- ***Advance cusatuzumab to regulatory approval through clinical proof-of-concept in AML and adjacent hematological tumors.*** In December 2016, we initiated an open-label, Phase 1/2 clinical trial of cusatuzumab in combination with the standard of care, azacytidine, in newly diagnosed AML and high-risk MDS patients. We reported topline results from the dose-escalation part of this clinical trial in December 2018, and we announced the transition into the Phase 2 part of this clinical trial in August 2018. In December 2018, argenx and Janssen have agreed to a joint global clinical development plan to evaluate cusatuzumab in AML, MDS and other potential future indications. We also reported full data on the Phase 2 part of an open-label Phase 1/2 clinical trial of cusatuzumab for the treatment of adult relapsed or refractory CD70-positive CTCL patients in December 2018. Given the potential of cusatuzumab in newly diagnosed AML patients based on early data from the Phase 1/2 proof-of-concept trial, we prioritized the development of cusatuzumab in AML and MDS over CTCL and do not expect to devote resources to its further development in CTCL.

- ***Expand applications for our existing product candidates.*** Our goal is to maximize the commercial potential of our existing product candidates by exploring additional indications, as well as formulations that may expand the target patient populations within existing indications. For example, our development work in efgartigimod is based on its ability to reduce circulating IgG antibodies, and this has given us the ability to leverage a single Phase 1 clinical trial in healthy volunteers into one Phase 3 and three Phase 2 clinical trials in different indications, MG, ITP, PV and CIDP where we believe this mechanism of action may have therapeutic benefit. In addition, we believe there are other autoimmune diseases beyond MG, ITP, PV and CIDP that may benefit from treatment with efgartigimod. We plan to employ a similar strategy of leveraging the strong biological rationale for other product candidates into multiple indications, thereby maximizing

the value of our pipeline. We also expanded the use of our product candidates in existing indications by developing new formulations, such as a 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 cancer.*** Our SIMPLE Antibody™ Platform allows us to access and explore a broad target universe, including novel and complex targets, while minimizing the long timelines associated with generating antibody candidates using traditional methods. By exploring a broad target universe, we are able to develop a breadth of antibodies to test many different epitopes. Being able to test many different epitopes with our antibodies enables us to search for an optimized combination of safety, potency and species cross-reactivity. We believe our Fc engineering technologies will allow us to augment our antibodies for maximum therapeutic effect.

- ***Independently commercialize our product candidates in indications and geographies where we believe we can extract maximum value.*** We plan to independently develop and commercialize those product candidates that we believe have a clear clinical and regulatory approval pathway and that we believe we can commercialize successfully, if approved. Our commercialization strategy for any product candidates that are approved will focus on key academic centers, specialist physicians and advocacy groups, as well as on providing patients with support programs and maximizing product access and reimbursement.

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

Our Suite of Technologies

Harnessing the Therapeutic Potential of Antibodies

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

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

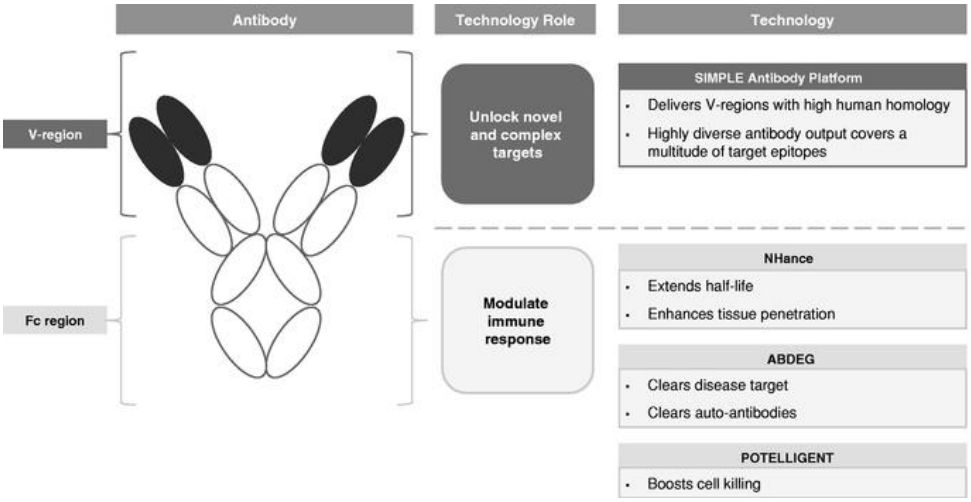


Figure 1: Overview of our suite of technologies

Our Proprietary SIMPLE Antibody™ Platform

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

Our Fc Engineering Technologies

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

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

An illustration of the FcRn-mediated antibody recycling mechanism is shown in *Figure 2*. ❶ Serum proteins, including IgG antibodies, are routinely removed from the circulation by cell uptake. ❷ Antibodies can bind to FcRn, which serves as a dedicated recycling receptor in the endosomes, which have an acidic environment, and then ❸A return to the circulation by binding with their Fc region to FcRn. ❸B Unbound antibodies end up in the lysosomes

and are degraded by enzymes. Because this Fc/FcRn interaction is highly pH-dependent, antibodies tightly bind to FcRn at acidic pH (pH 6.0) in the endosomes, but release again at neutral pH (pH 7. 4) in the circulation.

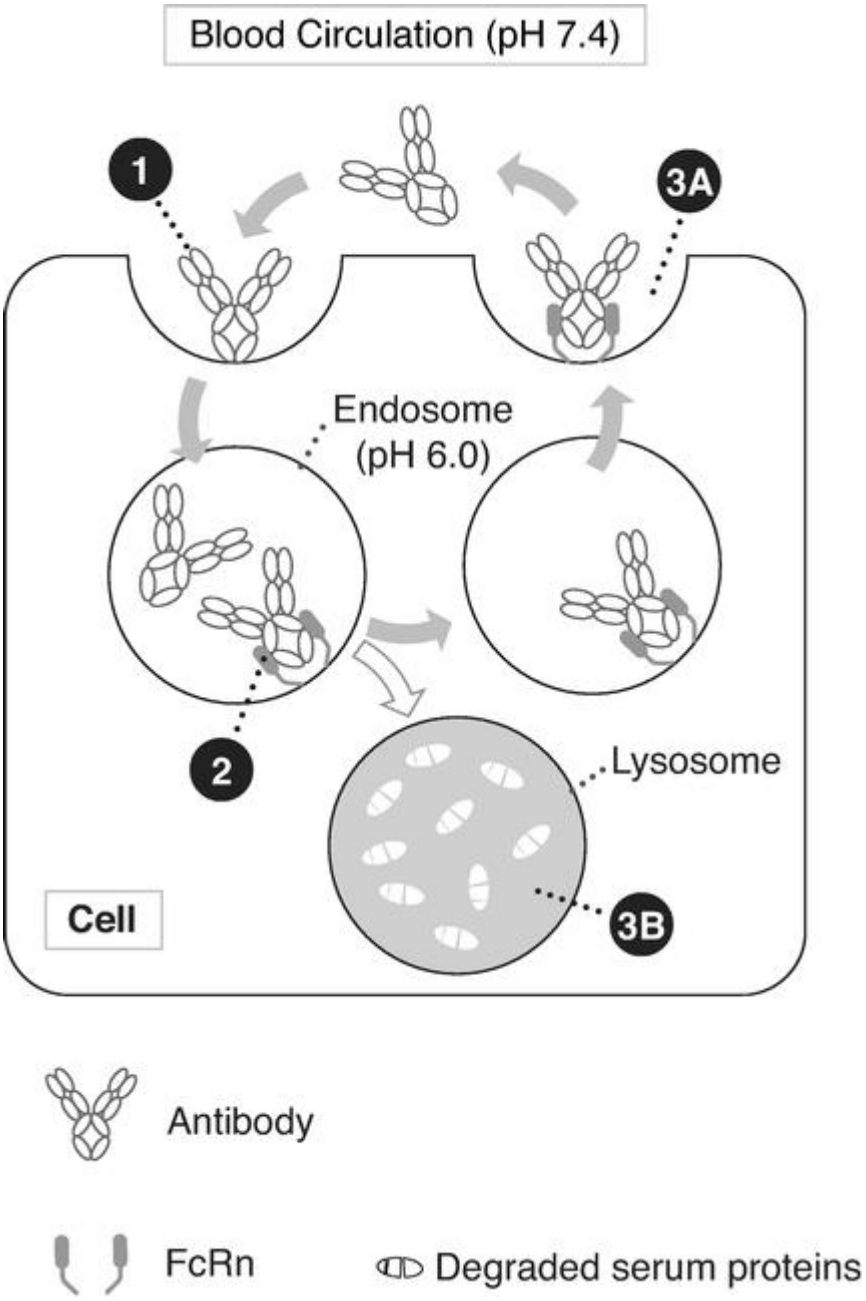


Figure 2: The FcRn-mediated recycling mechanism

NHance®

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

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

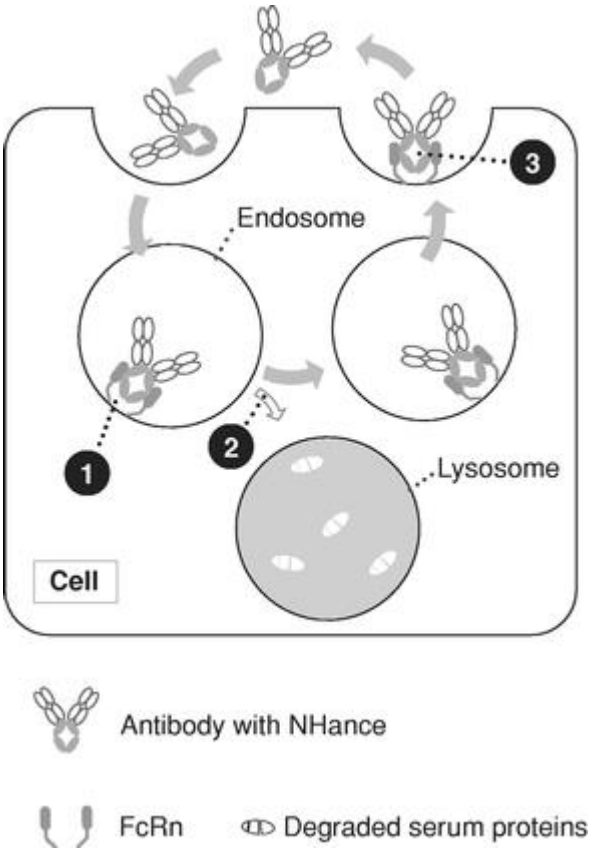


Figure 3: NHance® mutations favor the FcRn-mediated recycling of IgG antibodies

ABDEG™

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

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

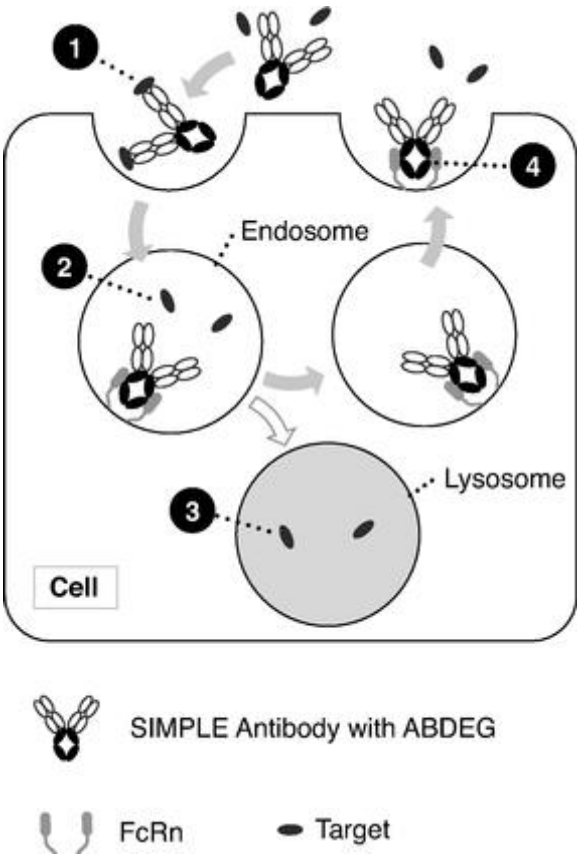


Figure 4: SIMPLE Antibody™ and ABDEG™ technologies work in concert to sweep disease targets

POTELLIGENT®: Modulation of Fc Interaction with NK Cells

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

Our Wholly-Owned Programs

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

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

Efgartigimod (formerly referred to as ARGX-113)

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

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

In parallel, we performed a second Phase 2 clinical trial of efgartigimod in 38 patients with ITP. In December 2018, we reported full study data. We will advance into a Phase 3 clinical trial, subject to discussions at an end-of-Phase 2 meeting with the FDA, which we intend to schedule in the first quarter of 2019, aiming for a second approval in this indication. In addition, we reported interim data of a third Phase 2 clinical trial of efgartigimod in patients with PV in June 2018. In addition to the intravenous formulation of efgartigimod that we are using in our current clinical trials, we are also developing a subcutaneous formulation designed to make efgartigimod accessible to larger patient populations, including patients requiring chronic therapy, potentially outside of the hospital setting. We initiated a Phase 1 clinical trial in healthy volunteers for a subcutaneous formulation of efgartigimod and reported in June 2018 data from this clinical trial demonstrating comparable characteristics to the intravenous formulation.

Overview of Myasthenia Gravis

MG is an autoimmune disorder associated with muscle weakness that is triggered by IgG auto-antibodies. These antibodies attack critical signaling proteins at the junction between nerve and muscle cells, thereby impairing their

communication signals. As shown in *Figure 5*, in MG these auto-antibodies either bind and occupy or cross-link and internalize the receptor on the muscle cells, thereby preventing the binding of acetylcholine, the signal sent by the nerve cell. In addition, these auto-antibodies can cause destruction of the neuromuscular junction by recruiting complement, a potent cell-destroying mechanism of the human immune system.

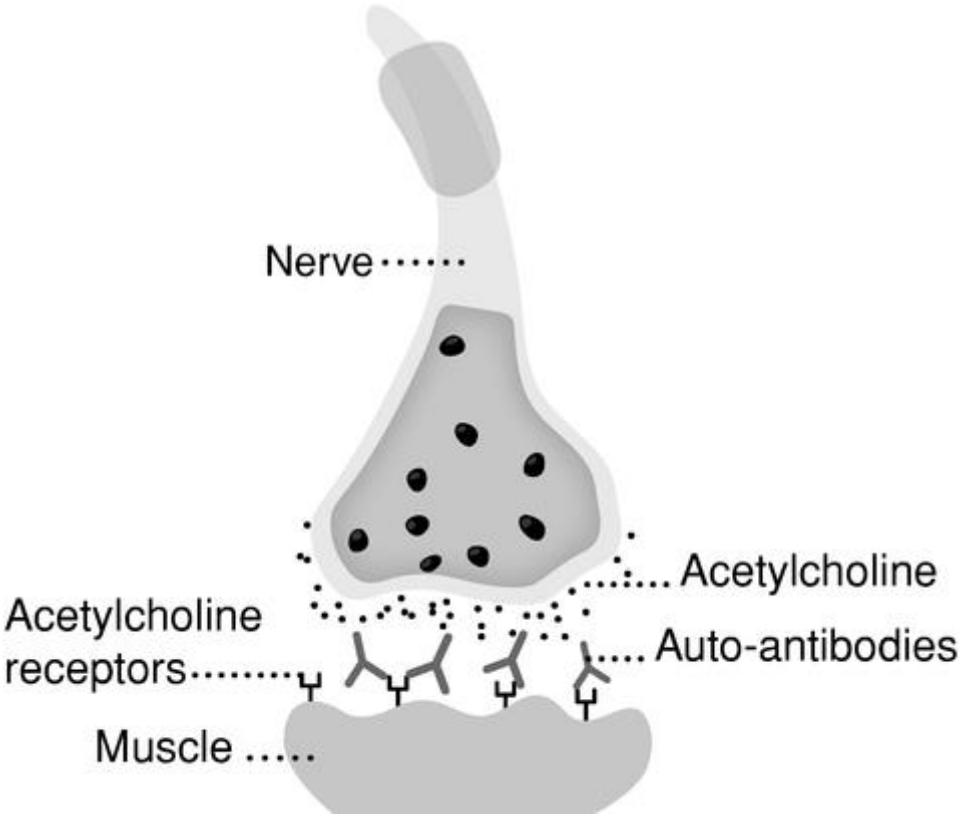


Figure 5: MG is caused by auto-antibodies attacking the transmission of nerve impulses to muscles

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

The U.S. prevalence of MG is estimated at approximately 20 cases per 100,000 (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.

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

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

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

Overview of Primary Immune Thrombocytopenia

ITP is a bleeding disease caused by an autoimmune reaction in which a patient develops antibodies that attack and destroy their own platelets, which are blood cells that help blood to clot, or their own platelet-forming cells. ITP, which develops for no known reason, is differentiated from secondary immune thrombocytopenia, which is associated with other illnesses, such as infections or autoimmune diseases, or which occurs after transfusion or taking other drugs, such as cancer drugs. Platelet deficiency, or thrombocytopenia, can cause bleeding in tissues, bruising and slow blood clotting after injury. ITP affects approximately 72,000 patients in the United States (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 auto-antibodies for various pathways including the FcRn-dependent antibody recycling pathway, thereby lowering the impact of the auto-antibodies. IVIg treatment for ITP requires intravenous dosing of up to 2 g/kg per day of IVIg and is associated with many of the adverse events seen with IVIg treatment of other autoimmune diseases, such as MG as described above. Both IVIg and plasmapheresis when used to treat ITP carry a high cost burden on the healthcare system as they do when used to treat MG.

The production of platelets in patients refractory to other treatments can be stimulated by drugs such as romiplostim (Nplate) or eltrombopag (Promacta) that mimic thrombopoietin. While these therapies lead to increases in blood platelet counts, they do not address the underlying cause of the disease, which is the destruction of platelets by the immune system. Romiplostim (Nplate) and Eltrombopag (Promacta) are approved as last-line therapy for ITP and have generated global revenues of $584 million and $635 million in 2016, respectively (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 auto-antibodies targeting desmoglein-1 and -3, which are present on the surface of keratinocytes and important for cell-to-cell adhesion in the epithelium. Auto-antibodies targeting desmogleins result in loss of cell adhesion, the primary cause of blister formation in PV. Similar to MG and ITP, disease severity of PV correlates to the amount of pathogenic IgGs targeting desmogleins.

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

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

Limitations of Current PV Treatments

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

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

Overview of Chronic Inflammatory Demyelinating Polyneuropathy

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

Limitations of Current CIDP Treatments

Most CIDP patients require treatment and 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 auto-antibodies for various pathways, including the FcRn-dependent antibody recycling pathway, thereby lowering the impact of the auto-antibodies. IVIg treatment for CIDP requires 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 and PV, including with respect to time of onset, magnitude and duration of therapeutic benefit and safety profile. We developed efgartigimod using our ABDEG™ Fc engineering technology.

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

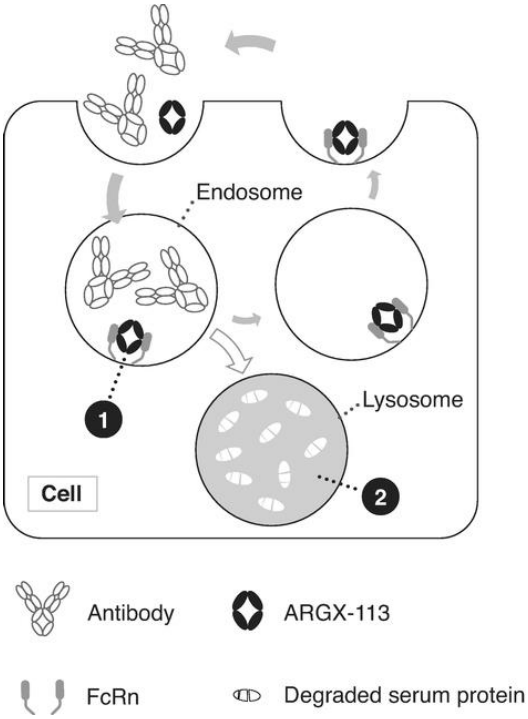


Figure 6: Efgartigimod's mechanism of action blocks the recycling of IgG antibodies and removes them from circulation

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

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

Clinical Development Plan

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

2018 we reported data from this clinical trial demonstrating comparable characteristics to the intravenous formulation.

Phase 2 Clinical Trial in MG

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

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

Phase 2 Topline Results

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

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

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

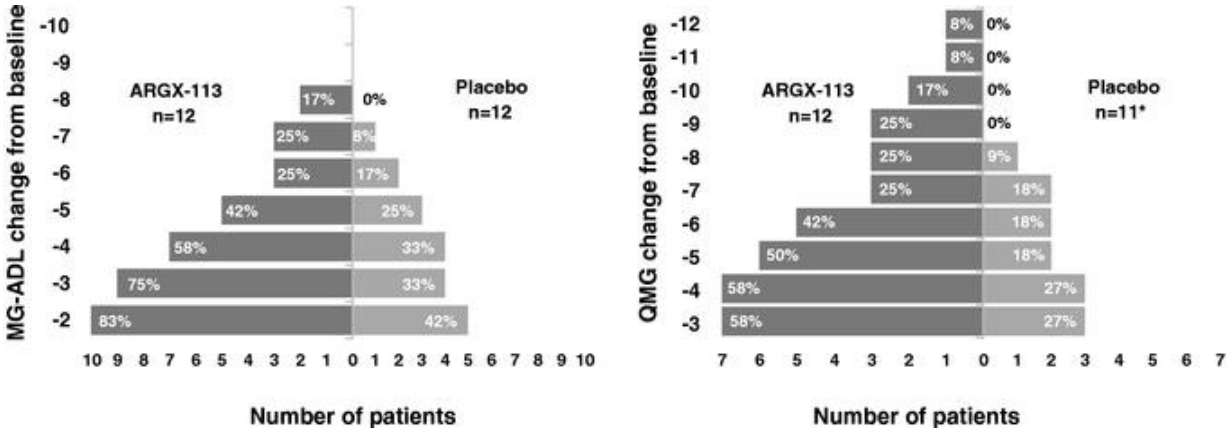
Treatment Emergent Adverse Events (TEAEs) Reported in ≥ 2 patients	Placebo (N = 12)	Efgartigimod (N = 12)
TEAEs (Total)	**10 (83.3%)**	**10 (83.3%)**
• Headache	3 (25.0%)	4 (33.3%)
• Nausea	1 (8.3%)	1 (8.3%)
• Diarrhea	1 (8.3%)	1 (8.3%)
• Abdominal pain upper	1 (8.3%)	1 (8.3%)
• Arthralgia	2 (16.7%)	-
• B-lymphocyte decrease	-	2 (16.7%)
• Lymphocyte count decrease	-	2 (16.7%)
• Monocyte count decrease	-	2 (16.7%)
• Neutrophil count increase	-	2 (16.7%)
• Myalgia	-	2 (16.7%)
• Pruritus	2 (16.7%)	1 (8.3%)
• Rhinorrhea	1 (8.3%)	1 (8.3%)
• Tooth abscess	2 (16.7%)	-
• Toothache	2 (16.7%)	-
Efgartigimod deemed related TEAEs	**3 (25.0%)**	**8 (66.7%)**
• Headache	1 (8.3%)	3 (25.0%)
• Monocyte count decrease	0 (0.0%)	2 (16.7%)
• Rhinorrhea	1 (8.3%)	1 (8.3%)

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

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

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

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



* Missing data point in one patient

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

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

Phase 2 Clinical Trial in ITP

We completed a randomized, double-blind, placebo-controlled Phase 2 clinical trial to evaluate the safety, efficacy and pharmacokinetics of efgartigimod in 38 adult primary ITP patients, who have platelet counts lower than 30 x 10^9/L while being on a stable dose of standard-of-care treatments consisting of corticosteroids, permitted immunosuppressants or thrombopoietin receptor agonists, or after having undergone a splenectomy or while being monitored under a ‘‘watch & wait’’ approach. We conducted the clinical trial at 19 clinical centers across eight countries in the European Union. Patients were randomly assigned to three arms of 12 or 13 patients for the placebo or efgartigimod arms, respectively. All patients in this clinical trial on a drug standard-of-care treatment were to continue to receive their stable dose of standard-of-care treatment as per the protocol. One treatment arm received 5

mg/kg efgartigimod, the second arm received 10 mg/kg efgartigimod and the third arm received placebo. Dosing took place in a three-week period, which included four weekly doses of efgartigimod or placebo. Patient follow-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 10^9/L.

Phase 2 Topline Results

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

We announced full data from this Phase 2 clinical trial in December 2018. The primary endpoint analysis demonstrated efgartigimod to be well-tolerated in all patients, with most 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

Bleeding TEAEs not included

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

Clinically meaningful improvements in platelet counts were seen across ITP classifications and standard of care. 46% of patients demonstrated improved platelet count to ≥ 50x10^9/L during two or more visits in each of the 5 mg/kg and 10 mg/kg dosing cohorts compared to 25% in the placebo cohort. 67% of patients in the OLE trial demonstrated improved platelet count to ≥ 50x10^9/L during two or more visits following the first dosing cycle. Responders from the 10 mg/kg arm in the primary trial all responded again upon retreatment in the OLE trial. Onset of platelet count reaching 50x10^9/L for the first time ranged from week 1 to week 10, consistent with disease heterogeneity. For efgartigimod-treated patients with clinically meaningful platelet responses (≥ 50x10^9/L during two or more visits), the mean duration of platelet response was 40 days versus 16 days for placebo treated patients, with responses lasting the trial duration.
38% of efgartigimod-treated patients showed durable platelet count improvements to clinically meaningful and statistically significant levels of ≥ 50x10^9/L for at least 10 cumulative days, compared to 0% of placebo patients (p=0.03). These data are summarized in figures 8 and 9.

Figure 8: Patients achieving platelet counts of ≥ 50x10^9/L at least two times.

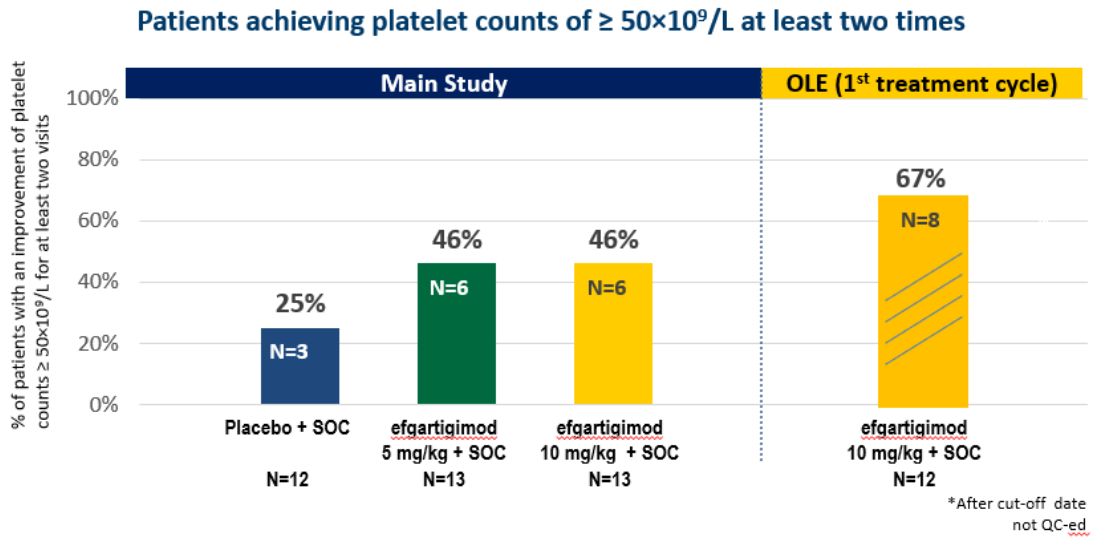
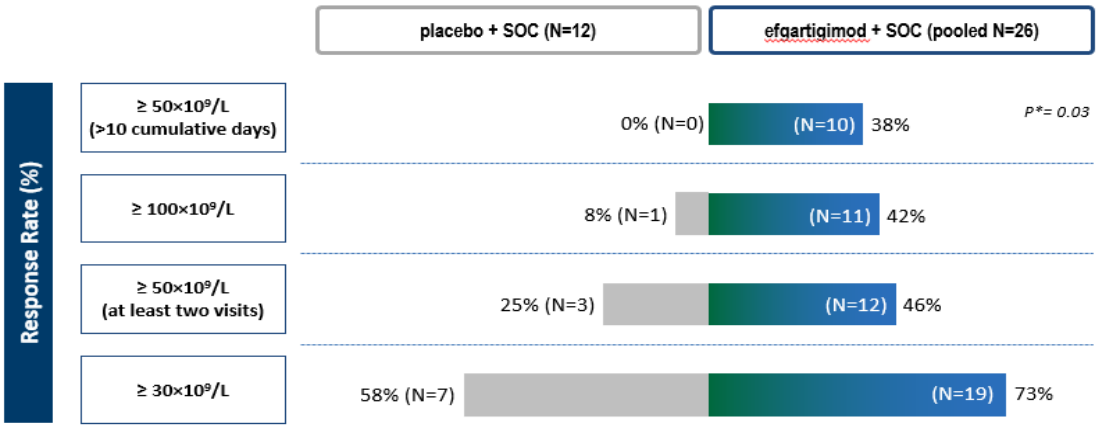


Figure 9: Post-hoc analysis of increasing thresholds of efficacy



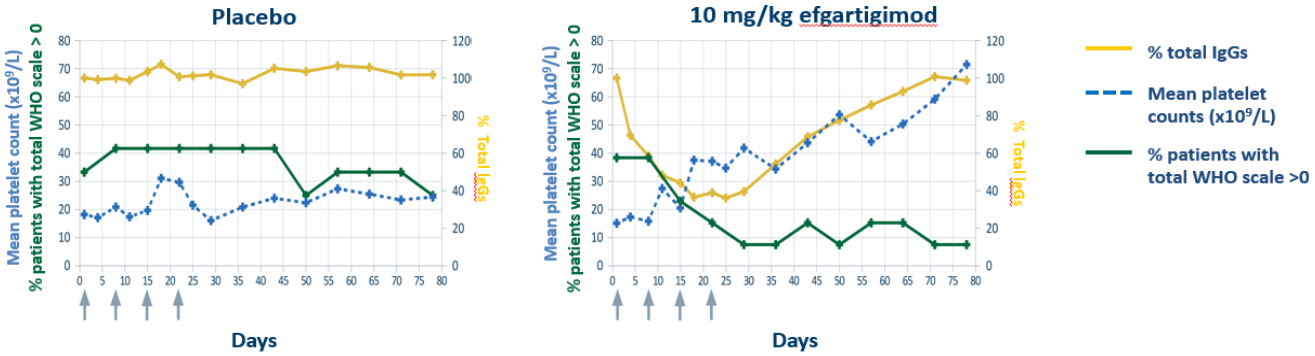
Note: Increasing threshold analysis based exact logistic regression model with the baseline result as a factor

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

Analysis of the pharmacokinetic and pharmacodynamic endpoints was generally consistent with the findings from the Phase 1 clinical trial as well as the MG Phase 2 clinical trial. Lasting IgG reductions were consistent with levels

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

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



Phase 2 Clinical Trial in PV

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

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

Phase 2 Interim Results

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

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

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

Phase 1 Clinical Trial for Subcutaneous Formulation of efgartigimod

In addition to the intravenous product formulation of efgartigimod that we are currently using in our clinical trials, 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 Data

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

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

Single Ascending Dose

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

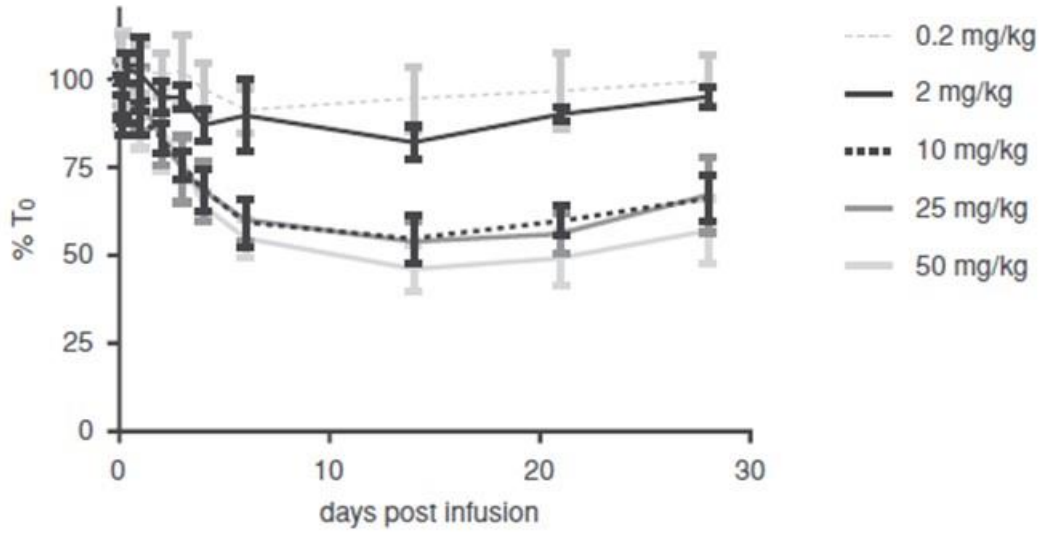


Figure 8. Selective reduction of IgG by administration of ARGX 113 to healthy volunteers in the single ascending dose part of our Phase 1 clinical trial

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

Multiple Ascending Dose

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

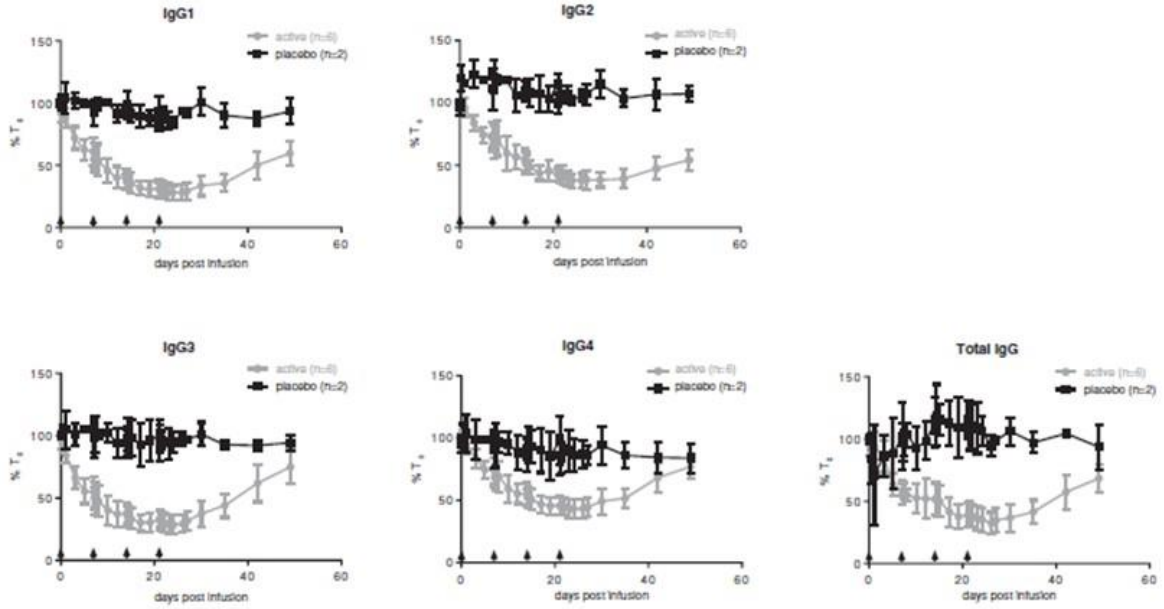


Figure 9. Reduction in the levels of four IgG antibody classes and total IgG levels in the multiple ascending dose part of our Phase 1 clinical trial of ARGX 113 in healthy volunteers at a dose of 10 mg/kg every seven days

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

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

Cusatuzumab (formerly referred to as ARGX-110)

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

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

Cusatuzumab is currently being evaluated in an open-label Phase 1/2 clinical trial, in combination with azacytidine, in newly diagnosed AML patients who are unfit for intensive chemotherapy or in patients with high-risk MDS.
We reported interim results for the first 12 patients from the dose-escalation part of the Phase 1/2 clinical trial in combination with azacytidine in AML or high-risk MDS in December 2018, which demonstrated a favorable tolerability profile of the combination therapy and suggested evidence of biological activity across the evaluated doses. In addition, we reported results of the Phase 2 part of the Phase 1/2 clinical trial in CTCL for 26 evaluable patients.

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

Overview of Acute Myeloid Leukemia and Myelodysplastic Syndrome

AML is a hematologic cancer characterized by excessive proliferation of myeloid stem cells and their failure to properly differentiate into mature white blood cells. AML is the second most common subtype of leukemia in adults. In the United States, AML has an incidence of approximately 22,000 new cases annually (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 expect the majority of patient enrollment in this clinical trial to be AML patients. We reported interim results from the dose-escalation part of this clinical trial in December 2018. Patient recruitment is currently ongoing for the Phase 2 part of this clinical trial.

In addition, cusatuzumab is being evaluated in an open-label Phase 1/2 clinical trial relapsed or refractory CD70-positive CTCL patients and an open-label Phase 1 clinical trial in patients with nasopharyngeal carcinoma. By De-

cember 2018, 27 and 11 patients have been enrolled in these clinical trials respectively and recruitment has been completed. Prior to this, cusatuzumab was evaluated in an extensive Phase 1 clinical trial in patients with advanced malignancies expressing CD70, following a step-wise adaptive clinical trial design enrolling a total of 86 patients (of whom 85 patients have been treated).

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

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

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

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

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

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

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

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

In December 2018, we entered into a collaboration agreement with Cilag GmbH International, an affiliate of the Janssen Pharmaceutical Companies of Johnson & Johnson or Janssen, to jointly develop and commercialize Cusatuzumab. See "—Collaborations."

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

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

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

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

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

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

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

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

Thrombocytopenia	—	—	—	1	—

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

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

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

ARGX-117

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

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

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

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

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

We conducted a Phase 1 clinical trial in Europe consisting of a dose escalation part in 19 treatment refractory patients whose tumors overexpress c Met and a safety expansion part in five treatment refractory patients whose

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

Dose Escalation Part

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

Safety Expansion Part

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

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

Preclinical Data

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

Intent to Partner

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

Our Partnered Programs

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

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

ARGX-112 (partnered with LEO Pharma)

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

ARGX-112 employs our SIMPLE Antibody™ technology and blocks the interleukin-22 receptor, or IL-22R, in order to neutralize the signaling of interleukin-22, or IL-22, and interleukin-20, or IL-20, both of which are cytokines involved in the proliferation and differentiation of skin cells. When overexpressed, IL-22 and IL-20 are implicated in autoimmune diseases of the skin, including atopic dermatitis, psoriasis and pustular psoriasis. In preclinical studies, ARGX-112 was observed to have high neutralization potency for IL-22R and favorable *in vivo* pharmacokinetics and distribution to the skin.

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

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

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

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

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

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

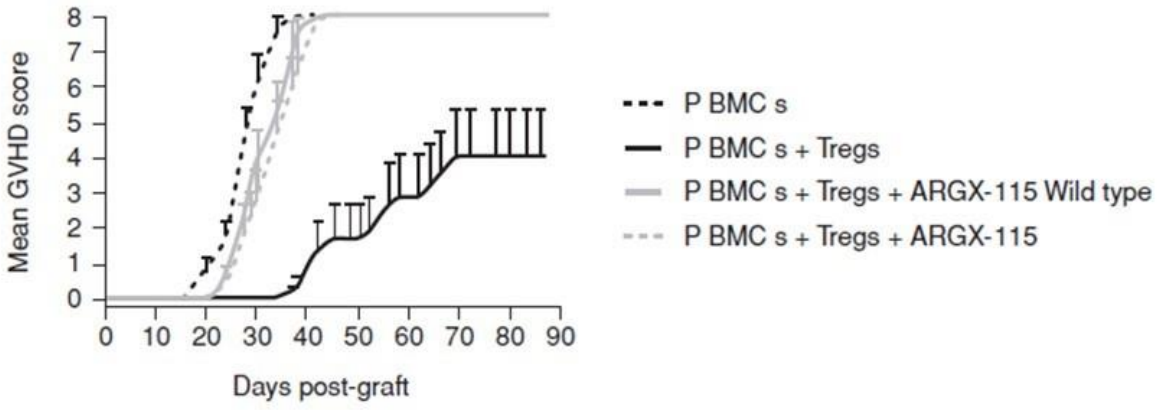


Figure 10. Preclinical data of ARGX-115 (ABBV-151) in a graft versus host disease model

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

ARGX-116 (partnered with Staten Biotechnology)

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

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

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

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

ARGX 109 (partnered with Bird Rock Bio)

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

ARGX 109 employs our SIMPLE Antibody and NHance® technologies and blocks interleukin 6, or IL 6, a cell signaling protein that is an important driver of inflammatory response implicated in the transition from acute to chronic inflammation. Chronic inflammation is a notable feature of several diseases, including RA, psoriatic arthritis and chronic kidney disease. In particular, IL 6 has been shown to stimulate the immune system to increase tissue destruction and joint damage in RA patients. By targeting a unique epitope, ARGX 109 potentially enables blocking of IL 6 with high potency, with the goal of mitigating inflammatory responses at lower and less frequent doses than current therapies directed at IL 6.

Bird Rock Bio has completed two Phase 1 clinical trials of ARGX 109 in 50 healthy volunteers to assess the safety and tolerability of the compound in single and multiple ascending doses compared to placebo. The clinical trials also explored the pharmacokinetics of ARGX 109. In these clinical trials, ARGX 109 was reported to be well tolerated with no serious adverse events. Further, ARGX 109 was observed to have a prolonged half life in circulation.

In January 2017, Bird Rock Bio announced that it had received approval for the initiation of a Phase 2 clinical trial in Brazil in approximately 200 patients with RA.

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

Innovative Access Program

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

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

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

Manufacturing and Supply

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

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

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

Competition

We participate in a highly innovative industry characterized by a rapidly growing understanding of disease biology, quickly changing technologies, strong intellectual property barriers to entry, a multitude of companies involved in

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

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

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

Competition in the leukemia and lymphoma space is intense, with many compounds in clinical trials by large multinational pharmaceutical companies and specialized biotech companies. Rituxan (Roche), Adcetris (Seattle Genetics, Inc. /Takeda Pharmaceutical Company Ltd), Darzalex (Janssen), Poteligeo (Kyowa Hakko Kirin Co., Ltd.) are some examples of monoclonal antibodies approved for the treatment of Hodgkin's lymphoma, non-Hodgkin's lymphoma, multiple myeloma or other blood cancers. We are aware of AML drugs recently approved by the FDA, such as Daurismo (Pfizer), Mylotarg (Pfizer), Rydapt (Amgen), Vyxos (Jazz Pharmaceuticals, Inc.) and IDHIFA (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 ARGX-116, if they are approved.

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

Collaborations

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

Our Strategic Partnership with Janssen (for cusatuzumab)

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

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

Under the terms of the collaboration agreement, we agreed to a joint global clinical development plan to develop cusatuzumab in AML, MDS and other potential indications in the future. Unless otherwise determined by the parties, Janssen shall be responsible for conducting the development activities specified in the global clinical development plan, subject to certain diligence obligations. The parties have equal decision-making authority and shall make consensus decisions regarding the global clinical development plan, with certain exceptions related to the territory outside of the 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., argenx shall have the right, but not the obligation, to elect to perform certain of the commercial efforts. Janssen has sole responsibility, at its sole cost and expense, to commercialize cusatuzumab outside of the U.S., subject to certain diligence obligations.

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

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).

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

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

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

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

million, $190.0 million and $325.0 million, respectively, as well as tiered royalties on sales at percentages ranging from the mid-single digits to the lower teens, subject to customary reductions.

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

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

Unless earlier terminated upon mutual agreement, for material breach or as otherwise specified in the agreement, the term of the option and license agreement ends, with respect to the ARGX-115 (ABBV-151) program, upon the earliest of (i) a technical failure of the IND-enabling studies which is outside of our control, (ii) AbbVie's election to not exercise its option, or (iii) following AbbVie's exercise of the option, fulfilment of all payment obligations under the agreement. AbbVie may terminate the agreement for any reason upon prior written notice to us. AbbVie's royalty payment obligations expire, on a product-by-product and country-by-country basis, on the date that is the later of (i) such time as there are no valid claims covering such product, (ii) expiration of regulatory or market exclusivity in respect of such product or (iii) 10 years after the first commercial sale of such product sold in that country under the agreement.

Our Collaboration with Bird Rock Bio (for ARGX 109)

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

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

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

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

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

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

In May 2015, we entered into a collaboration agreement with LEO Pharma A/S, or LEO Pharma, to develop and commercialize ARGX-112. Under the terms of the collaboration, LEO Pharma funded more than half of all product development costs up to CTA approval of a first product in a Phase 1 clinical trial, with our share of such costs capped. Now that CTA approval of a first product in a Phase 1 clinical trial has been received (in April 2018), LEO Pharma 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 ARGX-112 patent rights after completion of a Phase 2a clinical trial, LEO Pharma may exercise an option to obtain an exclusive, worldwide license to further develop and commercialize products. Following the exercise of the option, LEO Pharma would assume full responsibility for the continued development, manufacture and commercialization of such product, subject to certain diligence obligations. If LEO Pharma elects to exercise this option, it must pay us an option fee. We are also eligible to receive additional development, regulatory and commercial milestone payments in aggregate amounts of up to €11.5 million, €6.0 million and €102.5 million, respectively, as well as tiered royalties on product sales at percentages ranging from the low single digits to the low teens, subject to customary reductions.

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

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

Our Research Collaboration with Staten (for ARGX-116)

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

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

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

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

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

Our Strategic Collaboration with Shire

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

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

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

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

In addition to option fees, Shire would also be obligated to pay us on a per-product basis upon achievement of specified development, regulatory and commercial milestones and a percentage of net sales as a royalty. Milestones are paid on a first product per indication per study target basis, and we are eligible to receive payments in aggregate amounts of up to $3.8 million, $4.5 million and $22.5 million, upon achievement of development, regulatory and commercial milestones, respectively, for a product generated against one of the three initial targets named in the 2012 agreement. For products generated against additional targets nominated under the 2014 agreement, development and regulatory milestone payments remain the same, and we are eligible to receive payments in aggregate amounts of up to $60.0 million for achievement of commercial milestones. The royalties payable to us are tiered, single digit and are subject to customary reductions. Through December 31, 2018, pursuant to the agreement Shire has paid us an aggregate total of (i) €3.4 million in upfront payments, (ii) €0.3 million in milestone payments and (iii) $12.6 million in research and development funding. In addition, Shire purchased €12.0 million of our ordinary shares in July 2014 by participating in our initial public offering on Euronext Brussels.

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

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

License Agreements

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

Our Exclusive License with Halozyme (ENHANZE)

In February 2019, we entered into a license agreement with Halozyme Inc., or Halozyme, for the use of certain patents, materials and know-how owned by Halozyme and relating to its ENHANZE® Technology, for application in the field of prevention and treatment of human diseases. ENHANZE® Technology is referred to herein as ENHANZE. Under the terms of the license, we were granted exclusive rights to apply ENHANZE to biologic products against pre-specified targets, in order to research, develop and commercialize 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. Under the license terms, we also have the right to nominate future targets - again for an exclusive ENHANZE license if the target in question has not already been licensed by Halozyme, or is not already being pursued by Halozyme. From the effective date of the license agreement, we have a four-year period in which to conduct research and preclinical studies on other target-specific molecules in combination with ENHANZE and may nominate a maximum of two targets for an exclusive commercial license during the four-year term.

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

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

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

As also set out in chapter 9 "Management", our non-executive director James M. Daly is also a non-executive member of the board of directors of Halozyme. Despite this, our entering into the license agreement with Halozyme was not a related party transaction in accordance with IAS 24 – Related Party Disclosures, since Mr. Daly, in his role as non-executive director, does not control or have significant influence over our company or Halozyme. Mr. Daly did not participate in any discussions and decision making relating to the Halozyme license agreement. Consequently, no further disclosures regarding Halozyme have been added in chapter 10 “Related Party Transactions”.

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

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

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

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

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

Our Non-Exclusive License with BioWa (POTELLIGENT®)

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

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

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

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

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

To scale up production of our product candidates cusatuzumab and ARGX-111 for clinical trial and commercial supply, we required a license to a GMP cell line in which POTELLIGENT® antibodies could be expressed. This cell line, POTELLIGENT® CHOK1SV, was jointly developed by BioWa and Lonza. In December 2013 and August 2014, respectively, we entered non-exclusive commercial license agreements for cusatuzumab and ARGX-111 with BioWa and Lonza Sales AG, or Lonza, for use of certain patents and know-how relating to the POTELLIGENT® CHOK1SV Technology, which is a combination of Lonza's GS System and BioWa's POTELLIGENT® Technology, for use in the field of prevention and treatment of human diseases. Under the terms of each commercial license, we received a non-exclusive right to research, develop and commercialize products containing an antibody generated specifically against a specific target using 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, 2018, we have paid BioWa an aggregate amount of $1.625 million, which includes target reservation fees and annual research license fees under our POTELLIGENT® agreement and commercial license fees and milestone payments under our POTELLIGENT® CHOK1SV agreement. Through December 31, 2018, we have paid Lonza an aggregate amount of £0.52 million, which includes milestone payments under our POTELLIGENT® CHOK1SV agreement.

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

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

Our Collaboration with UCL and Sopartec (GARP)

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

In January 2015, we exercised the option we had been granted to enter into an exclusive, worldwide commercial license for use of certain GARP-related intellectual property rights owned by UCL and the Ludwig Institute for Cancer Research to further develop and commercialize licensed products, including the GARP-neutralizing antibody ARGX-115 (ABBV-151) which was discovered under the original collaboration. Upon the expiration of the agree-

ment, this license would become a fully paid up, perpetual worldwide exclusive license under the GARP intellectual property for any purpose, subject to UCL's retention of non-commercial research rights.

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

Intellectual Property

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

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

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

As of January 10, 2019, our patent estate (which includes both owned and in-licensed patent rights) included 21 issued U.S. patents, over 20 pending U.S. patent applications, 84 issued foreign patents (including six granted European patents that have been validated into 69 national patents) and 86 pending foreign patent applications (including 7 pending European patent applications).

Platform Technologies

With regard to our platform technologies, we own or have rights in patents and patent applications directed to our SIMPLE Antibody™ discovery platform, the ABDEG™ and NHance® platforms and the 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, Europe and Israel, and at least five patent applications pending in various other countries and regions in North America, Europe and Asia. In addition, we have a second patent family containing patents granted in the United States and Australia, and eight patent applications pending in the United States and other countries in North America, Europe and Asia, with composition of matter claims directed to a chimeric antibody containing variable regions with CDRs derived from a llama antibody and certain amino acid substitutions corre-

sponding to amino acids present in a human germline variable region. The granted U.S. patent and the pending U.S. patent application, if issued as a patent, are expected to expire in 2029.

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

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

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

Product Candidates: Wholly-Owned Programs

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

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

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

or the multi-specific antibody binds the epitope bound by the ARGX-111 antibody. The U.S. patent is expected to expire in 2033.

Product Candidates: Partnered Programs

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

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

With regard to the ARGX-112 product candidate, we have a pending international application with composition of matter claims directed to an antibody that binds human IL-22R. A U.S. patent, if it were to issue, that claims priority to the international application would be expected to expire in 2037, without taking a potential patent term extension into account. Furthermore, ARGX-112 incorporates the SIMPLE Antibody™ technology, which is covered by one or more of the patents and patent applications discussed above under "Platform Technologies."

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

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

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

Government Regulation

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

Licensure and Regulation of Biologics in the United States

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

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

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

Nonclinical Studies and Investigational New Drug Application

Before testing any biologic product candidate in humans, the product candidate must undergo nonclinical testing. Nonclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as animal studies to evaluate the potential for activity and toxicity. The conduct of the nonclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the nonclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an Investigational New Drug, or IND, application. The IND automatically becomes effective 30 days after receipt by the FDA, unless

before that time the FDA raises concerns or questions about the product or conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns before the clinical trial can begin.

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

Human Clinical Trials in Support of a BLA

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

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

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

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

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

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

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

Compliance with cGMP Requirements

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

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

Review and Approval of a BLA

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

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

On the basis of the FDA's evaluation of the application and accompanying information, including the results of the inspection of the manufacturing facilities and any FDA audits of clinical trial sites to assure compliance with GCPs,

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

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

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

Fast Track, Breakthrough Therapy and Priority Review Designations

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

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

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

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

Accelerated Approval Pathway

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

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

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

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

Post-Approval Regulation

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

effort in the areas of production and quality control to maintain compliance with cGMP regulations and other regulatory requirements.

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

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

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

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

Orphan Drug Designation

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

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

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

The period of exclusivity begins on the date that the marketing application is approved by the FDA and applies only to the indication for which the product has been designated. The FDA may approve a second application for the

same product for a different use or a second application for a clinically superior version of the product for the same use. The FDA cannot, however, approve the same product made by another manufacturer for the same indication during the market exclusivity period unless it has the consent of the sponsor or the sponsor is unable to provide sufficient quantities.

Pediatric Studies and Exclusivity

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

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

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

Biosimilars and Exclusivity

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

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

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

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

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

Clinical Trial Approval

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

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

Orphan Drug Designation and Exclusivity

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

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

Marketing Authorization

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

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

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

Periods of Authorization and Renewals

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

Regulatory Requirements after Marketing Authorization

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

Coverage, Pricing and Reimbursement

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

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

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

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

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

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

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

the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

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

Healthcare Law and Regulation

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

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

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

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

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

Healthcare Reform

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

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

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic products, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices and extending rebate liability to prescriptions for individuals enrolled in Medicare Advantage plans;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for products that are inhaled, infused, instilled, implanted or injected;
- expanding the types of entities eligible for the 340B drug discount program;
- establishing the Medicare Part D coverage gap discount program, which requires manufacturers to provide a 50% point-of-sale-discount off the negotiated price of applicable products to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient products to be covered under Medicare Part D;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of the Center for Medicare and Medicaid Innovation within Centers for Medicare & Medicaid, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription product spending (funding has been allocated to support the mission of the CMS Innovation through 2019).

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

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

Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed repeal legislation, it has enacted laws that modify certain provisions of the ACA, such as removing or delaying penalties, starting January 1, 2019, for not complying with the ACA’s individual mandate to carry health insurance, delaying the implementation of certain ACA-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. On December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and 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. It is unclear how this decision and any subsequent appeals and other efforts to repeal and replace the ACA will impact the ACA and our business. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. We will continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

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

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. The Trump administration’s budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of

drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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

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

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

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

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our current or any future products. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most European Union member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant

health service providers. Coupled with ever-increasing European Union and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize any products for which we obtain marketing approval. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

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

Employees

As of December 31, 2018, we had 105 employees (excluding consultants). At each date shown below, we had the following number of employees, broken out by department and geography:

		2018		**2017**
Function:				
Research and development		75		58
Selling, general and administrative		30		15
Total		105		73
Geography:				
Zwijnaarde, Belgium		94		73
Boston, USA		11		—
Breda, the Netherlands		—		—
Total		105		73

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.

Environment, Health and Safety

Our research and development activities take place in our facilities in Zwijnaarde, Belgium. For these activities we have obtained the necessary environmental and biohazard permits from the responsible governments. See Part 1 "Risk factors —Risks Related to Our Business and Industry."

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 also lease an office in Breda, the Netherlands.

We lease office space in Boston, Massachusetts. The lease runs on a yearly basis. In January 2019, we signed an agreement to lease additional office space to accommodate the anticipated growth of our U.S. activities in line with our business plan.

Legal Proceedings

From time to time we may become involved in legal, governmental or arbitration proceedings or be subject to claims arising in the ordinary course of our business. We are not presently a party to any legal, governmental or arbitration

proceeding. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

8 OVERVIEW OF OUR RESTRUCTURING AND POSSIBLE REDOMICILIATION

Transfer of our Intellectual Property from argenx SE to argenx BVBA

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

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

Dutch Tax Consequences of Our Restructuring

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

Belgian Tax Consequences of Our Restructuring

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

- the indemnification payment that was paid by the Belgian BVBA to argenx SE for the restructuring does not deviate from what would have been agreed by two independent companies in a similar relational situation including the previously built relationships which have effect in the framework of the restructuring and will not give rise to an adjustment on the basis of article 185 §2 of the Belgian Income Tax Code;
- the Belgian BVBA will not grant or receive an abnormal or benevolent advantage within the meaning of articles 26, 79 and 207 of the Belgian Income Tax Code;

- the indemnification payment paid by the Belgian BVBA to argenx SE for the restructuring is expected to qualify as a deductible cost for the Belgian BVBA under article 49 §2 of the Belgian Income Tax Code, being (partly) incurred in the fiscal period in which the restructuring has been implemented and (partly) incurred in the following years in the form of a periodical amortization if the accounting treatment of the restructuring requires that the compensation is to be (partly) activated; and
- the restructuring was justified by other motives than the avoidance of income taxes within the meaning of article 344 of the Belgian Income Tax Code.

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

As set out in "Risk factors—Risks Related to Our Organization and Operations— 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" we may not obtain the tax ruling from the Belgian ruling commission and we may not be allowed to treat the amount of €80 million as a deductible cost for the Belgian BVBA.

Transfer of Our Registered Office from the Netherlands to Belgium

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

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

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

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

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

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

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

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

9 MANAGEMENT

Our Board of Directors

We have a one-tier board structure consisting of an executive director who is responsible for our day-to-day management and non-executive directors who are responsible for the supervision of the executive 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 relevant information concerning our board of directors and certain provisions of the Articles of Association and Board By-Laws concerning our board of directors.

This summary does not purport to give a complete overview and should be read in conjunction with, and is 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.

Duties of Board Members

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 non-executive directors supervise the management of the executive directors and the general affairs in the company and the business connected with it and provide the executive directors with advice. In addition, both the executive directors and the non-executive directors must perform such duties as are assigned to them pursuant to the Articles of Association. The division of tasks within our board of directors is determined (and amended, if necessary) by our board of directors. Each director has a duty to properly perform the duties assigned to him or her and to act in our corporate interest. 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.

An executive director may not be allocated the tasks of: (i) serving as chairperson of our board of directors; (ii) determining the remuneration of the executive directors; or (iii) nominating directors for appointment. An executive director may not participate in the adoption of resolutions (including any deliberations in respect of such resolutions) relating to the remuneration of executive directors. Certain resolutions of our board can only be adopted with the consent of a majority of the non-executive directors.

Current composition of the Board

Our board of directors is currently comprised of one executive director and six 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 this Registration Document:

Name	Date of Birth	Age	Gender	Position	Nationality	Date of initial appointment	Date of last (re-)appointment	Term expiration
Tim Van Hauwermeiren	March 19, 1972	47	M	Executive Director (Chief Executive Director)	BE	September 9, 2008 (1)	May 8, 2018	2022
Peter K. M. Verhaeghe	November 9, 1958	60	M	Non-executive Director (chairperson)	BE	October 15, 2008 (2)	May 8, 2018	2022

David L. Lacey	July 25, 1952	66	M	Non-Executive Director	US	August 1, 2012 (3)	May 8, 2018	2022
Werner Lanthaler	September 2, 1968	50	M	Non-Executive Director (vice chairperson)	AT	April 8, 2014	May 8, 2018	2022
J. Donald deBethizy	December 11, 1950	68	M	Non-Executive Director	US	May 13, 2015	May 13, 2015	2019
Pamela Klein	October 13, 1961	57	F	Non-Executive Director	US	April 28, 2016	April 28, 2016	2020
A. A. Rosenberg	February 8, 1953	66	M	Non-Executive Director	UK	April 26, 2017	April 26, 2017	2021
James M. Daly	September 12, 1961	57	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 HA, Breda, the Netherlands.

Donald deBethizy is expected to be nominated for re-appointment at the General Meeting to be held in 2019.

Our board of directors has determined that all of the non-executive members of the board of directors are independent under the Nasdaq's listing requirements and that all of the non-executive members of the board of directors are independent under the Dutch Corporate Governance Code.

The following is the biographical information of the members of our board of directors:

Tim Van Hauwermeiren co-founded our company in 2008 and has served as our Chief Executive Officer since July 2008. He has served as a member of our board of directors since July 2014. Mr. Van Hauwermeiren has more than 20 years of general management and business development experience across the life sciences and consumer goods sectors. Mr. Van Hauwermeiren holds a B. Sc. and M. Sc. in bioengineering from Ghent University (Belgium) and an Executive MBA from The Vlerick School of Management.

Peter K. M. Verhaeghe has served as a member and chairperson of 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 and Swiss biotechnology and diagnostics companies. Mr. Verhaeghe served as the president of the board of directors of Merisant France SAS, as a member of the management board of Merisant Company 2 sàrl and serves as a member of the board of directors of CzechPak Manufacturing s. r. o. He previously served as the chairman of the board of directors of PharmaNeuroBoost NV from December 2006 to January 2013 and as liquidator in charge of KBC Private Equity Fund Biotech NV from April 2009 to December 2012. Mr. Verhaeghe holds a degree in law from the University of Leuven and an LLM degree from Harvard Law School.

Dr. David L. Lacey has served as a member of our board of directors since July 2014. Dr. Lacey is a biopharmaceutical consultant at David L. Lacey LLC, where he advises academic institutions, biotechnology companies and venture capital firms, a position he has held since July 2011. He currently serves as a director of Inbiomotion SL, Atreca, Inc. and Nurix, Inc. From 1994 until his retirement in 2011, he held various positions, including head of discovery research, at Amgen Inc., where he played a fundamental scientific role in the discovery of the

OPG/RANKL/RANK pathway, which led to the development of the anti-RANKL human mAb denosumab, for both osteoporosis (Prolia) and cancer-related bone diseases (XGEVA). He holds a Bachelor's degree in biology and an M. D. from the University of Colorado, and has his board certification in anatomic pathology.

Dr. Werner Lanthaler has served as a member of our board of directors since July 2014. Dr. Lanthaler is the chief executive officer of Evotec AG, a global drug discovery research organization, a position he has held since March 2009. Dr. Lanthaler previously served on the supervisory boards of Bioxell SpA and Pantec Biosolutions AG. Dr. Lanthaler holds a degree in psychology, a Ph. D. in business administration from Vienna University of Economics and Business and a Master's degree in public administration from Harvard University.

Dr. J. Donald deBethizy has served as a member of our board of directors since May 2015. Dr. deBethizy has 30 years of experience in research and development and financial, business and operating management in the biotechnology and consumer products industry. He is the president of White City Consulting ApS. Previously, Dr. deBethizy served as president and chief executive officer of Santaris Pharma A/S until October 2014, when the company was sold to Roche. From August 2000 to June 2012, Dr. deBethizy was co-founder and chief executive officer of Targacept, Inc., a U.S. biotechnology company listed on Nasdaq. He currently serves on the supervisory boards of Albumedix A/S, Newron Pharmaceuticals SpA, Noxxon Pharma NV and AG, Rigontec GmbH and Proterris, Inc. From May 2013 to November 2014, he served as executive chairman of Contera Pharma ApS. He previously served on the boards of Asceneuron SA, Serendex Pharmaceuticals A/S, Enbiotix Inc., Targacept Inc. and Biosource Inc. Dr. deBethizy has held adjunct appointments at Wake Forest University Babcock School of Management, Wake Forest University School of Medicine and Duke University. Mr. deBethizy holds a B. Sc. in biology from the University of Maryland, and an M. Sc. and a Ph. D. in toxicology from Utah State University.

Dr. Pamela Klein has served as a member of our board of directors since April 2016. Dr. Klein is a principal and founder of PMK BioResearch, which offers strategic consulting in oncology drug development to corporate boards, management teams and the investment community, a position she has held since 2008. She currently serves as a member of various scientific advisor boards. Previously, Dr. Klein spent seven years at the National Cancer Institute as Research Director of the NCI-Navy Breast Center, after which she joined Genentech and was VP, Development until 2001. She served as Chief Medical Officer for Intellikine which was acquired by Takeda. She was previously Vice President, Development for Genentech. Dr. Klein holds a Bachelor's degree in biology from California State University and an M. D. from Stritch School of Medicine, Loyola University Chicago and is trained in internal medicine and medical oncology.

Msc. A. A. Rosenberg has served as a member of our board of directors since April 2017. He currently serves as CEO of TR Advisory Services GmbH, a consultancy firm advising on business development, licensing and mergers and acquisitions. Mr. Rosenberg has also been a Managing Director of MPM Capital, a venture capital firm, since April 2015. From January 2013 until February 2015, he served as Corporate Head of M&A and Licensing at Novartis Pharma. He served as Global Head of Business Development and Licensing at Novartis Pharma from March 2005 to December 2012. Msc. A. A. Rosenberg holds non-executive board memberships Radius Health Inc., TriNetX, Inc., iOmx Therapeutics AG, Cullinan Oncology Inc. and Oculis SA. Msc. A.A. Rosenberg has a B.Sc. (Hons) from the University of Leicester and a M.Sc. Physiology from the University of London.

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

Our Executive Management

The following table sets forth certain information with respect to the current members of our executive management team including their ages as of March 22, 2019:

Name	Age	Position	Nationality	Date of first employment/engagement
Tim Van Hauwermeiren	47	Chief Executive Officer and Executive Director	BE	July 15, 2008
Eric Castaldi	54	Chief Financial Officer	F	April 1, 2014
Keith Woods	51	Chief Operating Officer	US	April 5, 2018
Nicolas Leupin	45	Chief Medical Officer	CH	February 1, 2016
Hans de Haard	59	Chief Scientific Officer	NL	July 1, 2008
Torsten Dreier	54	Chief Development Officer	DE	May 1, 2008
Debbie Allen	59	Senior VP Business Development	UK	November 1, 2010
Dirk Beeusaert	55	General Counsel	BE	April 1, 2017

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

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

Eric Castaldi has served as our Chief Financial Officer since April 2014 and served as a member of our board of directors from July 2014 to April 26, 2017. Mr. Castaldi has 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. 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.

Dr. Nicolas Leupin has served as our Chief Medical Officer since February 2016. Dr. Leupin has clinical and industry expertise in medical oncology as well as experience in drug development. He currently lectures at the University of Bern. From 2008 to 2015, Dr. Leupin served in different positions in clinical development at Celgene, including Director of Clinical Development of EMEA Celgene, where he contributed to building the clinical development department in Europe and then led the European lymphoma and myeloma teams, served as clinical lead for several compounds up to phase III clinical trials, and was responsible for running and managing hematology and oncology clinical trials, including both industry-sponsored trials and academic cooperative groups, several of them through to registration. Among other activities, he was responsible for specific clinical documents of registration dossiers that lead to European and American registrations. Dr. Leupin holds an MBA from Jones International University and an M. D. from the University of Bern and was board certified in medical oncology (Switzerland).

Prof. Hans de Haard has served as our Chief Scientific Officer since July 2008. Prof. de Haard has been active in the antibody engineering field since 1989. He also serves as a Professor of Immunology at University of Franche Comté (France). Prof. de Haard holds an M. Sc. in biochemistry from the Higher Professional Education for Laboratory Technicians (Oss, the Netherlands) and a M. Sc. in chemistry from the Institute of Technology (Rotterdam, the Netherlands) and a Ph. D. in molecular immunology from Maastricht University.

Dr. Torsten Dreier has served as our Chief Development Officer since May 2008. Dr. Dreier has been developing antibodies for more than 20 years and led teams that progressed seven antibody products from preclinical research into clinical trials. Dr. Dreier holds an M. Sc. and a Ph. D. in biochemistry from the University of Tübingen (Germany).

Dr. Debbie Allen has served as our Senior Vice President of Business Development since November 1, 2010. Dr. Allen has been active in the antibody engineering field since the 1980s. She has more than 30 years of corporate and business development experience with small and large biotech companies focused on biopharmaceuticals. Dr. Allen is an inventor of HUMIRA (adalimumab). Prior to joining us, Dr. Allen acted as an independent consultant to emerging biotech companies, providing strategic management and business development support. Dr. Allen holds an B. Sc. in cellular pathology from the University of Bristol and a Ph. D. in viral oncology from the University of London.

Dirk Beeusaert has served as our General Counsel since April 1, 2017. Mr. Beeusaert has extensive general experience in corporate governance and as general counsel of a listed company. Mr. Beeusaert worked in various roles from February 1996 to July 2016 for Gimv NV, a European private equity company listed on Euronext Brussels, including chief legal officer from January 2001 to 2006, and general counsel from 2006 to July 2016, where he was co-responsible for operations and corporate governance. Mr. Beeusaert currently serves as a member of the board of directors of Cubigo NV, and until November 2018 served as a member of the board of directors of Pragma Capital SAS. 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.

Director Independence

As a foreign private issuer, under the listing requirements and rules of Nasdaq, we are not required to have independent directors on our board of directors, except that our audit committee is required to consist fully of independent directors, subject to certain phase-in schedules. However, our board of directors has determined that, under current listing requirements and rules of Nasdaq and taking into account any applicable committee independence standards, all of our non-executive directors are "independent directors". In making such determination, our board of directors considered the relationships that each non-executive director has with us and all other facts and circumstances our board of directors deemed relevant in determining the director's independence, including the number of ordinary shares beneficially owned by the director and his or her affiliated entities (if any).

The 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.

Role of the Board in Risk Oversight

Our board of directors is responsible for the oversight of our risk management activities and has delegated to the audit committee the responsibility to assist our board in this task. While our board oversees our risk management, our management is responsible for day-to-day risk management processes. Our board of directors expects our management to consider risk and risk management in each business decision, to proactively develop and monitor risk management strategies and processes for day-to-day activities and to effectively implement risk management strategies adopted by the board of directors. We believe this division of responsibilities is the most effective approach for addressing the risks we face.

Composition, Appointment and Dismissal

The Articles of Association provide that our board of directors will consist of our executive 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, with the proviso that the board of directors must consist of at least three members.

Our directors are appointed by the shareholders at the General Meeting 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 subse-

quently 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 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.

Committees

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

The committees are advisory bodies only, and the decision-making remains within the collegial responsibility of the non-executive directors. The non-executive directors determine the terms of reference of each committee with respect to the organization, procedures, policies and activities of the committee.

Our non-executive directors have established and appointed an audit committee, a remuneration and nomination committee and a research and development 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 committee and the remuneration and nomination committee may not be chaired by the chairperson of the board of directors or by a former executive director of the company.

Audit Committee

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

Our board of directors has determined that all members of our audit committee are independent under Rule 10A-3 of the Exchange Act and the applicable rules of the Nasdaq Stock Market and all members of our audit committee are independent under the applicable rules of the Dutch Corporate Governance Code, and 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.

Our board of directors has determined that all members of our audit committee are independent under the applicable rules of the Dutch Corporate Governance Code and that the composition of the audit committee meets the requirements under the Dutch Decree on Establishing Audit Committees.

Our audit committee assists our board of directors in overseeing the accuracy and integrity of our accounting and financial reporting processes and audits of our consolidated financial statements, the implementation and effectiveness of an internal control system and our compliance with legal and regulatory requirements, the independent auditors' qualifications and independence and the performance of the independent auditors.

The audit committee is governed by a charter that complies with Nasdaq listing rules and the Dutch Corporate Governance Code. Our audit committee is responsible for, among other things:

- ensuring the integrity of our financial reporting, including review of period information before it is made public;
- supervising the company's policies with respect to financing and tax;
- evaluating our system of internal controls set up by our board of directors, including evaluation and approval of the explanatory notes on internal controls in our annual reports;
- reviewing the functions of our internal risk management system and the efficacy of these systems, including the review of ICT-applications with a view to e.g. cybersecurity ;
- assessing the necessity for setting up an internal audit function; and
- supervising our relationship with our independent auditors during the external audit process, including evaluation of our auditors' independence.

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

Our audit committee reports regularly to our board of directors on the exercise of its functions. It informs our board of directors about all areas in which action or improvement is necessary in its opinion and produces recommendations concerning the necessary steps that need to be taken. The audit review and the reporting on that review cover us and our subsidiaries as a whole. The members of the audit committee are entitled to receive all information which they need for the performance of their function, from our board of directors and employees. Every member of the audit committee shall exercise this right in consultation with the chairperson of the audit committee.

The audit committee has deliberated 7 times in the course of 2018. At these meetings, the main points of discussion were (annual, interim and quarterly) financial statements, quarterly forecasts, the presentation of the annual report and form 20-F report and the audit report from Deloitte, internal and external reviews with respect to risk management and internal controls (including SOx compliance, annual risk assessment and register) review of the 3 years business plan, transfer pricing with argenx In, the internal audit function and its charter, allocation of proceeds from the September 2018 financing, the audit fees and audit plan, updates on cash, cash equivalents and financial instruments, 2019 budget and evaluation of the functioning of the committee and its members.

Remuneration and Nomination Committee

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

Our board of directors has determined that all members of our remuneration and nomination committee are independent under the applicable rules of the Nasdaq Stock Market and all members of our remuneration and nomination committee are independent under the applicable rules of the Dutch Corporate Governance Code.

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

- reviewing and recommending the remuneration policy for approval by the shareholders at the General Meeting;
- reviewing and recommending the remuneration policy for the directors for approval by the shareholders at the General Meeting; such proposal shall, in any event, deal with: (i) the remuneration structure and (ii) the amount of the fixed remuneration, the shares and/or options to be granted and/or other variable remuner-

ation components, pension rights, redundancy pay and other forms of compensation to be awarded, as well as the performance criteria and their application;
- preparing the remuneration report;
- preparing selection criteria and appointment procedures for directors;
- periodically assessing the size and composition of our board of directors and making a proposal for a composition profile of the non-executive directors;
- periodically assessing the performance of individual directors and reporting on this to the non-executive directors;
- making proposals for appointments and reappointments; and
- supervising the policy of our board of directors on the selection criteria and appointment procedures for senior management.

The remuneration and nomination committee consists of at least three members. The remuneration and nomination committee meets as often as is required for its proper functioning, but at least once per year to evaluate its functioning.

The remuneration and nomination committee has deliberated 3 times in the course of 2018. The main topics of discussion were the composition of the board with regard to the non-executive directors, an update to the non-executive directors' profile, the vacant board position and the nomination of James M. Daly for such position, compensation and relevant external benchmarking reports, the draft remuneration report, the relevant re-appointments of non-executive directors and the executive-director and the management targets.

Research and Development Committee

Our research and development committee consists of three members: David L. Lacey (chairperson), J. Donald deBethizy and Pamela Klein.

Our board of directors has determined that all members of our research and development committee are independent under the applicable rules of the Nasdaq Stock Market and all members of our research and development committee are independent under the applicable rules of the Dutch Corporate Governance Code.

The research and development committee is responsible for, among other things:

- monitoring and overseeing the research and development goals, strategies and measures of the company;
- serving as a sounding board to the company's research and development management, general management and the board of directors;
- performing strategic reviews of the company's key research and development programs;
- reporting to the board of directors on the outcome of the strategic reviews;
- reviewing the company's scientific publication and communications plan;
- evaluating and challenging the effectiveness and competitiveness of the research and development endeavors of the company;
- reviewing and discussing emerging scientific trends and activities critical to the success of research and development of the company;
- reviewing the company's clinical and preclinical product pipeline; and
- engaging in attracting, retaining and developing senior research and development personnel of the company.

All members of the research and development committee shall have adequate industrial, academic and/or practical experience with the research and development of biopharmaceuticals.

One purpose of our research and development committee is to engage in discussion with our research and development management, and the committee's responsibilities to carry out this purpose include, among others: monitoring the research and development activities, performing strategic reviews of the key research and development programs; and reviewing the scientific publication plan.

Our research and development committee meets as often as is required for its proper functioning, but at least prior to each meeting of our board of directors, and reports regularly to our board of directors on the outcome of the strategic reviews. Our research and development committee consists of at least three members with adequate industrial experience with the research and development of biopharmaceuticals. The chairperson of our research and development committee shall report formally to our board of directors on the research and development com-

mittee's deliberations, findings and proceedings after each meeting on all matters within its duties and responsibilities.

General Information About the Current Members of Our Board of Directors and Executive Management

The following table sets forth the companies and partnerships of which the current members of our board of directors and 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 SE or our subsidiaries:

Name	**Current**	**Past**
Peter K. M. Verhaeghe	VVGB Advocaten – Avocats	PharmaNeuroBoost NV
	Merisant France SAS	Biocartis NV
	Merisant Company 2 sàrl	Fujirebio Europe NV (formerly Innogenetics NV)
	CzechPak Manufacturing s. r. o.	KBC Private Equity Fund Biotech NV
David L. Lacey	David L. Lacey LLC	-
	Inbiomotion SL	
	Atreca, Inc.	
	Nurix, Inc.	
Werner Lanthaler	Evotec AG	Bioxell SpA
		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
	Rigontec GmbH	Targacept, Inc.
	Protteris, Inc.	LigoCyte Pharmaceuticals Inc.
		Enbiotix Inc
		Biosource Inc.
Pamela Klein	PMK BioResearch	Intellikine
A. A. Rosenberg	Cullinan Oncology	Novartis Pharma
	Oculis	MPM Capital
	Radius Health, Inc.	
	TriNetX, Inc.	
	Clinincal Ink, Inc.	
	iOmx Therapeutics AG	
James M. Daly	Chimerix Inc	Incyte
	Acadia Pharmaceuticals	AMGEN
	Coherus Biosciences	GlaxoSmithKline
	Halozyme Therapeutics	
	Bellicum Pharmaceuticals	
Tim Van Hauwermeiren	Iteos NV	-

	Aelin Therapeutics	
Eric Castaldi	-	Nicox SA
		Hybrigenics Services SA
Hans de Haard	-	-
Nicolas Leupin	-	Celgene
Torsten Dreier	-	-
Debbie Allen	Andiamo Biotech	-
Dirk Beeusaert	Cubigo NV	Gimv NV (and group companies of Gimv NV)
	The Fourth Law NV	TINC NV
		CapMan plc
		Grandeco NV
		DG Infra+ NV
		Finimmo NV
		Pragma Capital SAS

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

As of the date of this 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 or liquidation;
- has been subject to any official public incrimination and/or sanction by any statutory or regulatory authority (including any designated professional body); or
- has ever been disqualified by a court from acting as a member of the administrative, management or supervisory bodies of any company or from acting in the management or conduct of affairs of any company.

Corporate Governance Practices

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.

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.

Board of Directors Resolutions Requiring a Special Majority

Under the Board By-Laws, the following actions require the consent of the majority of the non-executive directors:

- any proposal of our board of directors to the General Meeting with respect to the matters entailing a significant change in the identity or character of the company or its business as referred to in Section 2:107a of the Dutch Civil Code;
- any proposal of our board of directors to the General Meeting with respect to the dissolution, liquidation or winding up of the company;
- any proposal of our board of directors to the General Meeting with respect to an amendment of the Articles of Association;
- any proposal of our board of directors to the General Meeting with respect to an issue of shares in our capital or to grant rights to subscribe for shares in our capital or to designate our board of directors as the corporate body authorized to do so as well as a resolution of our board of directors to issue shares or to grant rights to subscribe for our shares;
- any proposal of our board of directors to the General Meeting with respect to the exclusion or restrictions of pre-emptive rights to subscribe for shares in our capital or to rights to subscribe for shares in our capital or to designate our board of directors as the corporate body authorized to do so as well as a resolution of our board of directors to restrict or exclude pre-emptive rights;
- acquisition of our own shares;
- any proposal of our board of directors to the General Meeting with respect to a reduction of share capital;
- any change to our accounting policies;
- adoption of as well as any changes to our reserves and dividends policy, as well as any proposal of our board of directors to the General Meeting for the payment of any dividends, an interim distribution as referred to in the first sentence of article 20, paragraph 6 of the Articles of Association, or any distribution out of our reserves;
- adoption of our annual budget and the group to which we form a part, which will include an investment plan and a financing plan, as well as any update or other change to the adopted annual budget;
- otherwise than in accordance with the adopted annual budget, subscribing or otherwise acquiring, or disposing of securities in the capital of other companies, or establishing any new branch or subsidiary as well as dissolving, liquidating, winding-up any such branch or subsidiary;
- otherwise than in accordance with the adopted annual budget, incurring any debt, issuing any guarantees, making any loan or advances or giving any credit;
- otherwise than in accordance with the adopted annual budget, the assignment or other sale of patents or other intellectual property other than the grant of non-exclusive licenses in the ordinary course of business;
- expenses, investments and divestments other than in accordance with the adopted annual budget;
- disposing of or acquiring any asset (including intellectual property rights) other than in accordance with the approved annual budget;
- adoption and amendment of an employee stock option plan as well as the increase of the number of shares in the capital, or to whom stock options can be granted and the conditions of the stock options under any existing employee stock incentive plan;
- establishing pension plans and granting pension rights in excess of those arising from existing arrangements;
- hiring and determining terms of employment, or changing any existing terms of employment, of key personnel, senior company officers or any other personnel with a gross salary (including bonus but excluding options) in excess of €150,000 per year;
- conducting any litigation on behalf of the company other than in relation to the collection of debts, and taking measures which cannot be delayed, and making settlements;
  directly or indirectly entering into any agreements, contracts or arrangements which are not of an at arm's length nature and the entering into an arrangement or agreement with (including, without limitation, an individual related to a shareholder of the company, executive director or non-executive director; and
- changing the business location of the company.

Our board of directors may designate further resolutions which also require the consenting vote of a majority of the non-executive directors. These further resolutions must be clearly specified and in writing.

Resolutions of the board of directors entailing a significant change in the identity or character of the company or its business require the approval of the shareholders at the General Meeting. This includes in any case: (i) the transfer to a third party of the business of the company or practically the entire business of the company; (ii) the entry into or breaking off of any long-term cooperation of the company or a subsidiary with another legal entity or company or as a fully liable partner of a general partnership or limited partnership, where such entry or breaking off is of far-reaching importance to the company; or (iii) the acquisition or disposal by the company or a subsidiary of an interest

in the capital of a company with a value of at least one-third of the company's assets according to the consolidated balance sheet with explanatory notes included in the last adopted annual accounts of the company. Failure to obtain the approval of the shareholders at the General Meeting for these resolutions of the board of directors does not affect the power of representation of the board of directors.

The board of directors as a whole is authorized to represent the company. In addition, two executive directors acting jointly are also authorized to represent the company. Our board of directors may appoint individuals (*procuratiehouders*) with general or limited power to represent the company. Each of these individuals shall be able to represent the company with due observance of any restrictions imposed on him. Our board of directors shall determine their titles. At the date of this Registration Document, Tim Van Hauwermeiren has the general power to represent the company.

Tasks that have not been specifically allocated fall within the power of our board of directors as a whole. All directors remain collectively responsible for proper management regardless of the allocation of tasks.

The executive directors and the non-executive directors may adopt legally valid resolutions with regard to matters that fall within the scope of their respective duties. Our board of directors may only adopt resolutions when the majority of the relevant directors in office will be present or represented, with a simple voting majority of the votes cast, which is 50% plus one.

Proxy Voting by Board Members

A non-executive director may issue a proxy for a specific board meeting but only to another non-executive director in writing. An executive director may issue a proxy for a specific board meeting but only to another executive director in writing. At the date of this Registration Document there are no other executive directors in office.

Corporate Governance Rules

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.corpgov.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.

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 currently do not envision to change our practices in this respect.
- We do not comply with best practice provision 2.3.2 of the Dutch Corporate Governance Code, which requires that our non-executive directors appoint among its members an audit committee, a remuneration committee and a selection and appointment committee. Our remuneration committee and the selection

and appointment committee are combined into a single committee, being the remuneration and nomination committee. This committee performs the tasks attributed by the Dutch Corporate Governance Code to the remuneration committee, as well as the tasks attributed by the Dutch Corporate Governance Code to the selection and appointment committee. Hence, the combination of these committees is an organizational matter only and we believe we achieve the objectives of this best practice provision through a single committee. We currently do not envision to change our practices in this respect.

- 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. 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 salary. 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 salary 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.
- We do not comply with best practice provision 2.1.3, which requires that if the Company has established an executive committee, the report of the board of directors shall contain certain information regarding the choice to work with an executive committee, the role and composition of that committee and the manner of communication between the board of directors and the executive committee. We have not formally established an executive committee and therefore did not include all such information in the report of the board of directors. We do have an established practice of involving members of our senior management in our board meetings and the preparation of decisions at our board level in order to provide our board members with information from our operations, thereby contributing to due and careful considerations at our board level. Although not intended as such by us, this might be perceived equivalent to an executive committee in the meaning of best practice provision 2.1.3. In the absence of a formally established executive committee, we have decided not to apply principle 2.1.3, which sets forth best practices that were not included in the previously applicable Dutch Corporate Governance Code prior to the 2016 update thereof. Our governance structure is currently under review and this best practice will be discussed as part of such review.
- We do not comply with best practice provision 2.3.1, which requires our board rules to contain a section on the interaction between the board of directors and the executive committee. As outlined above, we have not formally established an executive committee, and are in the process of reviewing our corporate governance structure also with respect to this best practice principle.
- In 2018, we did not comply with best practice provision 4.1.8, which requires that persons nominated for appointment to the board of directors, shall be present at the general meeting in which their appointment is voted on. In 2018, James Daly was nominated for appointment but was unable to attend the general meeting in person, as a result of which best practice provision 4.1.8 was not complied with in 2018.

Differences between Our Corporate Governance Practices and the Listing Rules of the Nasdaq Stock Market

We are 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.

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 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.

Equity Holdings

As at the date of this Registration Document Werner Lanthaler holds 25,972 shares.

All members of our board of directors and executive management hold stock options under the Option Plan, as set out below.

Compensation of Our Executive Management and Board of Directors

Our shareholders have adopted a policy governing the remuneration of our board of directors, which is aimed to attract, reward and retain highly qualified executive and non-executive directors and to provide and motivate the members of our board of directors with a balanced and competitive remuneration that is focused on sustainable results and is aligned with the long-term strategy of the company as set out in its business plan.

At the General Meeting on April 28, 2016, the shareholders approved an amended remuneration policy, or the Remuneration Policy, which allows for the granting of compensation packages to our directors in line with a benchmarking analysis performed by an independent consulting firm engaged by our remuneration and nomination committee and an assessment of the duties of the directors, and includes competitive severance arrangements intended to attract and retain highly qualified personnel. At the extraordinary shareholders' meeting of our shareholders held on November 7, 2017, the shareholders approved an amendment to the Remuneration Policy, discussed in more detail below. For a discussion of our employment arrangements with our executive management, see the section of this Registration Document titled "Related party transactions—Agreements with Our Executive Management".

Except for the arrangements described in the section of this Registration Document titled "Related-Party Transactions—Agreements with Our Executive Management" there are no arrangements or understanding between us and the executive director providing for benefits upon termination of his employment, other than as required by applicable law.

Compensation of our Executive Management

The remuneration of our executive management (including our executive director) consists of the following fixed and variable components:

- a fixed base salary;
- a variable annual cash bonus (short-term annual cash incentive);

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

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

Variable annual cash bonus. The objective of this short-term annual cash incentive is to ensure that our executive management is incentivized to achieve performance targets in the shorter term. Our executive management is eligible for an annual cash incentive up to a maximum percentage of his/her annual base salary. The maximum percentage for this purpose was set at 50% of base salary of the chief executive officer, 40% of base salary of the Chief Operating Officer and at 35% of base salary for other members of the executive management. Performance conditions are established by our board of directors before or at the beginning of the relevant calendar year and shall include criteria concerning our financial performance, qualitative criteria representing our performance and/or individual qualitative performance.

Long-term incentive awards. Our board of directors intends to incentivize our executive management by issuing Options from time to time to be able to attract and retain well-qualified executive management in connection with the Option Plan, as set out below.

Severance arrangements. We have entered into management contracts and employment agreements with our executive management, each of which provides for certain minimum notice periods if their service or employment with us is terminated in certain circumstances as described below in "Related party transactions—Agreements with our Executive Management".

Pension and fringe benefits. Our executive management participates in a defined contribution pension scheme operated by a third party pension insurance organization. Our executive management is entitled to customary fringe benefits, such as a company car and a hospitalization plan.

The following table sets forth information regarding compensation paid by us for Tim Van Hauwermeiren during the year ended December 31, 2018:

Tim Van Hauwermeiren

		Compensation
		(€)
Base salary		500,000
Option awards(1)		3,559,200
Employer social security contribution stock options		-
Non-equity incentive plan compensation		284,600
Pension contributions		15,102
Social security costs		10,011
Other(2)		33,855
Total		4,402,768

(1) Amount shown represents the expenses recorded with respect to the option awards granted in 2018 to Mr. Van Hauwermeiren measured using the Black Scholes formula. For a description of the assumptions used in valuing these awards, see note 4.9 to our financial statements included elsewhere in this annual report. These amounts do not reflect the actual economic value realized by Mr. Van Hauwermeiren.
(2) Consists of €21,292 rent paid by the company, €12,149 attributable to the lease of a company car and €414 in employer-paid medical insurance premiums.

The following table sets forth information regarding aggregate compensation paid by us for the members of our executive management (1) (excluding Tim Van Hauwermeiren) during the year ended December 31, 2018:

	Compensation (€)
Base salary	2,005,379
Option awards (2)	9,803,878
Employer social security contribution stock options (3)	2,792,503
Non-equity incentive plan compensation	793,347
Pension contributions	137,485
Social security costs	518,482
Other (4)	90,192
Total	16,141,266

(1) Pursuant to Section 2:383c of the Dutch Civil Code, only an individual break-down of compensation for the executive members of our board of directors is required.
(2) Amount shown represents the expenses recorded with respect to the option awards granted in 2018 to Mr. Keith Woods, Mr. Eric Castaldi, Mr. Nicolas Leupin, Prof. Hans de Haard, Dr. Torsten Dreier, Dr. Debbie Allen and Dirk Beeusaert measured using the Black Scholes formula. For a description of the assumptions used in valuing these awards, see note 4.9 to our financial statements incorporated by reference in this Registration Document. These amounts do not reflect the actual economic value realized by these members of our executive management.
(3) 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.
(4) Consists of €48,644 attributable to the leases of company cars, €25,342 in car, housing and other allowances and €16,206 in employer-paid medical insurance premiums.

The following table sets forth information regarding option awards granted to our executive management during the year ended December 31, 2018:

Item Directors OptionAwards

Name	Stock options	Expiration date	Exercise price
Tim Van Hauwermeiren (1)	80,000	12/21/2028	€ 86.32
Eric Castaldi (1)	50,000	12/21/2028	€ 86.32
Hans de Haard (1)	50,000	12/21/2028	€ 86.32
Keith Woods	50,000	12/21/2028	€ 86.32
Debbie Allen	28,200	12/21/2028	€ 86.32
Dirk Beeusaert	28,200	6/28/2023	€ 80.82
Dirk Beeusaert (1)	21,800	12/21/2028	€ 86.32

(1) On December 21, 2018, the Company has granted options for which the beneficiary had a 60-day period to choose between a contractual term of five or ten years.

The table below shows the stock options held at the start of the year ended December 31, 2018 and the stock options granted to our executive management which have vested during the year ended December 31, 2018, as well as the stock options to vest in the years ending December 31, 2019, December 31, 2020 and December 31, 2021 (in number of stock options), and the respective exercise price of such stock options:

Item_Directors_StockOptions

Name	Total options held on January 1, 2018	Options granted in 2018	Options exercised in 2018	Total options held on December 31, 2018	Options vested until 2017	Exercise price	Options vested in 2018	Exercise price	Options to vest in 2019	Exercise price	Options to vest in 2020	Exercise price	Options to vest in 2021	Exercise price
Tim Van Hauwermeiren	296,200	80,000	(40,000)	336,200	65,000	€ 7.17								
					20,400	€ 9.47	10,200	€ 9.47						
					26,389	€ 11.47	16,667	€ 11.47	6,944	€ 11.47				
					10,200	€ 14.13	10,200	€ 14.13	10,200	€ 14.13				
							26,667	€ 21.17	26,666	€ 21.17	26,667	€ 21.17		
									26,667	€ 86.32	26,666	€ 86.32	26,667	€ 86.32
Eric Castaldi	273,807	50,000	(74,039)	249,768	41,007	€ 2.44								
					30,961	€ 7.17								
					18,800	€ 9.47	9,400	€ 9.47						
					14,883	€ 11.47	9,400	€ 11.47	3,917	€ 11.47				
					9,400	€ 14.13	9,400	€ 14.13	9,400	€ 14.13				
							14,400	€ 21.17	14,400	€ 21.17	14,400	€ 21.17		
									16,667	€ 86.32	16,666	€ 86.32	16,667	€ 86.32
Nicolas Leupin	127,800	—	—	127,800	18,800	€ 9.47	9,400	€ 9.47						
					14,883	€ 11.47	9,400	€ 11.47	3,917	€ 11.47				
					9,400	€ 14.13	9,400	€ 14.13	9,400	€ 14.13				
							14,400	€ 21.17	14,400	€ 21.17	14,400	€ 21.17		
Hans De Haard	395,975	50,000	—	445,975	144,822	€ 2.44								
					109,000	€ 7.17								
					18,800	€ 9.47	9,400	€ 9.47						
					14,883	€ 11.47	9,400	€ 11.47	3,917	€ 11.47				
					9,400	€ 14.13	9,400	€ 14.13	9,400	€ 14.13				
							7,177	€ 18.41	4,784	€ 18.41	2,392	€ 18.41		
							14,400	€ 21.17	14,400	€ 21.17	14,400	€ 21.17		
									16,667	€ 86.32	16,666	€ 86.32	16,667	€ 86.32
Torsten Dreier	379,948	—	—	379,948	137,580	€ 2.44								
					105,000	€ 7.17								
					18,800	€ 9.47	9,400	€ 9.47						
					14,883	€ 11.47	9,400	€ 11.47	3,917	€ 11.47				
					9,400	€ 14.13	9,400	€ 14.13	9,400	€ 14.13				
							4,784	€ 18.41	3,189	€ 18.41	1,595	€ 18.41		
							14,400	€ 21.17	14,400	€ 21.17	14,400	€ 21.17		

Item_Directors_StockOptions

Name	Total options held on January 1, 2018	Options granted in 2018	Options exercised in 2018	Total options held on December 31, 2018	Options vested until 2017	Exercise price	Options vested in 2018	Exercise price	Options to vest in 2019	Exercise price	Options to vest in 2020	Exercise price	Options to vest in 2021	Exercise price
Debbie Allen	221,111	28,200	—	249,311	39,195	€ 2.44								
					10,616	€ 3.95								
					43,500	€ 7.17								
					18,800	€ 9.47	9,400	€ 9.47						
					14,883	€ 11.47	9,400	€ 11.47	3,917	€ 11.47				
					9,400	€ 14.13	9,400	€ 14.13	9,400	€ 14.13				
							14,400	€ 21.17	14,400	€ 21.17	14,400	€ 21.17		
									9,400	€ 86.32	9,400	€ 86.32	9,400	€ 86.32
Dirk Beeusaert	54,682	50,000	—	104,682	—	€ 18.41	19,841	€ 18.41	13,227	€ 18.41	6,614	€ 18.41		
					—	€ 21.17	5,000	€ 21.17	5,000	€ 21.17	5,000	€ 21.17		
									14,100	€ 80.82	9,400	€ 80.82	4,700	€ 80.82
									7,267	€ 86.32	7,266	€ 86.32	7,267	€ 86.32
Keith Woods	75,000	50,000	—	125,000	—	€ 21.17	25,000	€ 21.17	25,000	€ 21.17	25,000	€ 21.17		
									16,667	€ 86.32	16,666	€ 86.32	16,667	€ 86.32

The table below shows the remaining term of the stock options held by our executive management during the year ended December 31, 2018:

Item_Directors_RemainingTerm

Name	Number of stock options	Remaining term on December 31, 2018 (rounded up)	
Tim Van Hauwermeiren	65,000	6.0 years	
	30,600	7.0 years	
	50,000	7.5 years	
	30,600	8.0 years	
	80,000	9.0 years	
	80,000	5.0 / 10.0 years	(1)
Eric Castaldi	20,970	5.5 years	
	50,998	6.0 years	
	28,200	7.0 years	
	28,200	7.5 years	
	28,200	8.0 years	
	43,200	9.0 years	
	50,000	5.0 / 10.0 years	(1)
Nicolas Leupin	28,200	7.0 years	
	28,200	7.5 years	
	28,200	8.0 years	
	43,200	9.0 years	
Hans De Haard	69,360	4.5 years	
	39,636	5.0 years	
	144,826	6.0 years	
	28,200	7.0 years	
	28,200	7.5 years	
	28,200	8.0 years	
	14,353	8.5 years	
	43,200	9.0 years	
	50,000	5.0 / 10.0 years	(1)
Torsten Dreier	65,890	4.5 years	
	37,654	5.0 years	
	139,036	6.0 years	
	28,200	7.0 years	
	28,200	7.5 years	
	28,200	8.0 years	
	9,568	8.5 years	
	43,200	9.0 years	
Debbie Allen	7,180	1.5 years	
	810	2.0 years	
	18,770	4.5 years	
	10,727	5.0 years	
	55,824	6.0 years	
	28,200	7.0 years	
	28,200	7.5 years	
	28,200	8.0 years	
	43,200	9.0 years	
	28,200	10.0 years	
Dirk Beeusaert	39,682	8.5 years	
	15,000	9.0 years	
	28,200	4.5 years	
	21,800	5.0 / 10.0 years	(1)
Keith Woods	75,000	9.0 years	
	50,000	10.0 years	

(1) On December 21, 2018, 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, 2018 and the exercise price of those stock options. Per exercised option, one share was issued:

Item_Directors_StockOptionsExercised

Name	Number of stock options		Exercise price
Tim Van Hauwermeiren	40,000	€	7.17
Eric Castaldi	40,000	€	2.44
Eric Castaldi	34,039	€	7.17
Total	114,039		

Compensation of Our Non-Executive Directors

The remuneration of the individual members of the board of directors is determined by the non-executive directors, at the recommendation of the remuneration and nomination committee, within the limits of the Remuneration Policy adopted by the shareholders at the General Meeting. The description below reflects the status of our Remuneration Policy as updated by our board of directors on September 12, 2017 and giving effect to the update to the Remuneration Policy approved by our shareholders at the extraordinary shareholders' meeting held on November 7, 2017.

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

- a fixed fee, which fee will be prorated if the non-executive director does not attend all meetings where his or her presence is required;
- if applicable, a fee for chairing the audit committee, the research and development committee or the remuneration and nomination committee;
- a fixed fee for board committee membership; and
- a long-term variable incentive, in the form of stock options.

Fixed fee. The board of directors has set the annual base remuneration for non-executive directors at €35,000, additional remuneration for the chairperson of the board of directors at €30,000, additional remuneration for the chairperson of the audit committee and the research and development committee of the board of directors at €15,000 and additional remuneration for the chairperson of the remuneration and nomination committee of the board of directors at €10,000. Board committee members, other than the chairman of the relevant committee, receive an annual retainer of €5,000 for the remuneration and nomination committee and a €7,500 retainer for the members of the audit committee and the research and development committee.

Long-term incentive plan. The board of directors intends to incentivize the non-executive directors by issuing options from time to time to be able to attract and retain well-qualified non-executive directors in connection with the 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 "—Option Plan".

Success payment. In exceptional circumstances, the board of directors may decide to reward a non-executive director with a success payment relating to the occurrence of specific events achieved through the exceptional efforts of that person (such as a platform licensing or product licensing deal brokered by that non-executive director).

Pursuant to the Remuneration Policy, in case of a dismissal, non-executive directors will not be entitled to a severance payment.

The following table sets forth the information regarding the compensation earned by our non-executive directors during the year ended December 31, 2018:

	Fees earned or paid in cash	**Option awards**	
Name	**(€)**	**(€)(1)**	**Total**
Peter K.M. Verhaeghe	77,500	444,900	€522,400
David L. Lacey	50,000	444,900	494,900
Werner Lanthaler	55,000	444,900	499,900
Pamela Klein	42,500	444,900	487,400
J. Donald deBethizy	52,500	444,900	497,400
A.A. Rosenberg	42,500	444,900	487,400
James M Daly	35,000	926,750	961,750

(1) Amount shown represents the expenses recorded with respect to the option awards granted in 2018 to the non-executive directors measured using the Black Scholes formula. For a description of the assumptions used in valuing

these awards, see note 4.9 to our consolidated financial statements incorporated by reference in this Registration Document. These amounts do not reflect the actual economic value realized by the non-executive director.

The table below shows the stock options held at the start of the year ended December 31, 2018 and the stock options granted to the non-executive directors which have vested during the year ended December 31, 2018, as well as the stock options to vest in the years ending December 31, 2019, December 31, 2020 and December 31, 2021 (in number of stock options), and the respective exercise price of such stock options:

Item_Directors_RespectiveExercisePrice

Name	Total options held on January 1, 2018	Options granted in 2018	Options exercised in 2018	Total options held on December 31, 2018	Options vested until 2017	Exercise price	Options vested in 2018	Exercise price	Options to vest in 2019	Exercise price	Options to vest in 2020	Exercise price	Options to vest in 2021	Exercise price
Peter Verhaeghe	34,585	10,000		44,585	11,626	€ 2.44								
					7,959	€ 3.95								
					5,000	€ 7.17								
					5,000	€ 11.38	3,333	€ 11.38	1,667	€ 11.38				
									3,333	€ 86.32	3,334	€ 86.32	3,333	€ 86.32
David L. Lacey	44,443	10,000		54,443	6,643	€ 2.44								
					12,800	€ 7.17								
					5,000	€ 11.38	3,333	€ 11.38	1,667	€ 11.38				
							5,000	€ 21.17	5,000	€ 21.17	5,000	€ 21.17		
									3,333	€ 86.32	3,334	€ 86.32	3,333	€ 86.32
Werner Lanthaler	29,416	10,000	(24,972)	14,444	—	€ 2.44								
					—	€ 7.17								
					—	€ 11.38	2,777	€ 11.38	1,667	€ 11.38				
									3,333	€ 86.32	3,334	€ 86.32	3,333	€ 86.32
J. Donald deBethizy	25,000	10,000		35,000	12,500	€ 11.44	2,500	€ 11.44						
					5,000	€ 11.38	3,333	€ 11.38	1,667	€ 11.38				
									3,333	€ 86.32	3,334	€ 86.32	3,333	€ 86.32
Pamela Klein	25,000	10,000		35,000	12,500	€ 11.44	2,500	€ 11.44						
					5,000	€ 11.38	3,333	€ 11.38	1,667	€ 11.38				
									3,333	€ 86.32	3,334	€ 86.32	3,333	€ 86.32
A.A. Rosenberg	15,000	10,000		25,000	5,000	€ 14.13	5,000	€ 14.13	5,000	€ 14.13				
									3,333	€ 86.32	3,334	€ 86.32	3,333	€ 86.32
Jim Daley	—	25,000		25,000					7,500	€ 80.82	5,000	€ 80.82	2,500	€ 80.82
									3,333	€ 86.32	3,334	€ 86.32	3,333	€ 86.32

The table below shows the remaining term of the stock options held by the non-executive directors during the year ended December 31, 2018:

Name			Number of stock options		Remaining term on December 31, 2018 (rounded up)
Peter K.M. Verhaeghe			3,650		1.5 years
			2,340		2.0 years
			5,560		4.5 years
			3,181		5.0 years
			9,854		6.0 years
			10,000		7.5 years
			10,000		10.0 years
David L. Lacey			3,180		4.5 years
			1,818		5.0 years
			14,445		6.0 years
			10,000		7.5 years
			15,000		9.0 years
			10,000		10.0 years
Werner Lanthaler			4,444		7.5 years
			10,000		10.0 years
J. Donald deBethizy			15,000		6.5 years
			10,000		7.5 years
			10,000		10.0 years
Pamela Klein			15,000		6.5 years
			10,000		7.5 years
			10,000		10.0 years
A.A. Rosenberg			15,000		8.0 years
			10,000		10.0 years
James M. Daly			15,000		9.5 years
			10,000		10.0 years

The table below shows the stock options exercised by our non-executive directors during the year ended December 31, 2018 and the exercise price of those stock options. Per exercised option, one share was issued:

Name	Number of stock options	Exercise price
Werner Lanthaler	14,416	€ 2.44
Werner Lanthaler	5,000	€ 7.17
Werner Lanthaler	5,556	€ 11.38
Total	24,972	

Option Plan

On December 18, 2014, our board of directors adopted an employee stock option plan, or the Option Plan, which was approved by the shareholders at the General Meeting on May 13, 2015 and amended by the General Meeting on April 28, 2016. The aim of the Option Plan is to encourage our executive management, directors and key outside consultants and advisors to acquire an economic and beneficial ownership interest in the growth and performance of the company, to increase their incentive to contribute to our value and to attract and retain individuals who are key to our company.

In connection with the Option Plan, our board of directors has also established an option allocation scheme. The option allocation scheme contains (i) the date on which options are granted each year, which shall be the same date each year and (ii) the number of options granted to each person or to each group of persons, which shall be based on objective criteria only.

Our board of directors, in each case subject to the approval of the majority of the non-executive directors, may grant options to our executive management, directors or key outside consultants or advisors and in accordance with the option allocation scheme. Our board of directors may also grant options at its discretion outside of the option allocation scheme, but only in a period when no inside information (as specified 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 equal to 14.5% of our fully-diluted share capital. Shares issued pursuant to the exercise of an option are counted towards the share capital, and options that cease to exist (whether through exercise, termination or otherwise) are restored to the foregoing limit and shall again be available for issuance under the Option Plan. Shares shall be charged against the forgoing limit upon the grant of each option, but if such shares are thereafter forfeited or such option otherwise terminates without the issuance of such shares or of other consideration in lieu of such shares, the shares so forfeited or related to the terminated portion of such option shall be restored to the foregoing limit and shall again be available for options under the Option Plan.

Options granted pursuant to the Option Plan shall vest with respect to one third of the shares upon the first anniversary of the date of grant, with the remaining two thirds vesting in twenty-four equal monthly installments with the option fully vesting upon the third anniversary of the date of grant, subject, in each case, to the optionee's continued status.

Each option shall be granted with an exercise price equal to the fair market value upon the date of grant and shall have a term equal to ten years from the date of grant. In the case of a (i) sale, merger, consolidation, tender offer or similar acquisition of shares or other transaction or series of related transactions as a result of which a change in control occurs, (ii) sale or other disposition of all or substantially all of the company's assets or (iii) dissolution and/or liquidation of the company, then 100% of any unvested options shall vest.

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

The board of directors may seek shareholder approval at the 2019 General Meeting for certain amendments to the Option Plan, details of which will be disclosed in the convocation materials for the 2019 General Meeting. These relate primarily to amendments in applicable laws and regulations since the date the option plan was last amended, including the Regulation (EU) No 596/2014 of the European Parliament and of the Council of April 16, 2014 on market abuse (market abuse regulation) as well as changes in tax laws and regulations in Belgium.

Independent Auditor

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 committee and can be broken down as follows:

Fees (in thousands of euros)	**2018**	**2017**
Audit fees	648	179
Audit related fees	143	724
Tax and other services	-	-
Total	791	903

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 willful misconduct or intentional recklessness (*opzet of bewuste roekeloosheid*).

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. An executive 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 the executive directors, the non-executive directors will resolve on the matter. A non-executive 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 the non-executive directors or our board of directors as a whole, the shareholders at a General Meeting will resolve on the matter. 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 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.

At the date of this Registration Document, all current non-executive directors meet the independence criteria contained in the Dutch Corporate Governance Code. No member of our board of directors or executive management has a conflict of interest (actual or potential) between his duties to us and his private interests and/or other duties.

10 RELATED PARTY TRANSACTIONS

Since 31 December 2018, 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 "Management" and "Principal Shareholders," and the transactions we describe below.

Agreements with Our Executive Management

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

	Tim Van Hauwermeiren
Base salary	€ 500,000
Cash bonus	Maximum 50% of base salary based on previously determined bonus targets established by the non-executive directors (1)
Pension contributions(2)	€15,102
Duration	Indefinite

(1) We have an established practice to increase the variable pay with a certain percentage (for 2018: 13.84%) for those beneficiaries that opt to receive their bonus through over the counter (OTC) options rather than through a payment in cash. As a result, whereas the basis for calculating the cash bonus is a maximum of 50% of base salary, in practice this may be paid in OTC options, representing a higher percentage of the annual base salary (in 2018: 56.92%).

(2) Amounts shown represent pension contributions paid during the year-ended December 31, 2018.

We may terminate Mr. Van Hauwermeiren's services upon 18 months' notice, or payment of 18 months' pro-rated base salary in lieu of notice. Mr. Van Hauwermeiren would be entitled to the same payment in lieu of notice in the event he 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 BVBA, for an indefinite term. His employment contract may be terminated at any time by us, subject to a notice period and a severance payment of at least 12 months.

Keith Woods, our Chief Operating Officer, has an employment contract with our subsidiary, argenx US Inc., for an indefinite term. His employment contract may be terminated at any time by us, subject to a notice period and a severance payment of at least 12 months.

Nicolas Leupin, our Chief Medical Officer, has an employment contract with our subsidiary, argenx BVBA, for an indefinite term. His employment contract may be terminated at any time by us, subject to a notice period and a severance payment of at least 12 months.

Hans de Haard, our Chief Scientific Officer, has an employment contract with our subsidiary, argenx BVBA, for an indefinite term. His employment contract may be terminated at any time by us, subject to a notice period and a severance payment of at least 12 months.

Torsten Dreier, our Chief Development Officer, has an employment contract with our subsidiary, argenx BVBA, for an indefinite term. His employment contract may be terminated at any time by us, subject to a notice period and a severance payment of at least 12 months.

Dirk Beeusaert, our General Counsel, has an employment contract with our subsidiary, argenx BVBA, for an indefinite term. His employment contract may be terminated at any time by us, subject to a notice period and a severance payment of at least 12 months.

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.

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 LDA

FairJourney Biologics LDA, or FairJourney, is a fee-for-service company focused on antibody discovery and engineering services. FairJourney was founded in 2012 and, as compensation for their support with the formation of FairJourney, our chief executive officer and executive director Tim Van Hauwermeiren acquired shares representing 5% of the equity securities of FairJourney, and our chief scientific officer, Hans de Haard, acquired shares representing 20% of the equity securities of FairJourney. In July 2012, we entered into a license and exclusive option agreement with FairJourney, pursuant to which we granted FairJourney a worldwide, non-exclusive license to our SIMPLE Antibody™ Platform to develop, manufacture and commercialize SIMPLE Antibodies to certain targets selected by FairJourney. Under the terms of the agreement, once FairJourney has advanced a product candidate discovered under the agreement to near proof-of-concept stage, we have the option to acquire patent rights generated by FairJourney specific to such product candidate along with a non-exclusive license to additional FairJourney intellectual property useful for further development, manufacture, or commercialization of the product candidate. Upon exercising this option, we must pay FairJourney an option fee equal to two times the expenses incurred by FairJourney for advancing such product candidate through the option exercise date, and we are required to pay a specified royalty in the mid-single digits on any sub-licensing revenue received by us for such product candidate. Alternatively, if we elect not to exercise the option, FairJourney is required to pay us a specified royalty in the mid-single digits on any sub-licensing revenue received by FairJourney for such product candidate. In connection with the agreement, we acquired shares of FairJourney representing 15% of the fully-diluted equity securities of FairJourney at the time of issuance. In December 2017, the company and executive director Tim Van Hauwermeiren sold their respective shareholdings in FairJourney Biologics LDA.

Related party transactions Policy

In connection with our initial U.S. public offering, we established a related party transaction policy.

11 PRINCIPAL SHAREHOLDERS

Shareholder structure

At the date of this Registration Document the issued share capital of argenx SE amounts to €3,799,177.90 and is represented by 37,991,779 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 (see also Part 12 "Description of Share Capital and Group Structure— Our Obligations and Obligations of our Shareholders and Directors to Notify Holders of Shares and Voting Rights").

NAME OF BENEFICIAL OWNER	NUMBER	PERCENTAGE
FMR LLC (1)(2)	3,789,576	9.97%
Federated Equity Management Company of Pennsylvania(1)(3)	2,891,897	7.61%
Johnson & Johnson Innovation – JJDC, Inc (1)(4)	1,766,899	4.65%
T. Rowe Price Group, Inc. (1)(5)	1,680,077	4.42%
RTW Investments(1)(6)	1,436,705	3.78%
Entities affliated with Baker Bros. Advisors LLC(1)(7)	1,190,197	3.13%

(1) Based on the number of shares reported in, and at the time of, the most recent transparency notification.

(2) Consists of 3,789,576 ordinary shares beneficially held. Members of the Johnson family, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. Neither FMR LLC nor Abigail P. Johnson has the sole power to vote or direct the voting of the shares owned directly by the various investment companies registered under the Investment Company Act ("Fidelity Funds") advised by Fidelity Management & Research Company ("FMR Co"), a wholly owned subsidiary of FMR LLC, which power resides with the Fidelity Funds' Boards of Trustees. Fidelity Management & Research Company carries out the voting of the shares under written guidelines established by the Fidelity Funds' Boards of Trustees. The address for FMR LLC is 245 Summer Street, Boston, Massachusetts 02210.

(3) Consists of (i) 2,478,414 ordinary shares held by Federated Kaufmann Fund, a portfolio of Federated Equity Funds, (ii) 351,010 ordinary shares held by Federated Kaufmann Small Cap Fund, a portfolio of Federated Equity Funds and (iii) 62,473 ordinary shares held by Federated Kaufmann Fund II, a portfolio of Federated Insurance Series (collectively, the "Federated Kaufmann Funds"). The address of the Federated Kaufmann Funds is 101 Park Avenue, Suite 4100, New York, NY 10178.

(4) Consists of 25,260 ADSs and 1,411,445 ordinary shares held by RTW Master Fund, Ltd. and RTW Innovation Master Fund, Ltd. The address for RTW Investments is 250 West 55th Street, 16th Floor, Suite A, New York, NY 10019.

(5) The address for Johnson & Johnson Innovation – JJDC, Inc is 410 George Street, New Brunswick, NJ 08901, USA.

(6) Based on the most recent transparency notification filed by Baker Bros. Advisors GP LLC. Consists of 950,492 ADSs and 239,705 ordinary shares beneficially owned by Baker Bros. Advisors LP; Baker Brothers Life Sciences, L.P.; and 667, L.P. (collectively, the "Baker Funds"). Baker Bros. Advisors LP is the investment advisor to the Baker Funds and has sole voting and investment power with respect to the shares held by Baker Funds. Baker Bros. Advisors (GP) LLC is the sole general partner of Baker Bros. Advisors LP. The managing members of Baker Bros. Advisors (GP) LLC are Julian C. Baker and Felix J. Baker. Julian C. Baker and Felix J. Baker disclaim beneficial ownership of all shares except to the extent of their pecuniary interest. The address for each of these entities is 667 Madison Avenue, 21st Floor, New York, NY 10065.

(7) Consists of 1,680,077 ADSs held by T. Rowe Price Associates, Inc. The address for T. Rowe Price Group, Inc is 100 East Pratt Street, Baltimore, MD 21202.

The total number of stock options outstanding on 22 March 2019 totals 3,273,583.

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.

Relationship with Significant 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 the Section Management's Discussion And Analysis Of Financial Condition And Results Of Operations – Collaboration Agreements.

12 DESCRIPTION OF SHARE CAPITAL AND GROUP STRUCTURE

Set out below is a summary of certain relevant information concerning the ordinary shares, our current articles of association, or the Articles of Association, and certain provisions of Dutch law in force on the date of this registration document. Unless otherwise specified, the summary below describes the Articles of Association.

This section summarizes the Articles of Association, share capital and the rights attached to our ordinary shares, does not purport to give a complete overview and is qualified in its entirety by, and should be read in conjunction with, the Articles of Association and Dutch law, neither should it be considered as legal advice regarding these matters. The full text of the Articles of Association is incorporated by reference in this registration document and is available free of charge for the life of this registration document, in Dutch and in English, in electronic form on our website (*www.argenx.com*).

General

We were incorporated on April 25, 2008, as a private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*) under Dutch law. On May 28, 2014, we converted into a public company with limited liability (*naamloze vennootschap*) under Dutch law pursuant to a notarial deed of conversion and amendment. On April 26, 2017, we converted into a Dutch European public company with limited liability (*Societas Europaea* or *SE*) pursuant to a notarial deed of conversion and amendment, which notarial deed was executed on the same date.

We are registered with the trade register of the Dutch Chamber of Commerce under number 24435214. Our corporate seat is in Rotterdam, the Netherlands, and our registered office is at Willemstraat 5, 4811 AH, Breda, the Netherlands. Our telephone number is +31 (0) 10 70 38 441. Our website address is http://www.argenx.com.

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".

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 €4.5 million divided into 45 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 22, 2019, our issued and paid up share capital amounted to €3,799,177.90, represented by 37,991,779 ordinary shares with a nominal value of €0.10, each representing an identical fraction of our share capital. As of March 22, 2019, neither we nor any of our subsidiaries held any of our own shares.

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 3,536,651 options (where each option entitles the holder to subscribe for one new ordinary share) were outstanding and granted as of December 31, 2018. A total of 3,273,583 options (where each option entitles the holder to subscribe for one new ordinary share) were outstanding and granted as of March 22, 2019. Apart from the options and argenx Employee Stock 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, 2018, see note 4.9 to our Financial Statements for the financial year ended 31 December, 2018 incorporated by reference herein. For option information beginning on January 1, 2019, see the table below

Number of shares outstanding on December 31, 2015	**15,802,767**
Private placement (Federated Investment) on January 20, 2016	1,480,420
Exercise of options in February 2016	2,200
Exercise of options in March 2016	10,000

Exercise of options in April 2016	10,000
Exercise of options in May 2016	33,092
Private placement (Sunflower) on June 1, 2016	2,703,000
Exercise of options in September 2016	70,000
Exercise of options in October 2016	15,000
Number of shares outstanding on December 31, 2016	**20,126,479**
Initial U.S. public offering (Nasdaq) on May 17, 2017	5,865,000
Over-allotment option exercised by underwriters on May 19, 2017	879,750
Exercise of options in August 2017	5,000
Exercise of options in September 2017	15,000
Exercise of options in October 2017	1,400
Exercise of options in November 2017	106,782
U.S. second public offering on Nasdaq on December 13, 2017	4,440,000
Over-allotment option exercised by underwriters on December 14, 2017	666,000
Exercise of options in December 2017	75,230
Number of shares outstanding on December 31, 2017	**32,180,641**
Exercise of options in January 2018	111,727
Exercise of options in March 2018	113,075
Exercise of options in April 2018	34,039
Exercise of options in May 2018	5,900
Exercise of options in June 2018	5,393
Exercise of options in July 2018	469
Exercise of options in August 2018	2,300
Exercise of options in September 2018	5,913
U.S. third public offering on Nasdaq on September 18, 2018	3,475,000
Exercise of options in October 2018	556
Exercise of options in November 2018	9,768
Exercise of options in December 2018	30,531
Number of shares outstanding on December 31, 2018	**35,975,312**

History of Share Capital

New Shares Created During 2016

In January 2016, funds advised by subsidiaries of Federated Investors, Inc. (U.S.) subscribed to 1,480,420 new shares. In June 2016, certain institutional investors subscribed to 2,703,000 new shares.

As a result of the exercise of options under the argenx Employee Stock Option Plan, 2,200 new shares were created in February 2016, 10,000 in March 2016, 10,000 in April 2016, 33,092 in May 2016, 70,000 in September 2016 and 15,000 in October 2016.

New Shares created during 2017

On May 17, 2017, argenx SE offered 5,865,000 of its ordinary shares through an initial public offering in the United States in the form of ADSs at a price to the public of $17.00 per ADS, before underwriting discounts and commissions and offering expenses. On May 19, 2017, the underwriters of the offering exercised their over-allotment option to purchase 879,750 additional ADSs in full. As a result, argenx SE received €102.1 million of total gross proceeds from the offering, decreased by €9.6 million of underwriter discounts and commissions, and offering expenses, of which €8.9 million has been deducted from equity. The total net cash proceeds from this offering amounted to €92.5 million.

On December 14, 2017, argenx SE offered 4,440,000 of its ordinary shares through a public offering in the United States in the form of ADSs at a price to the public of $52.00 per ADS, before underwriting discounts and commissions and offering expenses. On December 15, 2017, the underwriters of the offering exercised their over-allotment option to purchase 666,000 additional ADSs in full. As a result, argenx SE received €225.6 million of gross proceeds from this offering, decreased by €14.3 million of underwriter discounts and commissions, and offering

expenses, of which €14.1 million has been deducted from equity. The total net cash proceeds from the Offering amounted to €211.3 million.

For both offerings completed in 2017, the ADSs are evidenced by American Depositary Receipts (ADRs), and each ADS represents the right to receive one ordinary share. These ADSs are listed on the Nasdaq Global Select Market under the symbol “ARGX”.

203,412 new shares were also issued in 2017 as a result of the exercise of stock options under the argenx Employee Stock Option Plan.

New Shares Created During 2018

As a result of the exercise of options under the argenx Employee Stock Option Plan, 318,329 new shares were created in 2018.

On September 18, 2018, argenx SE offered 3,475,000 of its ordinary shares through a public offering in the United States in the form of ADSs at a price to the public of $86.50 per ADS, before underwriting discounts and commissions and offering expenses. As a result, argenx SE received €255.7 million of gross proceeds from this offering, decreased by €14.8 million of underwriter discounts and commissions, and offering expenses, of which €14.6 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 7 "Business". The shareholding of Johnson & Johnson Innovation at the time of the issuance represented approximately 4.66% of argenx’s outstanding shares.

As a result of the exercise of options under the argenx Employee Stock Option Plan, 162,763 new shares were created in January 2019 and 2,500 in February 2019.

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 8, 2018, the shareholders at the General Meeting designated our board of directors as the corporate body competent to issue shares under the Option Plan and to limit or exclude 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 8, 2018, 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 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 its resolution, the shareholders at the General Meeting restricted the competency of our board of directors under this second authorization as regards the issue of shares and the grant of rights to subscribe for shares to a maximum of 20% of our total issued and outstanding share capital as at the day of that meeting. The purpose of this authorization is to allow the board of directors the general flexibility to issue additional shares as and when the need may arise or an opportunity would present itself, including to issue shares and grant rights to subscribe for shares and to limit or exclude pre-emptive rights of shareholders for such shares for the purpose of the admission to listing and trading of securities in our capital on Nasdaq and/or Euronext. 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 2:96aa 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.

On May 8, 2018, the shareholders at the General Meeting designated our board of directors as the corporate body competent to issue shares under the Option Plan and to limit or exclude 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 8, 2018, 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 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 its resolution, the shareholders at the General Meeting restricted the competency of our board of directors under this second authorization as regards the issue of shares and the grant of rights to subscribe for shares to a maximum of 20% of our total issued and outstanding share capital as at the day of that meeting. The purpose of this authorization is to allow the board of directors the

general flexibility to issue additional shares as and when the need may arise or an opportunity would present itself, including to issue shares and grant rights to subscribe for shares and to limit or exclude pre-emptive rights of shareholders for such shares for the purpose of the admission to listing and trading of securities in our capital on Nasdaq and/or Euronext. 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 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.

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.

Articles of Association and Dutch Law

When we refer to our Articles of Association in this Registration Document, we refer to our Articles of Association as they are in force at the date of this Registration Document.

Set forth below is a summary of relevant information concerning our share capital and material provisions of our Articles of Association and applicable Dutch law. This summary does not constitute legal advice regarding those matters and should not be regarded as such.

Amendment of Articles of Association

The shareholders at the General Meeting may resolve to amend the Articles of Association, at the proposal of our board of directors, with the consent of the majority of the non-executive directors. A resolution by the shareholders at the General Meeting to amend the Articles of Association requires a simple majority of the votes cast in a

meeting in which at least half of our issued and outstanding capital is present or represented, or at least two-thirds of the votes cast, if less than half of our issued and outstanding capital is present or represented at that meeting.

Changing the rights of any of the shareholders will require the Articles of Association to be amended.

Company's Shareholders' Register

Subject to Dutch law (Section 2:85 of the DCC), we must keep our shareholders' register accurate and up-to-date. Our board of directors keeps our shareholders' register and records names and addresses of all holders of shares, showing the date on which the shares were acquired, the date of the acknowledgement by or notification of us as well as the amount paid on each share. The register also includes the names and addresses of those with a right of usufruct (*vruchtgebruik*) in shares belonging to another or a pledge in respect of such shares.

If shares are transferred to an intermediary for inclusion in a collection deposit or to the central institute for inclusion in a giro deposit, the name and address of the intermediary or the central institute (as relevant), will be entered in our shareholders' register, mentioning the date on which the shares concerned were included in a collection deposit or a giro deposit (as relevant), the date of acknowledgement by or giving of notice to us, as well as the amount paid on each share and the number of shares.

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.

Limitation on Liability and Indemnification Matters

Under Dutch law (Section 2:138 of the DCC), our board of directors and certain other officers may be held liable for damages in the event of improper or negligent performance of their duties. They may be held jointly and severally liable for damages to our company and to third parties for infringement of the Articles of Association or of certain provisions of the Dutch Civil Code. In certain circumstances, they may also incur additional specific civil and criminal liabilities. Directors and certain other officers are insured under an insurance policy taken out by us against damages resulting from their conduct when acting in the capacities as such directors or officers. In addition, our Articles of Association provide for indemnification of our directors, including reimbursement for reasonable legal fees and damages or fines based on acts or failures to act in their duties. No indemnification will be given to a member of our board of directors if a Dutch court has established, without possibility for appeal, that the acts or omissions of such indemnified person that led to the financial losses, damages, suit, claim, action or legal proceedings resulted from either an improper performance of his or her duties as a director or an officer of our company or an unlawful or illegal act, and only to the extent that his or her financial losses, damages and expenses are covered by an insurance and the insurer has settled these financial losses, damages and expenses (or has indicated that it would do so). Furthermore, such indemnification will generally not be available in instances of willful (*opzettelijk*), intentionally reckless (*bewust roekeloos*) or seriously culpable (*ernstig verwijtbaar*) conduct unless Dutch law provides otherwise.

Shareholders' Meetings and Consents

General Meeting

General Meetings are held at the place where the company has its official seat. The annual General Meeting shall be held on the third Tuesday of the month of May on the hour and at the place mentioned in the convening notice. If such a date is not a business day, the annual General Meeting shall be held the first following business day. The annual General Meeting must be held within six months of the end of each financial year. Additional extraordinary General Meetings may also be held whenever considered appropriate by our board of directors. Pursuant to Dutch law (Section 2:110 of the DCC), one or more shareholders and others entitled to attend a General Meeting, who jointly represent at least one-tenth of the issued capital, may request our board of directors to convene a General Meeting. If our board of directors has not taken the steps necessary to ensure that a General Meeting will be held within the relevant statutory period after the request, the requesting persons may, at his/her/their request, be authorized by court in preliminary relief proceedings to convene a General Meeting. The court shall disallow the application if it does not appear that the applicants have previously requested our board of directors to convene a General Meeting and our board of directors has not taken the necessary steps so that the General Meeting could be held within six weeks after the request.

General Meetings can be convened by a notice, which will include an agenda stating the items to be discussed, including for the annual General Meeting, among other things, the adoption of the annual accounts, appropriation of our profits and proposals relating to the composition of our board of directors, including the filling of any vacancies in our board of directors. In addition, the agenda will include such items as have been included therein by our board. The agenda will also include such items requested by one or more shareholders, and others entitled to attend General Meetings, representing at least 3% of the issued share capital. Requests must be made in writing and received by our board of directors at least 60 days before the day of the convocation of the meeting. No resolutions will be adopted on items other than those which have been included in the agenda.

In accordance with the Dutch Corporate Governance Code, a shareholder may include an item on the agenda only after consulting our board of directors in that respect. If one or more shareholders intends to request that an item be put on the agenda that may result in a change in the company's strategy, our board of directors may invoke a response time of a maximum of 180 days until the day of the General Meeting.

The General Meeting is presided over by the chairperson or, if he is absent, by the vice chairperson of the board of directors. If the chairperson and the vice chairperson are absent, the non-executive directors present at the meeting will appoint one of them to be chairperson. Board members may attend a General Meeting. In these meetings, they have an advisory vote. The chairperson of the meeting may decide at its discretion to admit other persons to the meeting. The independent external auditor of the company shall attend the General Meeting in which the annual accounts are discussed. In connection with our General Meetings, ADS holders will not be treated as our shareholders and will not have shareholder rights.

Admission and Registration

All shareholders, and each usufructuary and pledgee to whom the right to vote on our shares accrues, are entitled, in person or represented by a proxy authorized in writing, to attend and address the General Meeting and exercise voting rights pro rata to their shareholding. Shareholders may exercise their rights if they are the holders of our shares on the record date as required by Dutch law (Section 2:119 of the DCC), which is currently the 28th day before the day of the General Meeting, and they or their proxy have notified us of their intention to attend the General Meeting in writing or by any other electronic means that can be reproduced on paper ultimately at a date set for that purpose by our board of directors which date may not be earlier than the seventh day prior to the General Meeting, specifying such person's name and the number of shares for which such person may exercise the voting rights and/or meeting rights at such General Meeting. The convocation notice will state the record date and the manner in which the persons entitled to attend the General Meeting may register and exercise their rights.

Quorum and Voting Requirements

Each ordinary share confers the right on the holder to cast one vote at the General Meeting. Shareholders may vote by proxy. The voting rights attached to any shares held by us are suspended as long as they are held in treasury. Nonetheless, the holders of a right of usufruct (*vruchtgebruik)* in shares belonging to another and the holders of a right of pledge in respect of ordinary shares held by us are not excluded from any right they may have to vote on such ordinary shares, if the right of usufruct (*vruchtgebruik*) or the right of pledge was granted prior to the time such ordinary share was acquired by us.

We may not cast votes in respect of a share in respect of which there is a right of usufruct (*vruchtgebruik*) or a right of pledge. Shares which are not entitled to voting rights pursuant to the preceding sentences will not be taken into account for the purpose of determining the number of shareholders that vote and that are present or represented, or the amount of the share capital that is provided or that is represented at a General Meeting. In accordance with Dutch law (Section 2:120 paragraph 1 of the DCC) and generally accepted business practices, our Articles of Association do not provide quorum requirements generally applicable to the General Meeting. Decisions of the General Meeting are taken by an absolute majority of votes cast, except where Dutch law (e.g. Sections 2:18 paragraph 2 under a; 2:96a paragraph 7; 2:99 paragraph 6; 2:133 paragraph 2 and 2:330 paragraph 1 of the DCC) or the Articles of Association provide for a qualified majority or unanimity.

Board Members

Election of Board Members
Under our Articles of Association, our directors are appointed by the shareholders at the General Meeting upon proposal by our board of directors.

Duties and Liabilities of Directors
Under Dutch law (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 non-executive directors supervise the management of the executive directors and the general affairs of our company and the business connected with it and provide the executive directors with advice. In addition, both the executive directors and the non-executive directors must perform such duties as are assigned to them pursuant to the Articles of Association. The division of tasks within our board of directors is determined (and amended, if necessary) by our board of directors. Each director has a duty to properly perform the duties assigned to him or her and to act in our corporate interest. Under Dutch law, the corporate interest extends to the interests of all corporate stakeholders, such as shareholders, creditors, employees and other stakeholders.

Dividends and Other Distributions

Amount Available for Distribution
Pursuant to Dutch law (Section 2:105 paragraph 3 of the DCC) and the Articles of Association, the distribution of profits will take place following the adoption of our annual accounts, from which we will determine whether such distribution is permitted. We may only make distributions to the shareholders, whether from profits or from our freely distributable reserves, only insofar as our shareholders' equity exceeds the sum of the paid-up and called-up share capital plus the reserves required to be maintained by Dutch law. The shareholders at the General Meeting may determine which part of our profits will be added to the reserves inconsideration of our reserves and dividends policy. The remaining part of the profits after the addition to the reserves will be at the disposal of the shareholders at the General Meeting. Distributions of dividends will be made pro rata to the nominal value of each share. Subject to Dutch law (Section 2:105 of the DCC) and the Articles of Association, our board of directors, with the consent of the majority of the non-executive directors, may resolve to distribute an interim dividend if it determines such interim dividend to be justified by our profits. For this purpose, our board of directors must prepare an interim statement of assets and liabilities. Such interim statement will show our financial position not earlier than on the first day of the third month before the month in which the resolution to make the interim distribution is announced. An interim dividend can only be paid if (a) an interim statement of assets and liabilities is drawn up showing that the funds available for distribution are sufficient, and (b) our shareholders 'equity exceeds the sum of the paid-up and called-up share capital plus the reserves required to be maintained by Dutch law. Our board of directors, with the consent of the majority of the non-executive directors, may resolve that we make distributions to shareholders from one or more of our freely distributable reserves, other than by way of profit distribution, subject to the due observance of our policy on reserves and dividends. Any such distributions will be made pro rata to the nominal value of each share. Dividends and other distributions will be made payable not later than the date determined by our board. Claims to dividends and other distributions not made within five years from the date that such dividends or distributions became payable, will lapse and any such amounts will be considered to have been forfeited to us (*perjuring*). We do not anticipate paying any cash dividends for the foreseeable future.

Exchange Controls

Pursuant to Dutch law, there are no exchange controls applicable to the transfer to persons outside of the Netherlands of dividends or other distributions with respect to, or of the proceeds from the sale of, shares of a Dutch company. Pursuant to Dutch law, there are no exchange controls applicable to our import or export of capital, including the availability of cash and cash equivalents to us as a Dutch company.

Annual Accounts and Semi-Annual Accounts

Our financial year is the calendar year. Within four months after the end of our financial year, our board of directors must prepare the annual accounts. It must make them available for inspection by the shareholders at our office. The annual accounts must be accompanied by an auditors' statement, an annual report, a report by our board of directors and certain other information required under Dutch law (Section 2 Title 9 of the DCC). The annual accounts, the annual report, the other information required under Dutch law (Section 2 Title 9 of the DCC) and the auditors' statement must be made available to shareholders for review from the day of the notice convening the annual General Meeting. All members of our board of directors must sign the annual accounts and if a member does not sign, the reasons for this must be stated. The annual accounts must be adopted by the General Meeting. Within two months after the end of the first six months of the financial year, our board of directors must prepare semi-annual accounts and make them publicly available. If the semi-annual accounts are audited or reviewed, the independent auditor's report must be made publicly available together with the semi-annual accounts.

Dissolution and Liquidation

argenx SE may only be dissolved by a resolution of the shareholders at a General Meeting upon a proposal made by our board of directors with the consent of the majority of the non-executive directors. If a resolution to dissolve argenx SE is to be put to the shareholders at a General Meeting, this must in all cases be stated in the notice convening the General Meeting. If the shareholders at a General Meeting resolve to dissolve argenx SE, the members of our board of directors will be charged with the liquidation of the business of argenx SE. During liquidation, the provisions of the Articles of Association will remain in force as far as possible. A resolution by the shareholders at a General Meeting to dissolve argenx SE requires a two-thirds majority of the votes cast if less than half the issued and outstanding share capital is represented at the meeting. Any surplus remaining after settlement of all debts and liquidation costs will be distributed to the shareholders in proportion to the nominal value of their shareholdings.

Public Offer

In accordance with Directive 2004/25/EC, each European Union member state should ensure the protection of minority shareholders by obliging any person that acquires control of a company to make an offer to all the holders of that company's voting securities for all their holdings at an equitable price. The Directive 2004/25/EC applies to all companies governed by the laws of a European Union member state of which all or some voting securities are admitted to trading on a regulated market in one or more European Union member states. The laws of the European Union member state in which a company has its registered office will determine the percentage of voting rights that is regarded as conferring control over that company. In accordance with Section 5:70 of the DFSA, any person—whether acting alone or in concert with others— who, directly or indirectly, acquires a controlling interest in a company will be obliged to launch a mandatory public offer for all our outstanding shares. A controlling interest is deemed to exist if a (legal) person is able to exercise, alone or acting in concert, at least 30% of the voting rights in the General Meeting. An exception is made for, amongst others, shareholders who—whether alone or acting in concert with others—(i) had an interest of at least 30% of our voting rights before our shares were first admitted to trading on Euronext Brussels and who still have such an interest after such first admittance to trading, and (ii) reduce their holding to below 30% of the voting rights within 30 days of the acquisition of the controlling interest provided that (a) the reduction of their holding was not effected by a transfer of shares to an exempted party and (b) during such period such shareholders or group of shareholders did not exercise their voting rights. The rules under the DFSA regarding mandatory public offers apply to us because the company has its statutory seat in the Netherlands. However, as the shares are not admitted to trading on a regulated market in the Netherlands but are admitted to trading on Euronext Brussels and the ADSs are admitted to trading on The Nasdaq Global Select Market, the Dutch Decree on public offers (*Besluit openbare biedingen Wft*) will only apply in relation to matters relating to information to be provided to trade unions and employees and company law matters, including the convocation of a General Meeting in the event of a public offer and a position statement by our board of directors. In case of a mandatory public offer, the provisions regarding the offered consideration and the bid procedure will be governed by Belgian law pursuant to article 4§1, 3° of the Belgian law dated April 1, 2007 on public takeover bids, 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 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. We have not implemented specific measures with the aim of deterring takeover attempts. No takeover bid has been instigated by third parties in respect of our equity during the previous financial year and the current financial year.

Squeeze Out Procedures

Pursuant to Section 92a, Book 2, Dutch Civil Code, a shareholder who for his own account holds at least 95% of our issued share capital may initiate proceedings against our minority shareholders jointly for the transfer of their shares to the claimant. The proceedings are held before the Dutch Enterprise Chamber of the Amsterdam Court of Appeal (*Ondernemingskamer van het Gerechtshof te Amsterdam*), or the Enterprise Chamber, and can be instituted by means of a writ of summons served upon each of the minority shareholders in accordance with the provisions of the Dutch Code of Civil Procedure (*Wetboek van Burgerlijke Rechtsvordering*). The Enterprise Chamber may grant the claim for squeeze out in relation to all minority shareholders and will determine the price to be paid for the shares, if necessary after appointment of one or three experts who will offer an opinion to the Enterprise Chamber on the value to be paid for the shares of the minority shareholders. Once the order to transfer becomes final before the Enterprise Chamber, the person acquiring the shares 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.

Market Abuse Rules

As of July 3, 2016, setting aside previously applicable national 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 trading, divulging inside information and tipping and market manipulation. The company, the members of our board of directors and other insiders and persons performing or conducting transactions in the company's financial instruments, as applicable, will be subject to the insider trading prohibition, the prohibition on divulging inside information and tipping and the prohibition on market manipulation. In certain circumstances, the company's investors may also be subject to market abuse rules.

Inside information is any information of a precise nature relating (directly or indirectly) to us, or to our shares or other financial instruments, which information has not been made public and which, if it were made public, would be likely to have a significant effect on the price of the shares or the other financial instruments or on the price of related derivative financial instruments.

Pursuant to the MAR, a person is prohibited to possess inside information and use that information by acquiring or disposing of, for its own account or for the account of a third party, directly or indirectly, our shares and other financial instruments to which that information relates (which is considered to be insider dealing). The use of inside information by cancelling or amending an order concerning our shares or other financial instruments to which the information relates where the order was placed before the person concerned possessed the inside information, is also prohibited. In addition, a person is also prohibited to recommend another person to engage in insider

dealing, or induce another person to engage in insider dealing, which arises where the person possesses inside information and (a) recommends, on the basis of that information, that another person acquires or disposes of our shares or other financial instruments to which that information relates, or induces that person to make such an acquisition or disposal or (b) recommends, on the basis of that information, that another person cancels or amends an order concerning our shares or other financial instruments to which that information relates, or induces that person to make such a cancellation or amendment.

The company is under an obligation to make any inside information immediately public by means of a press release. However, the company may, in its own discretion, delay the publication of inside information if it can ensure the confidentiality of the information. Such deferral is only permitted if the publication thereof could damage the company's legitimate interests and if the deferral does not risk misleading the market. If the company wishes to use this deferral right it needs to inform the Belgian Financial Services and Markets Authority thereof after the information is disclosed to the public and provide a written explanation of how the conditions for deferral were met.

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. Notification must be made within three working days after the date of the transaction. Under MAR, no notification of a transaction needs to be made until transactions in a calendar year by that director, persons discharging managerial responsibilities or persons closely associated with them exceed a threshold of €5,000 (without netting). Once the threshold has been reached, all transactions will need to be notified, regardless of amount and wherever concluded. Non-compliance with these reporting obligations could lead to criminal penalties, administrative fines and cease-and-desist orders (and the publication thereof), imprisonment or other sanctions.

Transparency Directive

We are a European public company with limited liability (*Societas Europaea* or *SE*) incorporated and existing under the laws of the Netherlands. The Netherlands is our home European Union member state (*lidstaat van herkomst*) for the purposes of Directive 2004/109/EC 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 Directive 2010/73/EU, or the Transparency Directive, as a consequence of which we will be subject to the DFSA in respect of certain ongoing transparency and disclosure obligations. In addition, as long as our shares are listed on Euronext Brussels and the ADSs on 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 to make public without delay any change in the rights attaching to our shares or any rights to subscribe our shares.

Dutch Financial Reporting Supervision Act

Pursuant to the Dutch Financial Reporting Supervision Act (*Wet toezicht financiële verslaggeving*), 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 if, based on publicly known facts or circumstances, it has reason to doubt that our financial reporting meets such standards and (ii) recommend to us that we make available further explanations and files these with the AFM. If we do not comply with such a request or recommendation, the AFM may request that the Enterprise Chamber 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.

Our Obligations and Obligations of our Shareholders and Directors to Notify Holders of Shares and Voting Rights

Pursuant to Chapter 5.3 of the DFSA, any person who, directly or indirectly, acquires or disposes of an actual or potential capital interest or voting rights in the company must immediately give written notice to the AFM of such acquisition or disposal if, as a result of such acquisition or disposal, the percentage of capital interest and/or voting rights held by such person reaches, exceeds or falls below the following thresholds: 3%, 5%, 10%, 15%, 20%, 25%, 30%, 40%, 50%, 60%, 75% and 95%.

For the purpose of calculating the percentage of capital interest or voting rights, the following interests must be taken into account: (i) shares and/or voting rights directly held (or acquired or disposed of) by any person; (ii) shares or voting rights held (or acquired or disposed of) by such person's controlled entities or by a third party for such person's account; (iii) voting rights held (or acquired or disposed of) by a third party with whom such person has concluded an oral or written voting agreement; (iv) voting rights acquired pursuant to an agreement providing for a temporary transfer of voting rights in consideration for a payment; (v) shares which such person, or any controlled entity or third party referred to above, may acquire pursuant to any option or other right to acquire shares; (vi) shares which determine the value of certain cash settled financial instruments such as contracts for difference and total return swaps; (vii) shares that must be acquired upon exercise of a put option by a counter-party; and (viii) shares which are the subject of another contract creating an economic position similar to a direct or indirect holding in those shares.

Controlled entities (*gecontroleerde ondernemingen*) within the meaning of the DFSA do not themselves have notification obligations under the DFSA as their direct and indirect interests are attributed to their (ultimate) parent. If a person who has a 3% or larger interest in the company's share capital or voting rights ceases to be a controlled entity it must immediately notify the AFM and all notification obligations under the DFSA will become applicable to such former controlled entity.

Special rules apply to the attribution of shares and/or voting rights which are part of the property of a partnership or other form of joint ownership. A holder of a pledge or right of usufruct in respect of shares can also be subject to notification obligations, if such person has, or can acquire, the right to vote on the shares. The acquisition of (conditional) voting rights by a pledgee or beneficial owner may also trigger notification obligations as if the pledgee or beneficial owner were the legal holder of the shares and/or voting rights.

Furthermore, when calculating the percentage of capital interest a person is also considered to be in possession of shares if (i) such person holds a financial instrument the value of which is (in part) determined by the value of the shares or any distributions associated therewith and which does not entitle such person to acquire any shares, (ii) such person may be obliged to purchase shares on the basis of an option, or (iii) such person has concluded another contract whereby such person acquires an economic interest comparable to that of holding a share.

Under the DFSA, we are required to notify the AFM promptly of any change of 1% or more in our issued and outstanding share capital or voting rights since the previous notification. Other changes in our issued and outstanding share capital or voting rights must be notified to the AFM within eight days after the end of the quarter in which the change occurred. If a person's capital interest or voting rights reaches, exceeds or falls below the above-mentioned thresholds as a result of a change in our issued and outstanding share capital or voting rights, such person is required to make a notification not later than on the fourth trading day after the AFM has published our notification as described above.

Every holder of 3% or more of our share capital or voting rights who, in relation to its previous notification, reaches, exceeds or falls below any of the above-mentioned thresholds as a consequence of a different composition by means of an exchange or conversion into shares or the exercise of rights pursuant to an agreement to acquire voting rights, must notify the AFM at the latest within four trading days.

Furthermore, each director must notify the AFM of each change in the number of shares he or she holds and of each change in the number of votes he or she is entitled to cast in respect of our issued and outstanding share capital, immediately after the relevant change.

The AFM does not issue separate public announcements of the notifications. It does, however, keep a public register of and publishes all notifications made pursuant to the DFSA at its website (www.afm.nl). Third parties

can request to be notified automatically by email of changes to the public register in relation to a particular company's shares or a particular notifying party.

Non-compliance with these notification obligations is an economic offence and may lead to criminal prosecution. The AFM may impose administrative penalties for non-compliance, and the publication thereof. In addition, a civil court can impose measures against any person who fails to notify or incorrectly notifies the AFM of matters required to be notified. A claim requiring that such measures be imposed may be instituted by us, or by one or more of our shareholders who alone or together with others represent at least 3% of our issued and outstanding share capital of or voting rights. The measures that the civil court may impose include:

- an order requiring the person with a duty to disclose to make the appropriate disclosure;
- suspension of the right to exercise the voting rights by the person with a duty to disclose for a period of up to three years as determined by the court;
- voiding a resolution adopted by the shareholders at the General Meeting, if the court determines that the resolution would not have been adopted but for the exercise of the voting rights of the person with a duty to disclose, or suspension of a resolution adopted by the shareholders at the General Meeting until the court makes a decision about such voiding; and
- an order to the person with a duty to disclose to refrain, during a period of up to five years as determined by the court, from acquiring shares or voting rights in the company.

Shareholders are advised to consult with their own legal advisors to determine whether the notification obligations apply to them.

Pursuant to the Dutch Corporate Governance Code and in accordance with the rules intended to prevent market abuse, on July 3, 2016, we adopted an insider trading policy in respect of the holding of and carrying out of transactions by board members and employees in our shares or in financial instruments the value of which is determined by the value of our shares. Furthermore, we have drawn up a list of those persons working for us who could have access to inside information on a regular or incidental basis and have informed such persons of the rules on insider trading and market manipulation, including the sanctions which can be imposed in the event of a violation of those rules.

Short Positions

Net Short Position

Pursuant to European Union regulation No 236/2012, each person holding a net short position attaining 0.2% of our issued share capital of must report it to the AFM. Each subsequent increase of this position by 0.1% above 0.2% will also have to be reported. Each net short position equal to 0.5% of our issued share capital and any subsequent increase of that position by 0.1% will be made public via the AFM short selling register. To calculate whether a natural person or legal person has a net short position, their short positions and long positions must be set off. A short transaction in a share can only be contracted if a reasonable case can be made that the shares sold can actually be delivered, which requires confirmation of a third party that the shares have been located. The notification will be made no later than 15:30 CET on the following trading day.

Gross Short Position

Furthermore, each person holding a gross short position in relation to our issued share capital that reaches, exceeds or falls below one of the following thresholds: 3%, 5%, 10%, 15%, 20%, 25%, 30%, 40%, 50%, 60%, 75% and 95%, must immediately give written notice to the AFM.

If a person's gross short position reaches, exceeds or falls below one of the abovementioned thresholds as a result of a change in our issued share capital, such person is required to make a notification not later than on the fourth trading day after the AFM has published our notification in the public register of the AFM.

The AFM keeps a public register of the short selling notifications. Shareholders are advised to consult with their own legal advisors to determine whether any of the above short selling notification obligations apply to them.

Group Structure

argenx SE is the top entity in our group and operates under Dutch law. argenx SE is the sole shareholder of argenx BVBA, a private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*) incorporated under the laws of Belgium, having its registered seat in Zwijnaarde, Belgium. argenx BVBA is the sole shareholder of argenx US Inc, 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.

argenx SE holds a small minority stake of 1% in Bird Rock Bio, a company incorporated under the laws of Delaware with its registered seat in La Jolla, U.S.

American Depositary 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.

Share Capital And Group Structure Upon Completion Of Our Possible Redomiciliation

As described in Part 8 "Overview of Our Restructuring and Possible Redomiciliation" we may in the future decide to transfer our registered office (*statutaire zetel*) to Belgium, after we have evaluated the impact of the new Belgian Companies Code and after the new Belgian Corporate Governance Code has entered into effect. In order to complete our possible redomiciliation, we will require the approval of our shareholders, and if we complete our possible redomiciliation, we will inform our shareholders of the relevant changes to our share capital structure and/or group structure upon completion of our possible redomiciliation in accordance with applicable law.

13 TAXATION

The information presented under the respective captions "Belgian Tax Consequences", "Dutch Tax Consequences" is a summary of certain material Belgian federal income tax consequences of the acquisition, ownership and disposal of our ordinary shares. The information presented under the caption "Certain Material U.S. Federal Income Tax Considerations to U.S. Holders" below is a discussion of certain material U.S. federal income tax considerations to a U.S. holder (as defined below) of investing in our ordinary shares.

Following such sections we provide a discussion of the material tax consequences of the acquisition, ownership and disposal of our ordinary shares, as shall become relevant if and when we complete of our possible redomiciliation, under Belgian and Dutch tax laws respectively.

You should consult your tax advisor regarding the applicable tax consequences to you of investing in our ordinary shares under the laws of Belgium, the United States (federal, state and local), the Netherlands, and any other applicable foreign jurisdiction.

Belgian Tax Consequences

The paragraphs below present a summary of certain material Belgian federal income tax consequences of the ownership and disposal of ordinary shares by an investor that purchases or holds such ordinary shares. The summary is based on laws, treaties and regulatory interpretations in effect in Belgium on the date of this Registration Document, all of which are subject to change, including changes that could have retroactive effect.

Investors should appreciate that, as a result of evolutions in law or practice, the eventual tax consequences may be different from what is stated below.

This summary does not purport to address all tax consequences of the ownership and disposal of ordinary shares, and does not take into account the specific circumstances of particular investors, some of which may be subject to special rules, or the tax laws of any country other than Belgium. This summary does not describe the tax treatment of investors that are subject to special rules, such as banks, insurance companies, collective investment undertakings, dealers in securities or currencies, persons that hold, or will hold, ordinary shares as a position in a straddle, share-repurchase transaction, conversion transactions, synthetic security or other integrated financial transactions. This summary does not address the local taxes that may be due in connection with an investment in shares, other than the additional municipal taxes which generally vary between 0% and 9% of the investor's income tax liability in Belgium.

Investors should consult their own advisors regarding the tax consequences of an investment in the ordinary shares in light of their particular situation, including the effect of any state, local or other national laws, treaties and regulatory interpretations thereof.

For purposes of this summary, a Belgian resident is an individual subject to Belgian personal income tax (that is, an individual who is domiciled in Belgium or has his seat of wealth in Belgium or a person assimilated to a resident for purposes of Belgian tax law), a company subject to Belgian corporate income tax (that is, a corporate entity that has its official seat, its main establishment, its administrative seat or seat of management in Belgium), an Organization for Financing Pensions subject to Belgian corporate income tax (that is a Belgian pension fund incorporated under the form of an Organization for Financing Pensions), or a legal entity subject to Belgian income tax on legal entities (that is, a legal entity other than a company subject to Belgian corporate income tax, that has its official seat, its main establishment, its administrative seat or seat of management in Belgium). A Belgian non-resident is any person that is not a Belgian resident.

Dividends

For Belgian income tax purposes, the gross amount of all benefits paid on or attributed to the ordinary shares is generally treated as a dividend distribution. By way of exception, the repayment of capital carried out in accordance with applicable Dutch company law provisions is not treated as a dividend distribution to the extent that such repayment is imputed to fiscal capital. This fiscal capital includes, in principle, the actual paid-up

statutory share capital and, subject to certain conditions, the paid-up share premiums and the cash amounts subscribed to at the time of the issue of profit sharing certificates. However, it is not possible to fully impute a repayment of capital to fiscal capital if the company also has certain reserves. Indeed, in such case, a reimbursement of capital is proratedly imputed on, on the one hand, fiscal capital and, on the other hand, taxed reserves (whether or not incorporated in capital) and tax exempt reserves incorporated in capital (according to a specific priority rule). The part imputed on the reserves is treated as a dividend distribution subject to applicable tax rules.

Belgian withholding tax of 30% is normally levied on dividends by any intermediary established in Belgium that is in any way involved in the processing of the payment of non-Belgian sourced dividends (e.g. a Belgian financial institution). This withholding tax rate is subject to such relief as may be available under applicable domestic or tax treaty provisions.

The Belgian withholding tax is calculated on the dividend amount after deduction of any non-Belgian dividend withholding tax.

In the case of a redemption of the ordinary shares, the redemption distribution (after deduction of the part of the fiscal capital represented by the redeemed ordinary shares) will be treated as a dividend subject to a Belgian withholding tax of 30%, subject to such relief as may be available under applicable domestic or tax treaty provisions. No withholding tax will be triggered if this redemption is carried out on a stock exchange and meets certain conditions.

In the event of our liquidation, any amounts distributed in excess of the fiscal capital will in principle be subject to the 30% withholding tax, subject to such relief as may be available under applicable domestic or tax treaty provisions.

Under Belgian law, non-Belgian dividend withholding tax is not creditable against Belgian income tax and is not reimbursable to the extent that it exceeds Belgian income tax. Please refer to "—Dutch Tax consequences–Dividend Withholding Tax" for a description of withholding tax that may be imposed on dividends by the Netherlands.

Belgian Resident Individuals

For Belgian resident individuals who acquire and hold ordinary shares as a private investment, the Belgian dividend withholding tax fully discharges their personal income tax liability. They may nevertheless need to report the dividends in their personal income tax return if no intermediary established in Belgium was in any way involved in the processing of the payment of the non-Belgian sourced dividends. Moreover, even if an intermediary established in Belgium was involved, they can opt to report the income in their personal income tax return. If (and only if) the dividends are reported, they will normally be eligible for a tax exemption with respect to ordinary dividends in an amount of up to €800 per year and per taxpayer (Article 21, first subsection, 14°, of the Belgian Income Tax Code ("ITC")). For the avoidance of doubt, all reported dividends (not only dividends distributed on our ordinary shares) are taken into account to assess whether the said maximum amount is reached.

Where the beneficiary needs or, as applicable, opts to report them, dividends will normally be taxable at the lower of the generally applicable 30% Belgian withholding tax rate on dividends or, in case globalization is more advantageous, at the progressive personal income tax rates applicable to the taxpayer's overall declared income. In addition, if the dividends are reported, the Belgian dividend withholding tax levied at source may be credited against the personal income tax due and is reimbursable to the extent that it exceeds the personal income tax due, provided that the dividend distribution does not result in a reduction in value of or a capital loss on our ordinary shares. The latter condition is not applicable if the individual can demonstrate that it has held ordinary shares in full legal ownership for an uninterrupted period of 12 months prior to the payment or attribution of the dividends.

For Belgian resident individual investors who acquire and hold ordinary shares for professional purposes, the Belgian withholding tax does not fully discharge their Belgian income tax liability. Dividends received must be reported by the investor and will, in such a case, be taxable at the investor's personal income tax rate increased with municipal surcharges. Belgian withholding tax levied may be credited against the personal income tax due

and is reimbursable to the extent that it exceeds the income tax due, subject to two conditions: (i) the taxpayer must own ordinary shares in full legal ownership on the dividend record date and (ii) the dividend distribution may not result in a reduction in value of or a capital loss on ordinary shares. The latter condition is not applicable if the investor can demonstrate that it has held the full legal ownership of ordinary shares for an uninterrupted period of 12 months prior to the payment or attribution of the dividends.

Belgian Resident Companies

Dividends received by Belgian resident companies are exempt from Belgian withholding tax provided that the investor satisfies the identification requirements in Article 117, par. 11 of the Royal Decree implementing the Belgian Income Tax Code.

For Belgian resident companies, the dividend income (after deduction of any non-Belgian withholding tax but including any Belgian withholding tax) must be declared in the corporate income tax return and will be subject to a corporate income tax rate of 29.58% (including a 2% surcharge), unless the reduced corporate income tax rate of 20.4% (including a 2% crisis surcharge) on the first €100,000 of taxable profits for certain qualifying companies with limited profits applies. As of assessment year 2021 linked to a tax year starting on or after 1 January 2020, the standard corporate income tax rate is 25% and the reduced rate is 20%.

Belgian resident companies can generally (although subject to certain limitations) deduct 100% of the gross dividend received from their taxable income, or the Dividend Received Deduction, provided that at the time of a dividend payment or attribution: (i) the Belgian resident company holds ordinary shares representing at least 10% of our share capital or a participation with an acquisition value of at least € 2,500,000 (it being understood that only one out of the two tests must be satisfied); (ii) the shares representing our share capital have been or will be held in full ownership for an uninterrupted period of at least one year; and (iii) the conditions described in Article 203 ITC (relating to the taxation of the underlying distributed income and the absence of abuse), or the Article 203 ITC Taxation Condition, are met, or together, the Conditions for the application of the dividend received deduction regime.

The Conditions for the application of the dividend received deduction regime depend on a factual analysis and for this reason the availability of this regime should be verified upon each dividend distribution.

Any Belgian dividend withholding tax levied at source can be credited against the ordinary Belgian corporate income tax and is reimbursable to the extent it exceeds such corporate income tax, subject to two conditions: (i) the taxpayer must own our ordinary shares in full legal ownership on the dividend record date and (ii) the dividend distribution does not result in a reduction in value of or a capital loss on our ordinary shares. The latter condition is not applicable: (i) if the taxpayer can demonstrate that it has held the ordinary shares in full legal ownership for an uninterrupted period of 12 months immediately prior to the payment or attribution of the dividends or (ii) if, during that period, the ordinary shares never belonged to a taxpayer other than a Belgian resident company or a non-resident company that has, in an uninterrupted manner, invested the ordinary shares in a permanent establishment, or PE, in Belgium.

Organizations For Financing Pensions

For organizations for financing pensions, or OFPs, i.e. Belgian pension funds incorporated under the form of an OFP (*organisme de financement de pensions/organisme voor de financiering van pensioenen*) within the meaning of Article 8 of the Belgian Law of October 27, 2006, dividend income generally does not constitute taxable income.

Dividends distributed through the intervention of a Belgian intermediary are generally subject to Belgian dividend withholding tax. If dividends are paid or attributed without the intervention of a Belgian intermediary, the applicable Belgian withholding tax will have to be reported and paid by the OFP to the Belgian tax administration.

The Belgian dividend withholding tax can in principle be credited against the OFPs' corporate income tax and is reimbursable to the extent it exceeds the corporate income tax due. However, such Belgian withholding cannot be credited by an OFP if the shares on which the dividends are paid have not been held uninterruptedly in full ownership for at least 60 days, unless the OFP demonstrates that the dividends are not connected to an

arrangement (or a series of arrangements) that is not genuine (*"kunstmatig"/"pas authentique"*) and has been put in place for the main purpose or one of the main purposes of obtaining this withholding tax credit.

Other Taxable Legal Entities

For taxpayers subject to the Belgian income tax on legal entities, the Belgian dividend withholding tax in principle fully discharges their income tax liability.

Belgian Non-Resident Individuals And Companies

Dividend payments on the ordinary shares through a professional intermediary in Belgium will, in principle, be subject to the 30% withholding tax, unless the shareholder is resident in a country with which Belgium has concluded a double taxation agreement and delivers the requested affidavit. Non-resident investors can also obtain an exemption of Belgian dividend withholding tax if they are the owners or usufructors of the ordinary shares and they deliver an affidavit confirming that they have not allocated the ordinary shares to business activities in Belgium and that they are non-residents, provided that the dividend is paid through a Belgian credit institution, stock market company or recognized clearing or settlement institution.

If our ordinary shares are acquired by a non-resident investor in connection with a business in Belgium, the investor must report any dividends received, which are taxable at the applicable non-resident individual or corporate income tax rate, as appropriate. Any Belgian withholding tax levied at source can be credited against the non-resident individual or corporate income tax and is reimbursable to the extent it exceeds the income tax due, subject to two conditions: (i) the taxpayer must own our ordinary shares in full legal ownership on the dividend record date and (ii) the dividend distribution does not result in a reduction in value of or a capital loss on the ordinary shares. The latter condition is not applicable if (i) the non-resident individual or the non-resident company can demonstrate that the ordinary shares were held in full legal ownership for an uninterrupted period of 12 months immediately prior to the payment or attribution of the dividends or (ii) with regard to non-resident companies only, if, during the said period, the ordinary shares have not belonged to a taxpayer other than a resident company or a non-resident company which has, in an uninterrupted manner, invested the ordinary shares in a Belgian PE.

Non-resident companies that have invested our ordinary shares in a Belgian establishment can deduct 100% of the gross dividends included in their taxable profits if, at the date dividends are paid or attributed, the Conditions for the application of the Dividend Received Deduction regime are satisfied. Application of the Dividend Received Deduction regime depends, however, on a factual analysis to be made upon each distribution and its availability should be verified upon each distribution.

Capital Gains And Losses On Ordinary Shares

Belgian Resident Individuals

In principle, Belgian resident individuals acquiring our ordinary shares as a private investment should not be subject to Belgian capital gains tax on the disposal of the ordinary shares; capital losses are not tax deductible.

Capital gains realized in a private (i.e. non-professional) context on the transfer for consideration of shares by a private individual, are taxable at 33% (plus local surcharges) if the capital gain is deemed to be realized outside the scope of the normal management of the individual's private estate. Capital losses are, however, not tax deductible in such event.

Gains realized by Belgian resident individuals upon the redemption of our ordinary shares or upon our liquidation are generally taxable as a dividend.

Belgian resident individuals who hold our ordinary shares for professional purposes are taxable at the ordinary progressive personal income tax rates (plus local surcharges) on any capital gains realized upon the disposal of the ordinary shares, except for ordinary shares held for more than five years, which are taxable at a flat rate of 16.5% (plus local surcharges). Capital losses on the ordinary shares incurred by Belgian resident individuals who hold the ordinary shares for professional purposes are in principle tax deductible.

Belgian Resident Companies

Belgian resident companies are normally not subject to Belgian capital gains taxation on gains realized upon the disposal of our ordinary shares provided that (i) the shares represent at least 10% of our share capital or a participation with an acquisition value of at least € 2,500,000 (it being understood that only one out of the two tests must be satisfied, (ii) the Article 203 ITC Taxation Condition is satisfied and (iii) the ordinary shares have been held in full legal ownership for an uninterrupted period of at least one year immediately preceding the disposal.

If the one-year minimum holding condition would not be satisfied (but the other conditions are) the capital gains realized upon the disposal of our ordinary shares by a Belgian resident company are taxable at a flat corporate income tax rate of, currently, 25.5% (including the 2% crisis surcharge). As of assessment year 2021 linked to a tax year starting on or after 1 January 2020, the tax rate in this case will be equal to the 25% standard tax rate.

If the Article 203 ITC Taxation Condition is not satisfied or the participation condition is not met, the capital gains are taxable at the standard corporate tax rate (of 29.58% currently and of 25% as of assessment year 2021 linked to a tax year starting on or after 1 January 2020), unless the reduced corporate income tax rate applies.

Capital losses on our ordinary shares incurred by resident companies are as a general rule not tax deductible.

Our ordinary shares held in the trading portfolios (*portefeuille commercial/handelsportefeuille*) of qualifying credit institutions, investment enterprises and management companies of collective investment undertakings which are subject to the Royal Decree of 23 September 1992 on the annual accounts of credit institutions, investment firms and management companies of collective investment undertakings (*comptes annuels des etablissements de credit, des entreprises d'investissement et des societes de gestion d'organismes de placement collectif/jaarrekening van de kredietinstellingen, de beleggingsondernemingen en de beheervennootschappen van instellingen voor collectieve belegging*) are subject to a different regime. The capital gains on such shares are taxable at the ordinary corporate income tax rate of 29.58% (including the 2% crisis surcharge), which is reduced to 25% as of assessment year 2021 linked to a tax year starting on or after 1 January 2020. Capital losses on such shares are tax deductible. Internal transfers to and from the trading portfolio are assimilated to a realization.

Capital gains realized by Belgian resident companies (both non-SMEs and SMEs and both ordinary Belgian resident companies and qualifying credit institutions, investment enterprises and management companies of collective investment undertakings) upon the redemption of our ordinary shares or upon our liquidation are, in principle, subject to the same taxation regime as dividends. See "Dividends" above.

Organizations for Financing Pensions

OFPs are, in principle, not subject to Belgian capital gains taxation realized upon the disposal of the ordinary shares, and capital losses are not tax deductible.

Other Taxable Legal Entities

Belgian resident legal entities subject to the legal entities income tax are, in principle, not subject to Belgian capital gains taxation on the disposal of ordinary shares.

Capital gains realized by Belgian resident legal entities upon the redemption of ordinary shares or upon our liquidation will in principle be taxed as dividends.

Capital losses on ordinary shares incurred by Belgian resident legal entities are not tax deductible.

Belgian Non-Resident Individuals And Companies

Non-resident individuals or companies are, in principle, not subject to Belgian income tax on capital gains realized upon disposal of the ordinary shares, unless such ordinary shares are held as part of a business conducted in

Belgium through a Belgian establishment. In such a case, the same principles apply as described with regard to Belgian individuals (holding the shares for professional purposes) or Belgian companies.

Non-resident individuals who do not use the shares for professional purposes and who have their fiscal residence in a country with which Belgium has not concluded a tax treaty or with which Belgium has concluded a tax treaty that confers the authority to tax capital gains on the ordinary shares to Belgium, might be subject to tax in Belgium if the capital gains arise from transactions which are to be considered speculative or beyond the normal management of one's private estate. See "Capital gains and losses on ordinary shares – Belgian resident individuals". Such non-resident individuals might therefore be obliged to file a tax return and should consult their own tax advisor.

Capital gains realized by non-resident individuals or non-resident companies upon repurchase of the shares or upon our liquidation will, in principle, be subject to the same taxation regime as dividends.

Tax On Stock Exchange Transactions

Upon the issue of ordinary shares (primary market), no Tax on Stock Exchange Transactions ("*taks op de beursverrichtingen" / "taxe sur les opérations de bourse*") is due.

The purchase and the sale and any other acquisition or transfer for consideration of our ordinary shares (secondary market transactions) is subject to the Tax on Stock Exchange Transactions if (i) it is executed in Belgium through a professional intermediary, or (ii) deemed to be executed in Belgium, which is the case if the order is directly or indirectly made to a professional intermediary established outside of Belgium, either by private individuals with habitual residence in Belgium, or legal entities for the account of their seat or establishment in Belgium (both, a Belgian Investor).

The Tax on Stock Exchange Transactions is levied at a rate of 0.35% of the purchase price, capped at €1,600 per transaction and per party.

A separate tax is due by each party to the transaction, and both taxes are collected by the professional intermediary. However, if the intermediary is established outside of Belgium, the tax will in principle be due by the Belgian Investor, unless that Belgian Investor can demonstrate that the tax has already been paid. Professional intermediaries established outside of Belgium can, subject to certain conditions and formalities, appoint a Belgian Stock Exchange Tax Representative, which will be liable for the Tax on Stock Exchange Transactions in respect of the transactions executed through the professional intermediary. If the Stock Exchange Tax Representative would have paid the Tax on Stock Exchange Transactions due, the Belgian Investor will, as per the above, no longer be the debtor of the Tax on Stock Exchange Transactions.

No tax on stock exchange transactions is due on transactions entered into by the following parties, provided they are acting for their own account: (i) professional intermediaries described in Article 2, 9° and 10° of the Belgian Law of August 2, 2002; (ii) insurance companies described in Article 2, §1 of the Belgian Law of July 9, 1975; (iii) professional retirement institutions referred to in Article 2, 1° of the Belgian Law of October 27, 2006 concerning the supervision on institutions for occupational pension; (iv) collective investment institutions; (v) regulated real estate companies; and (vi) Belgian non-residents provided they deliver a certificate to their financial intermediary in Belgium confirming their non-resident status.

The EU Commission adopted on February 14, 2013 the Draft Directive on a Financial Transaction Tax, or FTT. The Draft Directive currently stipulates that once the FTT enters into force, the Participating Member States shall not maintain or introduce taxes on financial transactions other than the FTT (or VAT as provided in the Council Directive 2006/112/EC of November 28, 2006 on the common system of value added tax). For Belgium, the tax on stock exchange transactions should thus be abolished once the FTT enters into force. The Draft Directive regarding the FTT is still subject to negotiation between the Participating Member States and therefore may be changed at any time.

Tax on Securities Accounts

On 10 March 2018, the law on the introduction of a tax on securities accounts entered into force. Pursuant to this law, Belgian resident and non-resident individuals are taxed at a rate of 0.15 percent. on their share in the average value of qualifying financial instruments (such as our ordinary shares and other shares, bonds, certain other type of debt instruments, units of undertakings for collective investment, warrants) held on one or more securities accounts during a reference period of 12 consecutive months starting on 1 October and ending on 30 September of the subsequent year ("Tax on Securities Accounts").

No Tax on Securities Accounts is due provided the holder's share in the average value of the qualifying financial instruments on those accounts amounts to less than €500,000. If, however, the holder's share in the average value of the qualifying financial instruments on those accounts amounts to €500,000 or more, the Tax on Securities Accounts is due on the entire share of the holder in the average value of the qualifying financial instruments on those accounts (and hence, not only on the part which exceeds the €500,000 threshold).

Qualifying financial instruments held by non-resident individuals only fall within the scope of the Tax on Securities Accounts provided they are held on securities accounts with a financial intermediary established or located in Belgium. Note that pursuant to certain double tax treaties, Belgium has no right to tax capital. Hence, to the extent the Tax on Securities Accounts is viewed as a tax on capital within the meaning of these double tax treaties, incompatibility of the Tax on Securities Accounts with a treaty may, subject to certain conditions, be claimed.

The Tax on Securities Accounts is in principle due by the financial intermediary established or located in Belgium if (i) the holder's share in the average value of the qualifying financial instruments held on one or more securities accounts with said intermediary amounts to €500,000 or more; or (ii) the holder instructed the financial intermediary to levy the Tax on Securities Accounts due (e.g. in case such holder holds qualifying financial instruments on several securities accounts held with multiple intermediaries of which the average value does not amount to €500,000 or more but of which the holder's share in the total average value of these accounts exceeds €500,000). Otherwise, the Tax on Securities Accounts must be declared and is due by the holder itself, unless the holder provides evidence that the Tax on Securities Accounts has already been withheld, declared and paid by an intermediary which is not established or located in Belgium. In that respect, intermediaries located or established outside of Belgium could appoint a Tax on the Securities Accounts representative in Belgium, subject to certain conditions and formalities. Such a Tax on the Securities Accounts Representative is then liable towards the Belgian Treasury for the Tax on the Securities Accounts due and for complying with certain reporting obligations in that respect.

Prospective investors are advised to seek their own professional advice in relation to the Tax on Securities Accounts.

Dutch Tax Consequences

The following summary outlines certain Dutch tax consequences in connection with the acquisition, ownership and disposal of our ordinary shares. All references in this summary to the Netherlands and Dutch law are to the European part of the Kingdom of the Netherlands and its law, respectively, only. The summary does not purport to present any comprehensive or complete picture of all Dutch tax aspects that could be of relevance to the acquisition, ownership and disposal of our ordinary shares by a (prospective) holder of our ordinary shares who may be subject to special tax treatment under applicable law. The summary is based on the tax laws and practice of the Netherlands as in effect on the date of this Registration Document, which are subject to changes that could prospectively or retrospectively affect the Dutch tax consequences.

For purposes of Dutch income and corporate income tax, shares legally owned by a third party such as a trustee, foundation or similar entity or arrangement, or a Third Party, may under certain circumstances have to be allocated to the (deemed) settlor, grantor or similar originator, or the Settlor, or, upon the death of the Settlor, his/her beneficiaries, or the Beneficiaries, in proportion to their entitlement to the estate of the Settlor of such trust or similar arrangement, or the Separated Private Assets.

The summary does not address the tax consequences of a holder of our ordinary shares who is an individual and who has a substantial interest (*aanmerkelijk belang*) in the company. Generally, a holder of our ordinary shares will have a substantial interest in the company if such holder of our ordinary shares, whether alone or together with his spouse or partner and/or certain other close relatives, holds directly or indirectly, or as Settlor or

Beneficiary of Separated Private Assets (i) (x) the ownership of, (y) certain other rights, such as usufruct, over, or (z) rights to acquire (whether or not already issued), shares representing 5% or more of the total issued and outstanding capital (or the issued and outstanding capital of any class of shares) of the company or (ii) (x) the ownership of, or (y) certain other rights, such as usufruct over, profit participating certificates (*winstbewijzen*) that relate to 5% or more of the annual profit of the company or to 5% or more of the liquidation proceeds of the company.

In addition, a holder of our ordinary shares has a substantial interest in the company if he, whether alone or together with his spouse or partner and/or certain other close relatives, has the ownership of, or other rights over, shares in, or profit certificates issued by, the company that represent less than 5% of the relevant aggregate that either (a) qualified as part of a substantial interest as set forth above and where shares, profit certificates and/or rights there over have been, or are deemed to have been, partially disposed of, or (b) have been acquired as part of a transaction that qualified for non recognition of gain treatment.

This summary does not address the tax consequences of a holder of our ordinary shares who:

a) receives income or realizes capital gains in connection with his or her employment activities or in his/her capacity as (former) board member and/or (former) supervisory board member; or

b) is a resident of any non European part of the Kingdom of the Netherlands.

PROSPECTIVE HOLDERS OF OUR ORDINARY SHARES SHOULD CONSULT THEIR OWN PROFESSIONAL ADVISER WITH RESPECT TO THE TAX CONSEQUENCES OF ANY ACQUISITION, OWNERSHIP OR DISPOSAL OF OUR ORDINARY SHARES IN THEIR INDIVIDUAL CIRCUMSTANCES.

Dividend Withholding Tax

General

The company is generally required to withhold dividend withholding tax imposed by the Netherlands at a rate of 15% on dividends distributed by the company in respect of our ordinary shares. The expression "dividends distributed by the company" as used herein includes, but is not limited to:

a) distributions in cash or in kind, deemed and constructive distributions and repayments of paid in capital ("*gestort kapitaal*") not recognized for Dutch dividend withholding tax purposes;

b) liquidation proceeds, proceeds of redemption of our ordinary shares or, as a rule, consideration for the repurchase of our ordinary shares by the company in excess of the average paid in capital recognized for Dutch dividend withholding tax purposes;

c) the par value of our ordinary shares issued to a holder of our ordinary shares or an increase of the par value of our ordinary shares, to the extent that it does not appear that a contribution, recognized for Dutch dividend withholding tax purposes, has been made or will be made; and

d) partial repayment of paid in capital, recognized for Dutch dividend withholding tax purposes, if and to the extent that there are net profits (*zuivere winst*), unless (i) the shareholders at the General Meeting have resolved in advance to make such repayment and (ii) the par value of our ordinary shares concerned has been reduced by an equal amount by way of an amendment of the articles of association.

Holders of Our Ordinary Shares Resident in the Netherlands

A holder of our ordinary shares that is resident or deemed to be resident in the Netherlands is generally entitled, subject to the anti dividend stripping rules described below, to a full credit against its (corporate) income tax liability, or a full refund, of the Dutch dividend withholding tax. The same generally applies to holders of our ordinary shares that are neither resident nor deemed to be resident in the Netherlands if our ordinary shares are attributable to a permanent establishment in the Netherlands of such non resident holder.

Holders of Our Ordinary Shares Resident Outside the Netherlands

A holder of our ordinary shares that is resident in a country with which the Netherlands has a double taxation convention in effect, may, depending on the terms of such double taxation convention and subject to the anti dividend stripping rules described below, be eligible for a full or partial exemption from, or full or partial refund of, Dutch dividend withholding tax on dividends received.

A holder of our ordinary shares, that is a legal entity (a) resident in (i) a Member State of the European Union, (ii) Iceland, Norway or Liechtenstein, or (iii) a country with which the Netherlands has concluded a tax treaty that includes an article on dividends and (b) that is in its state of residence under the terms of a double taxation agreement concluded with a third state, not considered to be resident for tax purposes in a country with which the Netherlands has not concluded a tax treaty that includes an article on dividends (not being a Member State of the European Union Iceland, Norway or Liechtenstein), is generally entitled, subject to the anti-abuse rules and the anti dividend stripping rules described below, to a full exemption from Dutch dividend withholding tax on dividends received if it holds an interest of at least 5% (in shares or, in certain cases, in voting rights) in the company or if it holds an interest of less than 5%, in either case where, had the holder of our ordinary shares been a Dutch resident, it would have had the benefit of the participation exemption (this may include a situation where another related party holds an interest of 5% or more in the company).

The full exemption from Dutch dividend withholding tax on dividends received by a holder of our ordinary shares, that is a legal entity (a) resident in (i) a Member State of the European Union, (ii) Iceland, Norway or Liechtenstein, or (iii) a country with which the Netherlands has concluded a tax treaty that includes an article on dividends is not granted if the interest held by such holder (i) is held with the avoidance of Dutch dividend withholding tax of another person as (one of) the main purpose(s) and (ii) forms part of an artificial structure or series of structures (such as structures which are not put into place for valid business reasons reflecting economic reality).

A holder of our ordinary shares, that is an entity resident in (i) a Member State of the European Union, or (ii) Iceland, Norway or Liechtenstein, or (iii) in a jurisdiction which has an arrangement for the exchange of tax information with the Netherlands (and such holder as described under (iii) holds our ordinary shares as a portfolio investment, i.e., such holding is not acquired with a view to the establishment or maintenance of lasting and direct economic links between the holder of our ordinary shares and the company and does not allow the holder of our ordinary shares to participate effectively in the management or control of the company), which is exempt from tax in its country of residence, and that would have been exempt from Dutch corporate income tax if it had been a resident of the Netherlands, is generally entitled, subject to the anti dividend stripping rules described below, to a full refund of Dutch dividend withholding tax on dividends received. This full refund will in general benefit certain foreign pension funds, government agencies and certain government controlled commercial entities.

According to the anti dividend stripping rules, no exemption, reduction, credit or refund of Dutch dividend withholding tax will be granted if the recipient of the dividend paid by the company is not considered the beneficial owner (*uiteindelijk gerechtigde*) of the dividend as defined in these rules. A recipient of a dividend is not considered the beneficial owner of the dividend if, as a consequence of a combination of transactions, (i) a person (other than the holder of the dividend coupon), directly or indirectly, partly or wholly benefits from the dividend, (ii) such person directly or indirectly retains or acquires a comparable interest in our ordinary shares, and (iii) such person is entitled to a less favorable exemption, refund or credit of dividend withholding tax than the recipient of the dividend distribution. The term "combination of transactions" includes transactions that have been entered into in the anonymity of a regulated stock market, the sole acquisition of one or more dividend coupons and the establishment of short term rights or enjoyment on our ordinary shares (e.g., usufruct).

Holders of Our Ordinary Shares Resident in the U.S.

Dividends distributed by the company to U.S. resident holders of our ordinary shares that are eligible for benefits under the Convention between the Kingdom of the Netherlands and the United States of America for the avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes and Income, dated December 18, 1992 as amended by the protocol of March 8, 2004, or the U.S. Tax Treaty, generally will be entitled to a reduced dividend withholding tax rate of 5% in case of certain U.S. corporate shareholders owning at least 10% of the company's total voting power. Certain U.S. pension funds and tax exempt organizations may qualify for a complete exemption from Dutch dividend withholding tax.

Under the U.S. Tax Treaty such benefits are generally available to U.S. residents if such resident is the beneficial owner of the dividends, provided that such shareholder does not have an enterprise or an interest in an enterprise that is, in whole or in part, carried on through a permanent establishment or permanent representative in the Netherlands and to which enterprise or part of an enterprise our ordinary shares are attributable. A person may, however, not claim the benefits of the U.S. Tax Treaty if such person's entitlement to such benefits is limited by the provisions of Article 26 (the limitation on benefits provision) of the U.S. Tax Treaty. The reduced dividend withholding tax rate can generally be applied at source upon the distribution of the dividends, provided that the proper forms have been filed in advance of the distribution. In the case of certain tax exempt organizations, as a general rule, the so called refund method applies; only when certain administrative conditions have been fulfilled may such tax exempt organization use the exemption method.

Taxes on Income and Capital Gains

Holders of Our Ordinary Shares Resident in the Netherlands: Individuals

A holder of our ordinary shares, who is an individual resident or deemed to be resident in the Netherlands will be subject to regular Dutch income tax on the income derived from our ordinary shares and the gains realized upon the acquisition, redemption and/or disposal of our ordinary shares by the holder thereof, if:

a) such holder of our ordinary shares has an enterprise or an interest in an enterprise, to which enterprise our ordinary shares are attributable; and/or

b) such income or capital gain forms "a benefit from miscellaneous activities" ("*resultaat uit overige werkzaamheden*") which, for instance, would be the case if the activities with respect to our ordinary shares exceed "normal active asset management" ("*normaal, actief vermogensbeheer*") or if income and gains are derived from the holding, whether directly or indirectly, of (a combination of) shares, debt claims or other rights (together, a "lucrative interest" (*lucratief belang*)) that the holder thereof has acquired under such circumstances that such income and gains are intended to be remuneration for work or services performed by such holder (or a related person), whether within or outside an employment relation, where such lucrative interest provides the holder thereof, economically speaking, with certain benefits that have a relation to the relevant work or services.

If either of the abovementioned conditions (a) or (b) applies, income derived from our ordinary shares and the gains realized upon the acquisition, redemption and/or disposal of our ordinary shares will in general be subject to Dutch income tax at the progressive rates up to 51.95%.

If the abovementioned conditions (a) and (b) do not apply, a holder of our ordinary shares who is an individual, resident or deemed to be resident in the Netherlands will not be subject to taxes on income and capital gains in the Netherlands. Instead, such individual is generally taxed at a flat rate of 30% on deemed income from "savings and investments" ("*sparen en beleggen*"), which deemed income is determined on the basis of the amount included in the individual's "yield basis" ("*rendementsgrondslag*") at the beginning of the calendar year (minus a tax free threshold). For the 2018 tax year, the deemed income derived from savings and investments will amount to 2.02% of the individual's yield basis up to €70,800, 4.33% of the individual's yield basis exceeding €70,800 up to and including €978,000 and 5.38% of the individual's yield basis in excess of €978,000. The tax-free threshold for 2018 is EUR 30,000.

Holders of Our Ordinary Shares Resident in the Netherlands: Corporate Entities

A holder of our ordinary shares that is resident or deemed to be resident in the Netherlands for corporate income tax purposes, and that is:

- a corporation;
- another entity with a capital divided into shares;
- a cooperative (association); or
- another legal entity that has an enterprise or an interest in an enterprise to which our ordinary shares are attributable,
- but which is not:

- a qualifying pension fund;
- a qualifying investment fund (fiscale beleggingsinstelling) or a qualifying exempt investment institution (vrijgestelde beleggingsinstelling); or
- another entity exempt from corporate income tax,

will in general be subject to regular corporate income tax, generally levied at a rate of 25% (20% over profits up to €200,000) over income derived from our ordinary shares and the gains realized upon the acquisition, redemption and/or disposal of our ordinary shares, unless, and to the extent that, the participation exemption (*deelnemingsvrijstelling*) applies.

Holders of Our Ordinary Shares Resident Outside the Netherlands: Individuals

A holder of our ordinary shares who is an individual, not resident or deemed to be resident in the Netherlands will not be subject to any Dutch taxes on income derived from our ordinary shares and the gains realized upon the acquisition, redemption and/or disposal of our ordinary shares (other than the dividend withholding tax described above), unless:

a) such holder has an enterprise or an interest in an enterprise that is, in whole or in part, carried on through a permanent establishment (*vaste inrichting*) or a permanent representative (*vaste vertegenwoordiger*) in the Netherlands and to which enterprise or part of an enterprise, as the case may be, our ordinary shares are attributable; or

b) such income or capital gain forms a "benefit from miscellaneous activities in the Netherlands" ("*resultaat uit overige werkzaamheden in Nederland*") which would for instance be the case if the activities in the Netherlands with respect to our ordinary shares exceed "normal active asset management" ("*normaal, actief vermogensbeheer*" or if such income and gains are derived from the holding, whether directly or indirectly, of (a combination of) shares, debt claims or other rights (together, a "lucrative interest" ("*lucratief belang*")) that the holder thereof has acquired under such circumstances that such income and gains are intended to be remuneration for work or services performed by such holder (or a related person), in whole or in part, in the Netherlands, whether within or outside an employment relation, where such lucrative interest provides the holder thereof, economically speaking, with certain benefits that have a relation to the relevant work or services.

If either of the abovementioned conditions (a) or (b) applies, income or capital gains in respect of dividends distributed by the company or in respect of any gains realized upon the acquisition, redemption and/or disposal of our ordinary shares will in general be subject to Dutch income tax at the progressive rates up to 51.95%.

Holders of Our Ordinary Shares Resident Outside the Netherlands: Legal and Other Entities

A holder of our ordinary shares, that is a legal entity, another entity with a capital divided into shares, an association, a foundation or a fund or trust, not resident or deemed to be resident in the Netherlands for corporate income tax purposes, will not be subject to any Dutch taxes on income derived from our ordinary shares and the gains realized upon the acquisition, redemption and/or disposal of our ordinary shares (other than the dividend withholding tax described above), unless:

a) such holder has an enterprise or an interest in an enterprise that is, in whole or in part, carried on through a permanent establishment (*vaste inrichting*) or a permanent representative (*vaste vertegenwoordiger*) in the Netherlands and to which enterprise or part of an enterprise, as the case may be, our ordinary shares are attributable; or

b) such holder has a substantial interest (*aanmerkelijk belang*) in the company, that (i) is held with the avoidance of Dutch income tax of another person as (one of) the main purpose(s) and (ii) forms part of an artificial structure or series of structures (such as structures which are not put into place for valid business reasons reflecting economic reality).

If one of the abovementioned conditions applies, income derived from our ordinary shares and the gains realized upon the acquisition, redemption and/or disposal of our ordinary shares will, in general, be subject to Dutch regular

corporate income tax, levied at a rate of 25% (20% over profits up to €200,000), unless, and to the extent that, with respect to a holder as described under (a), the participation exemption (*deelnemingsvrijstelling*) applies.

Gift, Estate and Inheritance Taxes

Holders of Our Ordinary Shares Resident in the Netherlands

Gift tax may be due in the Netherlands with respect to an acquisition of our ordinary shares by way of a gift by a holder of our ordinary shares who is resident or deemed to be resident of the Netherlands at the time of the gift.

Inheritance tax may be due in the Netherlands with respect to an acquisition or deemed acquisition of our ordinary shares by way of an inheritance or bequest on the death of a holder of our ordinary shares who is resident or deemed to be resident of the Netherlands, or by way of a gift within 180 days before his death by an individual who is resident or deemed to be resident in the Netherlands at the time of his death.

For purposes of Dutch gift and inheritance tax, an individual with the Dutch nationality will be deemed to be resident in the Netherlands if he has been resident in the Netherlands at any time during the ten years preceding the date of the gift or his death. For purposes of Dutch gift tax, an individual not holding the Dutch nationality will be deemed to be resident of the Netherlands if he has been resident in the Netherlands at any time during the twelve months preceding the date of the gift.

Holders of Our Ordinary Shares Resident Outside the Netherlands

No gift, estate or inheritance taxes will arise in the Netherlands with respect to an acquisition of our ordinary shares by way of a gift by, or on the death of, a holder of our ordinary shares who is neither resident nor deemed to be resident of the Netherlands, unless, in the case of a gift of our ordinary shares by an individual who at the date of the gift was neither resident nor deemed to be resident in the Netherlands, such individual dies within 180 days after the date of the gift, while being resident or deemed to be resident in the Netherlands.

Certain Special Situations

For purposes of Dutch gift, estate and inheritance tax, (i) a gift by a Third Party will be construed as a gift by the Settlor, and (ii) upon the death of the Settlor, as a rule his/her Beneficiaries will be deemed to have inherited directly from the Settlor. Subsequently, such Beneficiaries will be deemed the settlor, grantor or similar originator of the Separated Private Assets for purposes of Dutch gift, estate and inheritance tax in case of subsequent gifts or inheritances.

For the purposes of Dutch gift and inheritance tax, a gift that is made under a condition precedent is deemed to have been made at the moment such condition precedent is satisfied. If the condition precedent is fulfilled after the death of the donor, the gift is deemed to be made upon the death of the donor.

Value Added Tax

No Dutch value added tax will arise in respect of or in connection with the subscription, issue, placement, allotment or delivery of our ordinary shares.

Other Taxes and Duties

No Dutch registration tax, capital tax, custom duty, transfer tax, stamp duty or any other similar documentary tax or duty, other than court fees, will be payable in the Netherlands in respect of or in connection with the subscription, issue, placement, allotment or delivery of our ordinary shares.

Residency

A holder of our ordinary shares will not be treated as a resident, or a deemed resident, of the Netherlands by reason only of the acquisition, or the holding, of our ordinary shares or the performance by the company under our ordinary shares.

Certain Material U.S. Federal Income Tax Considerations to U.S. Holders

The following is a summary of certain material U.S. federal income tax considerations relating to the ownership and disposition of our ordinary shares by a U.S. holder (as defined below). This summary addresses only the U.S. federal income tax considerations for U.S. holders that hold ADSs as capital assets for U.S. federal income tax purposes. This summary does not address all U.S. federal income tax matters that may be relevant to a particular U.S. holder. This summary does not address tax considerations applicable to a holder of our ordinary shares that may be subject to special tax rules including, without limitation, the following:

- banks, financial institutions or insurance companies;
- brokers, dealers or traders in securities, currencies, commodities, or notional principal contracts;
- tax exempt entities or organizations, including an "individual retirement account" or "Roth IRA" as defined in Section 408 or 408A of the Code (as defined below), respectively;
- real estate investment trusts, regulated investment companies or grantor trusts;
- persons that hold our ordinary shares as part of a "hedging," "integrated" or "conversion" transaction or as a position in a "straddle" for U.S. federal income tax purposes;
- partnerships (including entities or arrangements classified as partnerships for U.S. federal income tax purposes) or other pass through entities, or persons that will hold our ordinary shares through such an entity;
- certain former citizens or long term residents of the United States;
- holders that own directly, indirectly, or through attribution 10% or more of the voting power or value of our ordinary shares and shares; and
- holders that have a "functional currency" for U.S. federal income tax purposes other than the U.S. dollar.

Further, this summary does not address U.S. federal estate, gift, or alternative minimum tax considerations, any election to apply Section 1400Z-2 of the Code to gains recognized with respect to ADSs or any U.S. state, local, or non U.S. tax considerations of the acquisition, ownership and disposition of our ordinary shares.

This description is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code; existing, proposed and temporary U.S. Treasury Regulations promulgated thereunder, administrative and judicial interpretations thereof; and the income tax treaties between the Netherlands and the United States, and Belgium and the United States in each case as in effect and available on the date hereof. All the foregoing is subject to change, which change could apply retroactively, and to differing interpretations, all of which could affect the tax considerations described below. There can be no assurances that the U.S. Internal Revenue Service, or the IRS, will not take a contrary or different position concerning the tax consequences of the ownership and disposition of our ordinary shares or that such a position would not be sustained. Holders should consult their own tax advisors concerning the U.S. federal, state, local and non U.S. tax consequences of owning and disposing of our ordinary shares in their particular circumstances.

For the purposes of this summary, a "U.S. holder" is a beneficial owner of our ordinary shares that is (or is treated as), for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation, or other entity that is treated as a corporation for U.S. federal income tax purposes, created or organized in or under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust, if a court within the United States is able to exercise primary supervision over its administration and one or more U.S. persons have the authority to control all of the substantial decisions of such trust or have a valid election in effect under applicable U.S. Treasury Regulations to be treated as a United States person.

If a partnership (or any other entity or arrangement treated as a partnership for U.S. federal income tax purposes) holds our ordinary shares, the U.S. federal income tax consequences relating to an investment in those ordinary shares will depend in part upon the status of the partner and the activities of the partnership. Such a partner or partnership should consult its tax advisor regarding the U.S. federal income tax considerations of owning and disposing of our ordinary shares in its particular circumstances.

In general, a U.S. holder who owns our ordinary shares will be treated as the beneficial owner of the underlying shares represented by those ordinary shares for U.S. federal income tax purposes. Accordingly, no gain or loss will generally be recognized if a U.S. holder exchanges our ordinary shares for the underlying shares represented by those ordinary shares.

As indicated below, this discussion is subject to U.S. federal income tax rules applicable to a "passive foreign investment company," or a PFIC, discussed under “—Passive Foreign Investment Company Considerations.”

Persons considering an investment in our ordinary shares should consult their own tax advisors as to the particular tax consequences applicable to them relating to the ownership and disposition of our ordinary shares, including the applicability of U.S. federal, state and local tax laws and non U.S. tax laws.

Distributions. Although we do not currently plan to pay dividends, and subject to the discussion under "—Passive Foreign Investment Company Considerations" below, the gross amount of any distribution (before reduction for any amounts withheld in respect of Dutch or Belgian withholding tax) actually or constructively received by a U.S. holder with respect to our ordinary shares will be taxable to the U.S. holder as a dividend to the extent of the U.S. holder’s pro rata share of our current and accumulated earnings and profits as determined under U.S. federal income tax principles. Distributions in excess of earnings and profits will be non taxable to the U.S. holder to the extent of, and will be applied against and reduce, the U.S. holder’s adjusted tax basis in our ordinary shares. Distributions in excess of earnings and profits and such adjusted tax basis will generally be taxable to the U.S. holder as either long term or short term capital gain depending upon whether the U.S. holder has held our ordinary shares for more than one year as of the time such distribution is received. However, since we do not calculate our earnings and profits under U.S. federal income tax principles, it is expected that any distribution will be reported as a dividend, even if that distribution would otherwise be treated as a non taxable return of capital or as capital gain under the rules described above. Non corporate U.S. holders may qualify for the preferential rates of taxation with respect to dividends on our ordinary shares applicable to long term capital gains (i.e., gains from the sale of capital assets held for more than one year) applicable to qualified dividend income (as discussed below) if we are a "qualified foreign corporation" and certain other requirements (discussed below) are met. A non U.S. corporation (other than a corporation that is a PFIC for the taxable year in which the dividend is paid or the preceding taxable year) generally will be considered to be a qualified foreign corporation with respect to any dividend it pays on shares which are readily tradable on an established securities market in the United States. We have been approved to list our ADSs on The Nasdaq Global Select Market which is an established securities market in the United States, and we expect our the ADSs to be readily tradable on The Nasdaq Global Select Market. However, there can be no assurance that our ordinary shares will be considered readily tradable on an established securities market in the United States in later years. Therefore, subject to the discussion under "—Passive Foreign Investment Company Considerations" below, such dividends will generally be "qualified dividend income" in the hands of non corporate U.S. holders, provided that a holding period requirement (more than 60 days of ownership, without protection from the risk of loss, during the 121 day period beginning 60 days before the ex dividend date) and certain other requirements are met. The dividends will not be eligible for the dividends received deduction generally allowed to corporate U.S. holders.

A U.S. holder generally may claim the amount of any Dutch or Belgian withholding tax as either a deduction from gross income or a credit against U.S. federal income tax liability. However, the foreign tax credit is subject to numerous complex limitations that must be determined and applied on an individual basis. Generally, the credit cannot exceed the proportionate share of a U.S. holder’s U.S. federal income tax liability that such U.S. holder’s taxable income bears to such U.S. holder’s worldwide taxable income. In applying this limitation, a U.S. holder’s various items of income and deduction must be classified, under complex rules, as either "foreign source" or "U.S. source." In addition, this limitation is calculated separately with respect to specific categories of income. The amount of a distribution with respect to our ordinary shares that is treated as a "dividend" may be lower for U.S. federal income tax purposes than it is for Dutch or Belgian income tax purposes, potentially resulting in a reduced foreign tax credit for the U.S. holder. Furthermore, Dutch or Belgian income taxes withheld in excess of the rate applicable under the income tax treaty between the Netherlands or Belgium and the United States will not be eligible for credit against U.S. holders’ federal income tax liability. Each U.S. holder should consult its own tax advisors regarding the foreign tax credit rules.

Sale, Exchange or Other Taxable Disposition of our Ordinary Shares. A U.S. holder will generally recognize gain or loss for U.S. federal income tax purposes upon the sale, exchange or other taxable disposition of our ordinary shares in an amount equal to the difference between the U.S. dollar value of the amount realized from such sale or exchange and the U.S. holder’s tax basis for those ordinary shares. Subject to the discussion under "—Passive Foreign Investment Company Considerations" below, this gain or loss will generally be a capital gain or loss. The adjusted tax basis in our ordinary shares generally will be equal to the cost of such ordinary shares. Capital gain from the sale, exchange or other taxable disposition of our ordinary shares of a non corporate U.S.

holder is generally eligible for a preferential rate of taxation applicable to capital gains, if the non corporate U.S. holder's holding period determined at the time of such sale, exchange or other taxable disposition for such ordinary shares exceeds one year (i.e., such gain is long term taxable gain). The deductibility of capital losses for U.S. federal income tax purposes is subject to limitations. Any such gain or loss that a U.S. holder recognizes generally will be treated as U.S. source income or loss for foreign tax credit limitation purposes.

Medicare Tax. Certain U.S. holders that are individuals, estates or trusts are subject to a 3.8% tax on all or a portion of their "net investment income," which may include all or a portion of their dividend income and net gains from the disposition of our ordinary shares. Each U.S. holder that is an individual, estate or trust is urged to consult its tax advisors regarding the applicability of the Medicare tax to its income and gains in respect of its investment in our ordinary shares.

Passive Foreign Investment Company Considerations. If we are classified as a passive foreign investment company, or PFIC for any taxable year, a U.S. holder would be subject to special rules generally intended to reduce or eliminate any benefits from the deferral of U.S. federal income tax that a U.S. holder could derive from investing in a non U.S. company that does not distribute all of its earnings on a current basis.

A corporation organized outside the United States generally will be a PFIC for U.S. federal income tax purposes for any taxable year in which, after applying certain look-through rules, either: (i) at least 75% of its gross income is "passive income" or (ii) at least 50% of the average quarterly value of its total gross assets (for which purpose the total value of our assets may be determined in part by reference to the market value of our ordinary shares, which is subject to change) is attributable to assets that produce "passive income" or are held for the production of "passive income."

Passive income for this purpose generally includes dividends, interest, royalties, rents, gains from commodities and securities transactions, the excess of gains over losses from the disposition of assets which produce passive income, and includes amounts derived by reason of the temporary investment of cash, including the funds raised in offerings of our ordinary shares. If a non U.S. corporation owns directly or indirectly at least 25% by value of the stock of another corporation, the non U.S. corporation is treated for purposes of the PFIC tests as owning its proportionate share of the assets of the other corporation and as receiving directly its proportionate share of the other corporation's income for purposes of the PFIC tests. If we are a PFIC for any year with respect to which a U.S. holder owns our ordinary shares, we will continue to be treated as a PFIC with respect to such U.S. holder in all succeeding years during which the U.S. holder owns our ordinary shares, regardless of whether we continue to meet the tests described above.

Whether we are a PFIC for any taxable year will depend on the composition of our income and the projected composition and estimated fair market values of our assets in each year, and because this is a factual determination made annually after the end of each taxable year, there can be no assurance that we will not be considered a PFIC for any taxable year. The market value of our assets may be determined in large part by reference to the market price of our ordinary shares, which is likely to fluctuate after a pubic offering. Based on the foregoing, we do not anticipate that we will be a PFIC for the 2018 taxable year based upon the expected value of our assets, including any goodwill, and the expected composition of our income and assets, however, as previously mentioned, we cannot provide any assurances regarding our PFIC status for the current or any prior or future taxable years.

If we are a PFIC, for any taxable year, then unless you make one of the elections described below, a special tax regime will apply to both (a) any "excess distribution" by us to you (generally, your ratable portion of distributions in any year which are greater than 125% of the average annual distribution received by you in the shorter of the three preceding years or your holding period for our ordinary shares) and (b) any gain realized on the sale or other disposition of our ordinary shares. Under this regime, any excess distribution and realized gain will be treated as ordinary income and will be subject to tax as if (a) the excess distribution or gain had been realized ratably over your holding period, (b) the amount deemed realized in each year had been subject to tax in each year of that holding period at the highest marginal rate for such year (other than income allocated to the current period or any taxable period before we became a PFIC, which would be subject to tax at the U.S. holder's regular ordinary income rate for the current year and would not be subject to the interest charge discussed below), and (c) the interest charge generally applicable to underpayments of tax had been imposed on the taxes deemed to have

been payable in those years. In addition, dividend distributions made to you will not qualify for the lower rates of taxation applicable to long term capital gains discussed above under "—Distributions."

Certain elections exist that would result in an alternative treatment (such as mark to market treatment) of our ordinary shares. If a U.S. holder makes the mark to market election, the U.S. holder generally will recognize as ordinary income any excess of the fair market value of our ordinary shares at the end of each taxable year over their adjusted tax basis, and will recognize an ordinary loss in respect of any excess of the adjusted tax basis of our ordinary shares over their fair market value at the end of the taxable year (but only to the extent of the net amount of income previously included as a result of the mark to market election). If a U.S. holder makes the election, the U.S. holder's tax basis in our ordinary shares will be adjusted to reflect these income or loss amounts. Any gain recognized on the sale or other disposition of our ordinary shares in a year when we are a PFIC will be treated as ordinary income and any loss will be treated as an ordinary loss (but only to the extent of the net amount of income previously included as a result of the mark to market election). The mark to market election is available only if we are a PFIC and our ordinary shares are "regularly traded" on a "qualified exchange." Our ordinary shares will be treated as "regularly traded" in any calendar year in which more than a de minimis quantity of our ordinary shares are traded on a qualified exchange on at least 15 days during each calendar quarter (subject to the rule that trades that have as one of their principal purposes the meeting of the trading requirement as disregarded). Nasdaq is a qualified exchange for this purpose and, consequently, if our ordinary shares are regularly traded, the mark to market election will generally be available to a U.S. holder.

If we are a PFIC for any year during which a U.S. holder holds our ordinary shares, we must generally continue to be treated as a PFIC by that U.S. holder for all succeeding years during which the U.S. holder holds our ordinary shares, unless we cease to meet the requirements for PFIC status and the U.S. holder makes a "deemed sale" election with respect to our ordinary shares. If such election is made, the U.S. holder will be deemed to have sold our ordinary shares it holds at their fair market value on the last day of the last taxable year in which we qualified as a PFIC, and any gain from such deemed sale would be subject to the consequences applicable to sales of PFIC shares described above. After the deemed sale election, the U.S. holder's ordinary shares with respect to which the deemed sale election was made will not be treated as shares in a PFIC unless we subsequently become a PFIC.

The tax consequences that would apply if we were a PFIC would also be different from those described above if a U.S. holder were able to make a valid "qualified electing fund," or QEF, election. However, we do not currently intend to provide the information necessary for U.S. holders to make a QEF election if we were treated as a PFIC for any taxable year and prospective investors should assume that a QEF election will not be available. U.S. holders should consult their tax advisors to determine whether any of these above elections would be available and if so, what the consequences of the alternative treatments would be in their particular circumstances.

If we are determined to be a PFIC, the general tax treatment for U.S. holders described in this section would apply to indirect distributions and gains deemed to be realized by U.S. holders in respect of any of our subsidiaries that also may be determined to be PFICs.

If a U.S. holder owns our ordinary shares during any taxable year in which we are a PFIC, the U.S. holder generally will be required to file an IRS Form 8621 (Information Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund) with respect to the company, generally with the U.S. holder's federal income tax return for that year. If our company were a PFIC for a given taxable year, then you should consult your tax advisor concerning your annual filing requirements.

The U.S. federal income tax rules relating to PFICs are complex. Prospective U.S. investors are urged to consult their own tax advisors with respect to the ownership and disposition of our ordinary shares, the consequences to them of an investment in a PFIC, any elections available with respect to our ordinary shares and the IRS information reporting obligations with respect to the ownership and disposition of our ordinary shares.

Backup Withholding and Information Reporting. U.S. holders generally will be subject to information reporting requirements with respect to dividends on our ordinary shares and on the proceeds from the sale, exchange or disposition of our ordinary shares that are paid within the United States or through U.S. related financial intermediaries, unless the U.S. holder is an "exempt recipient." In addition, U.S. holders may be subject to backup

withholding on such payments, unless the U.S. holder provides a correct taxpayer identification number and a duly executed IRS Form W 9 or otherwise establishes an exemption. Backup withholding is not an additional tax, and the amount of any backup withholding will be allowed as a credit against a U.S. holder's U.S. federal income tax liability and may entitle such holder to a refund, provided that the required information is timely furnished to the IRS.

Foreign Asset Reporting. Certain U.S. holders who are individuals and certain entities controlled by individuals may be required to report information relating to an interest in our ordinary shares, subject to certain exceptions (including an exception for shares held in accounts maintained by U.S. financial institutions) by filing IRS Form 8938 (Statement of Specified Foreign Financial Assets) with their federal income tax return. U.S. holders are urged to consult their tax advisors regarding their information reporting obligations, if any, with respect to their ownership and disposition of our ordinary shares.

THE DISCUSSION ABOVE IS A GENERAL SUMMARY. IT DOES NOT COVER ALL TAX MATTERS THAT MAY BE OF IMPORTANCE TO A PROSPECTIVE INVESTOR. EACH PROSPECTIVE INVESTOR IS URGED TO CONSULT ITS OWN TAX ADVISOR ABOUT THE TAX CONSEQUENCES TO IT OF AN INVESTMENT IN OUR ORDINARY SHARES IN LIGHT OF THE INVESTOR'S OWN CIRCUMSTANCES.

PROSPECTIVE HOLDERS OF OUR SECURITIES SHOULD CONSULT THEIR OWN PROFESSIONAL ADVISER WITH RESPECT TO THE TAX CONSEQUENCES OF ANY ACQUISITION, OWNERSHIP OR DISPOSAL OF OUR SECURITIES IN THEIR INDIVIDUAL CIRCUMSTANCES.

Tax Consequences Upon Completion of our Possible Redomiciliation

As set out in the Section "Overview Of Our Restructuring And Possible Redomiciliation - Transfer of Our Registered Office from the Netherlands to Belgium", we may seek to implement a redomiciliation from the Netherlands to Belgium. The following two sections provide a discussion of the material tax consequences of the acquisition, ownership and disposal of our ordinary shares, as shall become relevant if and when we complete of our possible redomiciliation, under Belgian and Dutch tax laws respectively.

Belgian Taxation Upon Completion of Our Possible Redomiciliation

The summary below presents certain material Belgian federal income tax consequences of the ownership and disposal of ordinary shares by an investor that purchases such ordinary shares, if and when our possible redomiciliation is completed. The summary is based on laws, treaties and regulatory interpretations in effect in Belgium on the date of this Registration Document, all of which are subject to change, including changes that could have retroactive effect.

Investors should appreciate that, as a result of evolutions in law or practice, the eventual tax consequences may be different from what is stated below.

This summary does not purport to address all tax consequences of the ownership and disposal of ordinary shares, and does not take into account the specific circumstances of particular investors, some of which may be subject to special rules, or the tax laws of any country other than Belgium. This summary does not describe the tax treatment of investors that are subject to special rules, such as banks, insurance companies, collective investment undertakings, dealers in securities or currencies, persons that hold, or will hold, ordinary shares as a position in a straddle, share-repurchase transaction, conversion transactions, synthetic security or other integrated financial transactions. This summary does not address the local taxes that may be due in connection with an investment in shares, other than the additional municipal taxes which generally vary between 0% and 9% of the investor's income tax liability in Belgium.

Investors should consult their own advisors regarding the tax consequences of an investment in the ordinary shares in light of their particular situation, including the effect of any state, local or other national laws, treaties and regulatory interpretations thereof.

For purposes of this summary, a Belgian resident is an individual subject to Belgian personal income tax (that is, an individual who is domiciled in Belgium or has his seat of wealth in Belgium or a person assimilated to a resident for purposes of Belgian tax law), a company subject to Belgian corporate income tax (that is, a corporate entity that has its official seat, its main establishment, its administrative seat or seat of management in Belgium), an Organization for Financing Pensions subject to Belgian corporate income tax (that is a Belgian pension fund incorporated under the form of an Organization for Financing Pensions), or a legal entity subject to Belgian income tax on legal entities (that is, a legal entity other than a company subject to Belgian corporate income tax, that has its official seat, its main establishment, its administrative seat or seat of management in Belgium). A Belgian non-resident is any person that is not a Belgian resident.

Dividends

For Belgian income tax purposes, the gross amount of all benefits paid on or attributed to ordinary shares is generally treated as a dividend distribution. By way of exception, the repayment of capital carried out in accordance with the Belgian Companies Code is not treated as a dividend distribution to the extent such repayment is imputed to fiscal capital. This fiscal capital includes, in principle, the actual paid-up statutory share capital and, subject to certain conditions, the paid-up share premiums and the cash amounts subscribed to at the time of the issue of profit sharing certificates. However, it is not possible to fully impute a repayment of capital to fiscal capital if the company also has certain reserves. Indeed, in such case, a reimbursement of capital is proratedly imputed on, on the one hand, fiscal capital and, on the other hand, on taxed reserves (whether or not

incorporated in capital) and tax exempt reserves incorporated in capital (in accordance with a certain priority rule). The part imputed on reserves is treated as a dividend distribution subject to applicable tax rules.

Belgian dividend withholding tax of 30% is levied on dividends, subject to such relief as may be available under applicable domestic or tax treaty provisions.

In the case of a redemption of the ordinary shares, the redemption distribution (after deduction of the part of the fiscal capital represented by the redeemed ordinary shares) will be treated as a dividend subject to Belgian withholding tax of 30%, subject to such relief as may be available under applicable domestic or tax treaty provisions. No withholding tax will be triggered if this redemption is carried out on a stock exchange and meets certain conditions.

In the event of our liquidation, any amounts distributed in excess of the fiscal capital will in principle be subject to the 30% withholding tax, subject to such relief as may be available under applicable domestic or tax treaty provisions.

Belgian Resident Individuals

For Belgian resident individuals who acquire and hold ordinary shares as a private investment, the Belgian dividend withholding tax fully discharges their personal income tax liability. They may nevertheless elect to report the dividends in their personal income tax return. If (and only if) the dividends are reported, they will normally be eligible for a tax exemption with respect to ordinary dividends in an amount of up to €800 per year and per taxpayer (Article 21, first subsection, 14°, ITC). For the avoidance of doubt, all reported dividends (not only dividends distributed on our ordinary shares) are taken into account to assess whether the said maximum amount is reached.

Where the beneficiary opts to report them, dividends will normally be taxable at the lower of the generally applicable 30% Belgian withholding tax rate on dividends, or in case globalization is more advantageous, at the progressive personal income tax rates applicable to the taxpayer's overall declared income. In addition, if the dividends are reported, the Belgian dividend withholding tax levied at source may be credited against the personal income tax due and is reimbursable to the extent that it exceeds the personal income tax due, provided that the dividend distribution does not result in a reduction in value of or a capital loss on our ordinary shares. The latter condition is not applicable if the individual can demonstrate that it has held ordinary shares in full legal ownership for an uninterrupted period of 12 months prior to the payment or attribution of the dividends.

For Belgian resident individual investors who acquire and hold ordinary shares for professional purposes, the Belgian withholding tax does not fully discharge their Belgian income tax liability. Dividends received must be reported by the investor and will, in such a case, be taxable at the investor's personal income tax rate increased with municipal surcharges. Belgian withholding tax levied may be credited against the personal income tax due and is reimbursable to the extent that it exceeds the income tax due, subject to two conditions: (i) the taxpayer must own ordinary shares in full legal ownership on the dividend record date, and (ii) the dividend distribution may not result in a reduction in value of or a capital loss on ordinary shares. The latter condition is not applicable if the investor can demonstrate that it has held the full legal ownership of ordinary shares for an uninterrupted period of 12 months prior to the payment or attribution of the dividends.

Belgian Resident Companies

Corporate Income Tax

For Belgian resident companies, the dividend withholding tax does not fully discharge corporate income tax liability. The gross dividend income (including any Belgian withholding tax) must be declared in the corporate income tax return and will be subject to a corporate income tax rate of 29.58% (including a 2% crisis surcharge), unless the reduced corporate income tax rate of 20.4% (including a 2% crisis surcharge) on the first €100,000 of taxable profits for certain qualifying companies with limited profits applies. As of assessment year 2021 linked to a tax year starting on or after 1 January 2020, the standard corporate income tax rate is 25% and the reduced rate is 20%.

Belgian resident companies can generally (although subject to certain limitations) deduct 100% of the gross dividend received from their taxable income, or the Dividend Received Deduction, provided that at the time of a dividend payment or attribution: (i) the Belgian resident company holds shares representing at least 10% of our share capital or a participation in our shares with an acquisition value of at least € 2,500,000 (it being understood that only one out of the two tests must be satisfied); (ii) the shares representing our share capital have been or will be held in full ownership for an uninterrupted period of at least one year immediately prior to the payment or attribution of the dividend; and (iii) the conditions described in Article 203 of the ITC (relating to the taxation of the underlying distributed income and the absence of abuse), or the Article 203 ITC Taxation Condition, are met, or together, the Conditions for the application of the dividend received deduction regime). Under certain circumstances the conditions referred to under (i) and (ii) do not need to be fulfilled in order for the Dividend Received Deduction to apply.

The Conditions for the application of the dividend received deduction regime depend on a factual analysis and for this reason the availability of this regime should thus be verified upon each dividend distribution.

Any Belgian dividend withholding tax levied at source can be credited against the ordinary Belgian corporate income tax and is reimbursable to the extent it exceeds such corporate income tax, subject to two conditions: (i) the taxpayer must own our ordinary shares in full legal ownership on the dividend record date and (ii) the dividend distribution does not result in a reduction in value of or a capital loss on our ordinary shares. The latter condition is not applicable if: (i) the taxpayer can demonstrate that it has held the ordinary shares in full legal ownership for an uninterrupted period of 12 months immediately prior to the payment or attribution of the dividends or (ii) during that period, the ordinary shares never belonged to a taxpayer other than a Belgian resident company or a non-resident company that has, in an uninterrupted manner, invested the ordinary shares in a permanent establishment, or PE, in Belgium.

Withholding Tax

Dividends distributed to a Belgian resident company will be exempt from Belgian withholding tax provided that the Belgian resident company holds, upon payment or attribution of the dividends, at least 10% of our share capital and such minimum participation is or will be held for an uninterrupted period of at least one year.

In order to benefit from this exemption, the investor must provide us or our paying agent with a certificate confirming its qualifying status and the fact that it satisfies the two conditions set out above. If the investor holds a qualifying participation for less than one uninterrupted year, at the time the dividends are paid or attributed, we will levy the withholding tax but not transfer it to the Belgian Treasury provided the investor certifies its qualifying status, the date from which it has held such minimum participation, and its commitment to hold the qualifying participation for an uninterrupted period of at least one year. The investor must also inform us or our paying agent when the one-year period expires or if its shareholding will drop below 10% of our share capital before the end of the one-year holding period. Upon satisfying the one-year shareholding requirement, the levied dividend withholding tax will be refunded to the investor.

The above withholding tax exemption will not be applicable to dividends which are connected to an arrangement or a series of arrangements ("*rechtshandeling of geheel van rechtshandelingen*"/"*acte juridique ou un ensemble d'actes juridiques*") for which the Belgian tax administration, taking into account all relevant facts and circumstances, has proven, unless evidence to the contrary, that this arrangement or this series of arrangements is not genuine ("*kunstmatig*"/"*non authentique*") and has been put in place for the main purpose or one of the main purposes of obtaining the dividend received deduction, the above dividend withholding tax exemption or one of the advantages of the EU Parent Subsidiary Directive of November 30, 2011 (2011/96/EU), or the Parent-Subsidiary Directive, in another Member State of the European Union. An arrangement or a series of arrangements is regarded as not genuine to the extent that they are not put into place for valid commercial reasons which reflect economic reality.

Organizations For Financing Pensions

For OFPs, the dividend income is generally tax-exempt. Dividends distributed on our shares to OFPs are in principle subject to 30% Belgian withholding tax. This Belgian dividend withholding tax can be credited against an OFP's corporate income tax and is reimbursable to the extent it exceeds the corporate income tax due, provided

that the shares on which the dividends are paid have been held uninterruptedly in full ownership for at least 60 days. The latter condition does not apply if the OFP demonstrates that the dividends are not connected to an arrangement (or a series of arrangements) that is not genuine (*"kunstmatig"/"pas authentique"*) and has been put in place for the main purpose or one of the main purposes of obtaining this withholding tax credit.

Other Taxable Legal Entities

For taxpayers subject to the Belgian income tax on legal entities, the Belgian dividend withholding tax in principle fully discharges their income tax liability.

Belgian Non-Resident Individuals And Companies

Non resident Income Tax

For non-resident individuals and companies, dividend withholding tax will be the only tax on dividends in Belgium, unless the non-resident holds ordinary shares in connection with a business conducted in Belgium through a fixed base in Belgium or a Belgian PE.

If our ordinary shares are acquired by a non-resident investor in connection with a business in Belgium, the investor must report any dividends received, which are taxable at the applicable non-resident individual or corporate income tax rate, as appropriate. Any Belgian withholding tax levied at source can be credited against the non-resident individual or corporate income tax and is reimbursable to the extent it exceeds the income tax due, subject to two conditions: (i) the taxpayer must own our ordinary shares in full legal ownership on the dividend record date and (ii) the dividend distribution does not result in a reduction in value of or a capital loss on the ordinary shares. The latter condition is not applicable if (i) the non-resident individual or the non-resident company can demonstrate that the ordinary shares were held in full legal ownership for an uninterrupted period of 12 months immediately prior to the payment or attribution of the dividends or (ii) with regard to non-resident companies only, if, during the said period, the ordinary shares have not belonged to a taxpayer other than a resident company or a non-resident company which has, in an uninterrupted manner, invested the ordinary shares in a Belgian PE.

Non-resident companies that have invested our ordinary shares in a Belgian establishment can deduct 100% of the gross dividends included in their taxable profits if, at the date dividends are paid or attributed, the Conditions for the application of the Dividend Received Deduction regime are satisfied. See "Belgian resident companies". Application of the Dividend Received Deduction regime depends, however, on a factual analysis to be made upon each distribution and its availability should be verified upon each distribution.

Belgian Dividend Withholding Tax Relief for Non residents

Dividends distributed to non-resident individuals who do not use the Shares in the exercise of a professional activity, may be eligible for a tax exemption with respect to ordinary dividends in an amount of up to €800 per year and per taxpayer (Article 21, first subsection, 14°, of the ITC). For the avoidance of doubt, all dividends (not only dividends distributed on our ordinary shares) are taken into account to assess whether the said maximum amount is reached. Consequently, if Belgian withholding tax has been withheld on dividends eligible for the exemption and up to the maximum amount, such non-resident individual may claim reimbursement of such withholding tax from the competent tax service or, if the non-resident is required to file a tax return, may request in such tax return that such withholding tax be credited and, as the case may be, reimbursed.

Under Belgian tax law, Belgian withholding tax is not due on dividends paid to a foreign pension fund which satisfies the following conditions: (i) it is a non resident saver in the meaning of Article 227, 3° ITC which implies that it has separate legal personality and fiscal residence outside of Belgium; (ii) whose corporate purpose consists solely in managing and investing funds collected in order to pay legal or complementary pensions; (iii) whose activity is limited to the investment of funds collected in the exercise of its corporate purpose, without any profit making aim; (iv) which is exempt from income tax in its country of residence; and (v) except in specific circumstances provided that it is not contractually obligated to redistribute the dividends to any ultimate beneficiary of such dividends for whom it would manage our ordinary shares, nor obligated to pay a manufactured dividend with respect to the shares under a securities borrowing transaction. This withholding tax exemption however does not apply if the pension fund has not held the shares on which dividends are distributed uninterruptedly in full

ownership for at least 60 days, unless the pension fund demonstrates that the arrangement (or series of arrangements) with which the dividend is connected, is genuine ("niet kunstmatig"/"authentique"). The exemption will only apply if the foreign pension fund provides a certificate confirming that it is the full legal owner or usufruct holder of the shares and that the above conditions are satisfied. The foreign pension fund must then provide us or our paying agent with that certificate.

Dividends distributed to non-resident qualifying parent companies established in a Member State of the European Union or in a country with which Belgium has concluded a double tax treaty that includes a qualifying exchange of information clause, will, under certain conditions, be exempt from Belgian withholding tax provided that the shares held by the non resident company, upon payment or attribution of the dividends, amount to at least 10% of our share capital and such minimum participation is held or will be held during an uninterrupted period of at least one year. A company qualifies as a parent company provided that (i) for companies established in a Member State of the European Union, it has a legal form as listed in the annex to the Parent-Subsidiary Directive, or, for companies established in a country with which Belgium has concluded a qualifying double tax treaty, it has a legal form similar to the ones listed in such annex; (ii) it is considered to be a tax resident of the country where it is established according to the tax laws of such country and the double tax treaties concluded between such country and third countries; and (iii) it is in such country subject to corporate income tax or a similar tax without benefiting from a tax regime that derogates from the ordinary tax regime.

In order to benefit from this exemption, the non-resident company must provide us or our paying agent with a certificate confirming its qualifying status and the fact that it meets the required conditions.

If the non-resident company holds a minimum participation for less than one year at the time the dividends are paid or attributed to the shares, we will levy the Belgian withholding tax but not transfer it to the Belgian Treasury provided that the non-resident company provides us or our paying agent at the latest upon the attribution of the dividends with a certificate confirming, in addition to its qualifying status, the date as of which it has held the minimum participation, and its commitment to hold the minimum participation for an uninterrupted period of at least one year. The non-resident company must also inform us or our paying agent if the one-year period has expired or if its shareholding drops below 10% of our share capital before the end of the one-year holding period. Upon satisfying the one-year holding requirement, the dividend withholding tax which was temporarily withheld, will be refunded to the non-resident company.

The above withholding tax exemptions will not be applicable to dividends which are connected to an arrangement or a series of arrangements ("rechtshandeling of geheel van rechtshandelingen"/"acte juridique ou un ensemble d'actes juridiques") for which the Belgian tax administration, taking into account all relevant facts and circumstances, has proven, unless evidence to the contrary, that this arrangement or this series of arrangements is not genuine ("kunstmatig"/"non authentique") and has been put in place for the main purpose or one of the main purposes of obtaining the dividend received deduction, the above dividend withholding tax exemptions or one of the advantages of the Parent-Subsidiary Directive in another Member State of the European Union. An arrangement or a series of arrangements is regarded as not genuine to the extent that they are not put into place for valid commercial reasons which reflect economic reality.

Dividends distributed to non-resident companies are exempt from Belgian withholding tax, in case (i) the non-resident company is established in the European Economic Area or in a country with which Belgium has concluded a tax treaty that includes a qualifying exchange of information clause, (ii) the non-resident company and the dividend distributing company are subject to corporate income tax or a similar tax without benefiting from a tax regime that derogates from the ordinary tax regime, (iii) the non-resident company has a participation in our share capital with an acquisition value of at least €2,500,000 but representing less than 10% of our share capital on the date the dividend is paid on or attributed, (iv) the dividends relate to shares which are or will be held in full ownership for at least one year without interruption, and (v) the non resident company has a legal form as listed in the annex to the Parent-Subsidiary Directive, as amended by Directive 2014/86/EU of July 8, 2014, or, has a legal form similar to the ones listed in such annex that is governed by the laws of another Member State of the EEA, or, has a legal form similar to the ones listed in such annex in a country with which Belgium has concluded a qualifying double tax treaty. This exemption only applies to the extent that the ordinary Belgian withholding tax is, in principle, neither creditable nor reimbursable in the hands of the non resident company.

In order to benefit from this exemption, the investor must provide us or our paying agent with a certificate confirming (i) it is established in another EEA Member State or in a State with which Belgium has concluded a tax treaty, provided that the tax treaty or any other treaty provides for the exchange or information which is necessary to give effect to the provisions of the domestic laws of the Contracting States, (ii) it has a legal form as listed in the Annex I, part A of the Parent-Subsidiary Directive, as amended by Directive 2014/86/EU of 8 July 2014, or a legal form similar to the ones listed in said Annex and governed by the laws of the EEA Member State, or a legal form similar to the ones listed in said Annex in a country with which Belgium has concluded a tax treaty, (iii) it is subject to corporate income tax or a similar tax without benefiting from a tax regime that deviates from the ordinary domestic tax regime, (iv) it holds a participation of less than 10% in our share capital but with an acquisition value of at least €2,500,000 on the date the dividend is paid on or attributed, (v) the dividends relate to shares which it has held or will hold in full legal ownership for an uninterrupted period of at least one year, (vi) it cannot in principle credit the Belgian withholding tax paid on the dividends or obtain a refund thereof according to the legal provisions in force on 31 December of the year preceding the year of the payment or attribution of the dividends. We or our paying agent may also request confirmation from the investor that the investor commits to keep the shares until the completion of the minimum holding period of one year and that the investor immediately notifies us or our paying agent of the completion of said one year holding period. The investor must furthermore provide on the certificate its full name, legal form, address and tax identification number, if applicable.

Belgium has concluded tax treaties with more than 90 countries, reducing the Belgian dividend withholding tax rate to 20%, 15%, 10%, 5% or 0% for residents of those countries, depending on conditions, among others, related to the size of the shareholding and certain identification formalities. Such reduction may be obtained either directly at source or through a refund of taxes withheld in excess of the applicable tax treaty rate.

Prospective holders should consult their own tax advisers to determine whether they qualify for a reduction of Belgian withholding tax and, if so, to understand the procedural requirements for obtaining a reduced rate of Belgian withholding tax upon the payment of dividends or for making claims for reimbursement.

Capital Gains And Losses On Ordinary Shares

Belgian Resident Individuals

In principle, Belgian resident individuals acquiring our ordinary shares as a private investment should not be subject to Belgian capital gains tax on the disposal of the ordinary shares; capital losses are not tax deductible.

Capital gains realized in a private (i.e. non-professional) context on the transfer for consideration of shares by a private individual, are taxable at 33% (plus local surcharges) if the capital gain is deemed to be realized outside the scope of the normal management of the individual's private estate. Capital losses are, however, not tax deductible in such event.

Capital gains realized by Belgian resident individuals on the disposal of the shares to a non-resident company (or body constituted in a similar legal form), to a foreign state (or one of its political subdivisions or local authorities) or to a non-resident legal entity, each time established outside the European Economic Area, are taxable at a rate of 16.5% (plus local surcharges) if, at any time during the five years preceding the sale, the Belgian resident individual has owned, directly or indirectly, alone or with his/her spouse or with certain relatives, a substantial shareholding in us (i.e. a shareholding of more than 25% in our shares). Capital losses are, however, not tax deductible in such event.

Gains realized by Belgian resident individuals upon the redemption of our ordinary shares or upon our liquidation are generally taxable as a dividend. See "—Dividends—Belgian resident individuals".

Belgian resident individuals who hold our ordinary shares for professional purposes are taxable at the ordinary progressive personal income tax rates (plus local surcharges) on any capital gains realized upon the disposal of the ordinary shares, except for ordinary shares held for more than five years, which are taxable at a flat rate of 16.5% (plus local surcharges). Capital losses on the ordinary shares incurred by Belgian resident individuals who hold the ordinary shares for professional purposes are in principle tax deductible.

Belgian Resident Companies

Belgian resident companies are normally not subject to Belgian capital gains taxation on gains realized upon the disposal of our ordinary shares provided that (i) the shares represent at least 10% of our share capital or a participation with an acquisition value of at least € 2,500,000 (it being understood that only one out of the two tests must be satisfied, (ii) the Article 203 ITC Taxation Condition is satisfied and (iii) the ordinary shares have been held in full legal ownership for an uninterrupted period of at least one year immediately preceding the disposal.

If the one-year minimum holding condition would not be satisfied (but the other conditions are) the capital gains realized upon the disposal of our ordinary shares by a Belgian resident company are taxable at a flat corporate income tax rate of 25.5% (including the 2% crisis surcharge). As of assessment year 2021 linked to a tax year starting on or after 1 January 2020, the tax rate in this case will be equal to the standard tax rate of 25%.

If the Article 203 ITC Taxation Condition is not satisfied or the participation condition is not met, the capital gains are taxable at the standard corporate tax rate (of 29.58% currently and of 25% as of assessment year 2021 linked to a tax year starting on or after 1 January 2020), unless the reduced corporate income tax rate applies.

Capital losses on our ordinary shares incurred by resident companies are as a general rule not tax deductible.

Our ordinary shares held in the trading portfolios (*portefeuille commercial / handelsportefeuille*) of qualifying credit institutions, investment enterprises and management companies of collective investment undertakings which are subject to the Royal Decree of September 23, 1992 on the annual accounts of credit institutions, investment firms and management companies of collective investment undertakings (*comptes annuels des établissements de crédit, des entreprises d'investissement et des sociétés de gestion d'organismes de placement / jaarrekening van de kredietinstellingen, de beleggingsondernemingen en de beheervennootschappen van instellingen voor collectieve belegging*) are subject to a different regime. The capital gains on such shares are taxable at the ordinary corporate income tax rate of 29.58% (including the 2% crisis surcharge), which is reduced to 25% as of assessment year 2021 linked to a tax year starting on or after 1 January 2020. Capital losses on such shares are tax deductible. Internal transfers to and from the trading portfolio are assimilated to a realization.

Capital gains realized by Belgian resident companies (both non-SMEs and SMEs and both ordinary Belgian resident companies and qualifying credit institutions, investment enterprises and management companies of collective investment undertakings) upon the redemption of our ordinary shares or upon our liquidation are, in principle, subject to the same taxation regime as dividends. See "—Dividends" above.

Organizations For Financing Pensions

OFPs within the meaning of article 8 of the Belgian Act of 27 October 2006 are, in principle, not subject to Belgian capital gains taxation realized upon the disposal of the ordinary shares, and capital losses are not tax deductible.

However, in general, capital gains realized by Belgian resident OFPs upon redemption of our ordinary shares or upon our liquidation will, in principle, be subject to the same taxation regime as dividends. See "Dividends" above.

Other Taxable Legal Entities

Belgian resident legal entities subject to the legal entities income tax are, in principle, not subject to Belgian capital gains taxation on the disposal of ordinary shares.

Capital gains realized by Belgian resident legal entities upon the redemption of our ordinary shares or upon our liquidation will in principle be taxed as dividends. See "—Dividends" above.

Capital losses on ordinary shares incurred by Belgian resident legal entities are not tax deductible.

Belgian Non-Resident Individuals And Companies

Non-resident individuals or companies are, in principle, not subject to Belgian income tax on capital gains realized upon disposal of the ordinary shares, unless such ordinary shares are held as part of a business conducted in

Belgium through a Belgian PE. In such a case, the same principles apply as described with regard to Belgian individuals (holding the shares for professional purposes) or Belgian companies.

Non-resident individuals who do not use the shares for professional purposes and who have their fiscal residence in a country with which Belgium has not concluded a tax treaty or with which Belgium has concluded a tax treaty that confers the authority to tax capital gains on the ordinary shares to Belgium, might be subject to tax in Belgium if the capital gains arise from transactions which are to be considered speculative or beyond the normal management of one's private estate or if the transfer concerns a substantial shareholding. See "—Capital gains and losses on shares—Belgian resident individuals". Such non-resident individuals might therefore be obliged to file a tax return and should consult their own tax advisor. Capital losses in such cases are however not tax-deductible.

Capital gains realized by non-resident individuals or non-resident companies upon repurchase of our shares or upon our liquidation will, in principle, be subject to the same taxation regime as dividends.

Tax On Stock Exchange Transactions

Upon the issue of the ordinary shares (primary market), no Tax on Stock Exchange Transactions ("*taks op de beursverrichtingen" / "taxe sur les opérations de bourse*") is due.

The purchase and the sale and any other acquisition or transfer for consideration of our ordinary shares (secondary market transactions) is subject to the Tax on Stock Exchange Transactions if (i) it is executed in Belgium through a professional intermediary, or (ii) deemed to be executed in Belgium, which is the case if the order is directly or indirectly made to a professional intermediary established outside of Belgium, either by private individuals with habitual residence in Belgium, or legal entities for the account of their seat or establishment in Belgium (both, a Belgian Investor).

The Tax on Stock Exchange Transactions is levied at a rate of 0.35% of the purchase price, capped at €1,600 per transaction and per party.

A separate tax is due by each party to the transaction, and both taxes are collected by the professional intermediary. However, if the intermediary is established outside of Belgium, the tax will in principle be due by the Belgian Investor, unless that Belgian Investor can demonstrate that the tax has already been paid. Professional intermediaries established outside of Belgium can, subject to certain conditions and formalities, appoint a Belgian Stock Exchange Tax Representative, which will be liable for the Tax on Stock Exchange Transactions in respect of the transactions executed through the professional intermediary. If the Stock Exchange Tax Representative would have paid the Tax on Stock Exchange Transactions due, the Belgian Investor will, as per the above, no longer be the debtor of the Tax on Stock Exchange Transactions.

No tax on stock exchange transactions is due on transactions entered into by the following parties, provided they are acting for their own account: (i) professional intermediaries described in Article 2, 9° and 10° of the Belgian Law of August 2, 2002; (ii) insurance companies described in Article 2, §1 of the Belgian Law of July 9, 1975; (iii) professional retirement institutions referred to in Article 2, 1° of the Belgian Law of October 27, 2006 concerning the supervision on institutions for occupational pension; (iv) collective investment institutions; (v) regulated real estate companies; and (vi) Belgian non-residents provided they deliver a certificate to their financial intermediary in Belgium confirming their non-resident status.

The EU Commission adopted on February 14, 2013 the Draft Directive on a Financial Transaction Tax, or FTT. The Draft Directive currently stipulates that once the FTT enters into force, the Participating Member States shall not maintain or introduce taxes on financial transactions other than the FTT (or VAT as provided in the Council Directive 2006/112/EC of November 28, 2006 on the common system of value added tax). For Belgium, the tax on stock exchange transactions should thus be abolished once the FTT enters into force. The Draft Directive regarding the FTT is still subject to negotiation between the Participating Member States and therefore may be changed at any time.

Tax on Securities Accounts

On 10 March 2018, the law on the introduction of a tax on securities accounts entered into force. Pursuant to this law, Belgian resident and non-resident individuals are taxed at a rate of 0.15 percent. on their share in the average value of qualifying financial instruments (such as our ordinary shares and other shares, bonds, certain other type of debt instruments, units of undertakings for collective investment, warrants) held on one or more securities accounts during a reference period of 12 consecutive months starting on 1 October and ending on 30 September of the subsequent year ("Tax on Securities Accounts").

No Tax on Securities Accounts is due provided the holder's share in the average value of the qualifying financial instruments on those accounts amounts to less than €500,000. If, however, the holder's share in the average value of the qualifying financial instruments on those accounts amounts to €500,000 or more, the Tax on Securities Accounts is due on the entire share of the holder in the average value of the qualifying financial instruments on those accounts (and hence, not only on the part which exceeds the €500,000 threshold).

Qualifying financial instruments held by non-resident individuals only fall within the scope of the Tax on Securities Accounts provided they are held on securities accounts with a financial intermediary established or located in Belgium. Note that pursuant to certain double tax treaties, Belgium has no right to tax capital. Hence, to the extent the Tax on Securities Accounts is viewed as a tax on capital within the meaning of these double tax treaties, incompatibility of the Tax on Securities Accounts with a treaty may, subject to certain conditions, be claimed.

The Tax on Securities Accounts is in principle due by the financial intermediary established or located in Belgium if (i) the holder's share in the average value of the qualifying financial instruments held on one or more securities accounts with said intermediary amounts to €500,000 or more; or (ii) the holder instructed the financial intermediary to levy the Tax on Securities Accounts due (e.g. in case such holder holds qualifying financial instruments on several securities accounts held with multiple intermediaries of which the average value does not amount to €500,000 or more but of which the holder's share in the total average value of these accounts exceeds €500,000). Otherwise, the Tax on Securities Accounts must be declared and is due by the holder itself, unless the holder provides evidence that the Tax on Securities Accounts has already been withheld, declared and paid by an intermediary which is not established or located in Belgium. In that respect, intermediaries located or established outside of Belgium could appoint a Tax on the Securities Accounts representative in Belgium, subject to certain conditions and formalities. Such a Tax on the Securities Accounts Representative is then liable towards the Belgian Treasury for the Tax on the Securities Accounts due and for complying with certain reporting obligations in that respect.

Prospective investors are advised to seek their own professional advice in relation to the Tax on Securities Accounts.

Dutch Tax Consequences Upon Completion of Our Possible Redomiciliation

The following summary outlines certain Dutch tax consequences in connection with the acquisition, ownership and disposal of our ordinary shares, if and when our possible redomiciliation is completed. All references in this summary to the Netherlands and Dutch law are to the European part of the Kingdom of the Netherlands and its law, respectively, only. The summary does not purport to present any comprehensive or complete picture of all Dutch tax aspects that could be of relevance to the acquisition, ownership and disposal of our ordinary shares by a (prospective) holder of our ordinary shares who may be subject to special tax treatment under applicable law. The summary is based on the tax laws and practice of the Netherlands as in effect on the date of this Registration Document, which are subject to changes that could prospectively or retrospectively affect the Dutch tax consequences.

For purposes of Dutch income and corporate income tax, shares legally owned by a third party such as a trustee, foundation or similar entity or arrangement, or a Third Party, may under certain circumstances have to be allocated to the (deemed) settlor, grantor or similar originator, or the Settlor, or, upon the death of the Settlor, his/her beneficiaries, or the Beneficiaries, in proportion to their entitlement to the estate of the Settlor of such trust or similar arrangement, or the Separated Private Assets.

The summary does not address the tax consequences of a holder of our ordinary shares who is an individual and who has a substantial interest (*aanmerkelijk belang*) in the company. Generally, a holder of our ordinary shares will have a substantial interest in the company if such holder of our ordinary shares, whether alone or together

with his spouse or partner and/or certain other close relatives, holds directly or indirectly, or as Settlor or Beneficiary of Separated Private Assets (i) (x) the ownership of, (y) certain other rights, such as usufruct, over, or (z) rights to acquire (whether or not already issued), shares representing 5% or more of the total issued and outstanding capital (or the issued and outstanding capital of any class of shares) of the company or (ii) (x) the ownership of, or (y) certain other rights, such as usufruct over, profit participating certificates (*winstbewijzen*) that relate to 5% or more of the annual profit of the company or to 5% or more of the liquidation proceeds of the company.

In addition, a holder of our ordinary shares has a substantial interest in the company if he, whether alone or together with his spouse or partner and/or certain other close relatives, has the ownership of, or other rights over, shares in, or profit certificates issued by, the company that represent less than 5% of the relevant aggregate that either (a) qualified as part of a substantial interest as set forth above and where shares, profit certificates and/or rights there over have been, or are deemed to have been, partially disposed of, or (b) have been acquired as part of a transaction that qualified for non recognition of gain treatment.

This summary does not address the tax consequences of a holder of our ordinary shares who:

a) receives income or realizes capital gains in connection with his or her employment activities or in his/her capacity as (former) board member and/or (former) supervisory board member; or

b) is a resident of any non European part of the Kingdom of the Netherlands.

PROSPECTIVE HOLDERS OF OUR ORDINARY SHARES SHOULD CONSULT THEIR OWN PROFESSIONAL ADVISER WITH RESPECT TO THE TAX CONSEQUENCES OF ANY ACQUISITION, OWNERSHIP OR DISPOSAL OF OUR ORDINARY SHARES IN THEIR INDIVIDUAL CIRCUMSTANCES.

Dividend Withholding Tax

General

From a Dutch domestic tax perspective, and subject to double tax treaty relief, dividends distributed by the Belgian argenx SE would continue to be subject to Dutch dividend withholding tax as before our possible redomiciliation, on the basis that we are a company incorporated under Dutch law. Pursuant to the Netherlands/Belgium double tax treaty, however, holders of our ordinary shares will not be subject to Dutch dividend withholding tax on dividends distributed by the company, unless such holder is resident or deemed to be resident in the Netherlands.

Accordingly, the company could be required to withhold dividend withholding tax imposed by the Netherlands at a rate of 15% on dividends distributed by the company in respect of our ordinary shares in the situation described below under "—Holders of Our Ordinary Shares Resident in the Netherlands". The expression "dividends distributed by the company" as used herein includes, but is not limited to:

a) distributions in cash or in kind, deemed and constructive distributions and repayments of paid in capital ("*gestort kapitaal*") not recognized for Dutch dividend withholding tax purposes;

b) liquidation proceeds, proceeds of redemption of our ordinary shares or, as a rule, consideration for the repurchase of our ordinary shares by the company in excess of the average paid in capital recognized for Dutch dividend withholding tax purposes;

c) the par value of our ordinary shares issued to a holder of our ordinary shares or an increase of the par value of our ordinary shares, to the extent that it does not appear that a contribution, recognized for Dutch dividend withholding tax purposes, has been made or will be made; and

d) partial repayment of paid in capital, recognized for Dutch dividend withholding tax purposes, if and to the extent that there are net profits (*zuivere winst*), unless (i) the shareholders at the General Meeting have resolved in advance to make such repayment and (ii) the par value of our ordinary shares concerned has been reduced by an equal amount by way of an amendment of the articles of association.

Holders of Our Ordinary Shares Resident in the Netherlands

Dividends paid by the company to holders of our ordinary shares that are resident or deemed to be resident in the Netherlands will be subject to Dutch dividend withholding tax.

A holder of our ordinary shares that is resident or deemed to be resident in the Netherlands is generally entitled, subject to the anti dividend stripping rules described below, to a full credit against its (corporate) income tax liability, or a full refund, of the Dutch dividend withholding tax. The same generally applies to holders of our ordinary shares that are neither resident nor deemed to be resident in the Netherlands if our ordinary shares are attributable to a permanent establishment in the Netherlands of such non resident holder.

Holders of Our Ordinary Shares Resident Outside the Netherlands

A holder of our ordinary shares, who is an individual or that is a legal entity, another entity with a capital divided into shares, an association, a foundation or a fund or trust, not resident or deemed to be resident in the Netherlands for (corporate) income tax purposes, will not be subject to any Dutch dividend withholding tax on distributions made on our ordinary shares.

Taxes on Income and Capital Gains

Holders of Our Ordinary Shares Resident in the Netherlands: Individuals

A holder of our ordinary shares, who is an individual resident or deemed to be resident in the Netherlands will be subject to regular Dutch income tax on the income derived from our ordinary shares and the gains realized upon the acquisition, redemption and/or disposal of our ordinary shares by the holder thereof, if:

a) such holder of our ordinary shares has an enterprise or an interest in an enterprise, to which enterprise our ordinary shares are attributable; and/or

b) such income or capital gain forms "a benefit from miscellaneous activities" ("re*sultaat uit overige werkzaamheden*") which, for instance, would be the case if the activities with respect to our ordinary shares exceed "normal active asset management" ("*normaal, actief vermogensbeheer*") or if income and gains are derived from the holding, whether directly or indirectly, of (a combination of) shares, debt claims or other rights (together, a "lucrative interest" (*lucratief belang*)) that the holder thereof has acquired under such circumstances that such income and gains are intended to be remuneration for work or services performed by such holder (or a related person), whether within or outside an employment relation, where such lucrative interest provides the holder thereof, economically speaking, with certain benefits that have a relation to the relevant work or services.

If either of the abovementioned conditions (a) or (b) applies, income derived from our ordinary shares and the gains realized upon the acquisition, redemption and/or disposal of our ordinary shares will in general be subject to Dutch income tax at the progressive rates up to 51.95%.

If the abovementioned conditions (a) and (b) do not apply, a holder of our ordinary shares who is an individual, resident or deemed to be resident in the Netherlands will not be subject to taxes on income and capital gains in the Netherlands. Instead, such individual is generally taxed at a flat rate of 30% on deemed income from "savings and investments" ("*sparen en beleggen*"), which deemed income is determined on the basis of the amount included in the individual's "yield basis" ("*rendementsgrondslag*") at the beginning of the calendar year (minus a tax free threshold). For the 2018 tax year, the deemed income derived from savings and investments will amount to 2.02% of the individual's yield basis up to €70,800, 4.33% of the individual's yield basis exceeding €70,800 up to and including €978,000 and 5.38% of the individual's yield basis in excess of €978,000. The tax-free threshold for 2018 is €30,000.

Holders of Our Ordinary Shares Resident in the Netherlands: Corporate Entities

A holder of our ordinary shares that is resident or deemed to be resident in the Netherlands for corporate income tax purposes, and that is:

- a corporation;
- another entity with a capital divided into shares;
- a cooperative (association); or
- another legal entity that has an enterprise or an interest in an enterprise to which our ordinary shares are attributable,

but which is not:

- a qualifying pension fund;
- a qualifying investment fund (*fiscale beleggingsinstelling*) or a qualifying exempt investment institution (*vrijgestelde beleggingsinstelling*); or
- another entity exempt from corporate income tax,

will in general be subject to regular corporate income tax, generally levied at a rate of 25% (20% over profits up to €200,000) over income derived from our ordinary shares and the gains realized upon the acquisition, redemption and/or disposal of our ordinary shares, unless, and to the extent that, the participation exemption (*deelnemingsvrijstelling*) applies.

Holders of Our Ordinary Shares Resident Outside the Netherlands: Individuals

A holder of our ordinary shares who is an individual, not resident or deemed to be resident in the Netherlands will not be subject to any Dutch taxes on income derived from our ordinary shares and the gains realized upon the acquisition, redemption and/or disposal of our ordinary shares (other than the dividend withholding tax described above), unless:

a) such holder has an enterprise or an interest in an enterprise that is, in whole or in part, carried on through a permanent establishment (*vaste inrichting*) or a permanent representative (*vaste vertegenwoordiger*) in the Netherlands and to which enterprise or part of an enterprise, as the case may be, our ordinary shares are attributable; or

b) such income or capital gain forms a "benefit from miscellaneous activities in the Netherlands" ("*resultaat uit overige werkzaamheden in Nederland*") which would for instance be the case if the activities in the Netherlands with respect to our ordinary shares exceed "normal active asset management" ("*normaal, actief vermogensbeheer*" or if such income and gains are derived from the holding, whether directly or indirectly, of (a combination of) shares, debt claims or other rights (together, a "lucrative interest" ("*lucratief belang*")) that the holder thereof has acquired under such circumstances that such income and gains are intended to be remuneration for work or services performed by such holder (or a related person), in whole or in part, in the Netherlands, whether within or outside an employment relation, where such lucrative interest provides the holder thereof, economically speaking, with certain benefits that have a relation to the relevant work or services.

If either of the abovementioned conditions (a) or (b) applies, income or capital gains in respect of dividends distributed by the company or in respect of any gains realized upon the acquisition, redemption and/or disposal of our ordinary shares will in general be subject to Dutch income tax at the progressive rates up to 51.95%.

Holders of Our Ordinary Shares Resident Outside the Netherlands: Legal and Other Entities

A holder of our ordinary shares, that is a legal entity, another entity with a capital divided into shares, an association, a foundation or a fund or trust, not resident or deemed to be resident in the Netherlands for corporate income tax purposes, will not be subject to any Dutch taxes on income derived from our ordinary shares and the gains realized upon the acquisition, redemption and/or disposal of our ordinary shares (other than the dividend withholding tax described above), unless:

a) such holder has an enterprise or an interest in an enterprise that is, in whole or in part, carried on through a permanent establishment (*vaste inrichting*) or a permanent representative (*vaste vertegenwoordiger*)

in the Netherlands and to which enterprise or part of an enterprise, as the case may be, our ordinary shares are attributable; or

b) such holder has a substantial interest (*aanmerkelijk belang*) in the company, that (i) is held with the avoidance of Dutch income tax of another person as (one of) the main purpose(s) and (ii) forms part of an artificial structure or series of structures (such as structures which are not put into place for valid business reasons reflecting economic reality).

If one of the abovementioned conditions applies, income derived from our ordinary shares and the gains realized upon the acquisition, redemption and/or disposal of our ordinary shares will, in general, be subject to Dutch regular corporate income tax, levied at a rate of 25% (20% over profits up to €200,000), unless, and to the extent that, with respect to a holder as described under (a), the participation exemption (*deelnemingsvrijstelling*) applies.

Gift, Estate and Inheritance Taxes

Holders of Our Ordinary Shares Resident in the Netherlands

Gift tax may be due in the Netherlands with respect to an acquisition of our ordinary shares by way of a gift by a holder of our ordinary shares who is resident or deemed to be resident of the Netherlands at the time of the gift.

Inheritance tax may be due in the Netherlands with respect to an acquisition or deemed acquisition of our ordinary shares by way of an inheritance or bequest on the death of a holder of our ordinary shares who is resident or deemed to be resident of the Netherlands, or by way of a gift within 180 days before his death by an individual who is resident or deemed to be resident in the Netherlands at the time of his death.

For purposes of Dutch gift and inheritance tax, an individual with the Dutch nationality will be deemed to be resident in the Netherlands if he has been resident in the Netherlands at any time during the ten years preceding the date of the gift or his death. For purposes of Dutch gift tax, an individual not holding the Dutch nationality will be deemed to be resident of the Netherlands if he has been resident in the Netherlands at any time during the twelve months preceding the date of the gift.

Holders of Our Ordinary Shares Resident Outside the Netherlands

No gift, estate or inheritance taxes will arise in the Netherlands with respect to an acquisition of our ordinary shares by way of a gift by, or on the death of, a holder of our ordinary shares who is neither resident nor deemed to be resident of the Netherlands, unless, in the case of a gift of our ordinary shares by an individual who at the date of the gift was neither resident nor deemed to be resident in the Netherlands, such individual dies within 180 days after the date of the gift, while being resident or deemed to be resident in the Netherlands.

Certain Special Situations

For purposes of Dutch gift, estate and inheritance tax, (i) a gift by a Third Party will be construed as a gift by the Settlor, and (ii) upon the death of the Settlor, as a rule his/her Beneficiaries will be deemed to have inherited directly from the Settlor. Subsequently, such Beneficiaries will be deemed the settlor, grantor or similar originator of the Separated Private Assets for purposes of Dutch gift, estate and inheritance tax in case of subsequent gifts or inheritances.

For the purposes of Dutch gift and inheritance tax, a gift that is made under a condition precedent is deemed to have been made at the moment such condition precedent is satisfied. If the condition precedent is fulfilled after the death of the donor, the gift is deemed to be made upon the death of the donor.

Value Added Tax

No Dutch value added tax will arise in respect of or in connection with the subscription, issue, placement, allotment or delivery of our ordinary shares.

Other Taxes and Duties

No Dutch registration tax, capital tax, custom duty, transfer tax, stamp duty or any other similar documentary tax or duty, other than court fees, will be payable in the Netherlands in respect of or in connection with the subscription, issue, placement, allotment or delivery of our ordinary shares.

Residency

A holder of our ordinary shares will not be treated as a resident, or a deemed resident, of the Netherlands by reason only of the acquisition, or the holding, of our ordinary shares or the performance by the company under our ordinary shares.

14 INDEPENDENT AUDITORS

The audited consolidated financial statements as of and for the financial years ended December 31, 2018 and 2017 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.

15 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 otherwise.

AbbVie	AbbVie S. Á. R. L.
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
ALCL	anaplastic large cell lymphoma
ALL	acute lymphocytic leukemia
AML	acute myeloid leukemia
Articles of Association	our current articles of association
auto-antibodies	self-directed antibodies
B-cell	B lymphocyte producing a specific antibody
BE	Belgium
Belgian Articles of Association	our articles of association to be adopted under Belgian law if we should complete our possible redomiciliation
Belgian Board	our board of directors in Belgium if we should complete our possible redomiciliation
Belgian BVBA	argenx BVBA
Belgian Corporate Governance Code	the Belgian Corporate Governance Code of March 12, 2009
Belgian GAAP	the generally accepted accounting principles in Belgium
Belgian Governance Charter	our corporate governance charter to be adopted under the Belgian Corporate Governance Code after we complete our possible redomiciliation
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 Biologics Price Competition and Innovation Act of 2009
BPCIA	the U.S. Biologics Price Competition and Innovation Act
Brexit	the United Kingdom's withdrawal from the European Union
CBA	a collective bargaining agreement
cGMP	current good manufacturing practices
CH	Switzerland
CHMP	Committee for Medicinal Products for Human Use
CMOs	contract manufacturing organizations
CMS	Centers for Medicare & Medicaid
Code of Conduct	our Code of Business Conduct and Ethics
COMP	the EMA's Committee for Orphan Medicinal Products
CRO	contract research organization
CTA	clinical trial authorization application
CTCL	cutaneous T-cell lymphoma
D	Germany
DASB	Dutch Accounting Standards Board
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
DTC	The Depository Trust Company
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
Enterprise Chamber	the Dutch Enterprise Chamber of the Amsterdam Court of Appeal (*Ondernemingskamer van het Gerechtshof te Amsterdam*)
ETASU	elements to assure safe use
Euronext Brussels	the regulated market operated by Euronext Brussels SA/NV, a regulated market within the meaning of Directive 2004/39/EC of the European Parliament and of the Council of April 21, 2004 on markets in financial instruments amending Council Directives 85/611/EEC and 93/6/EEC and Directive 2000/12/EC of the European Parliament and of the Council and repealing Council Directive 93/22/EEC (MiFID)
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
FDASIA	the U.S. Food and Drug Administration Safety and Innovation Act
FDCA	the U.S. Federal Food, Drug, and Cosmetic Act
FSMA	the Belgian Financial Services and Markets Authority
FTE	full time equivalent
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
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
IL-20	interleukin-20
IL-22	interleukin-22
IL-22R	interleukin-22 receptor
IMM	irreversible morbidity or mortality
IND	investigational new drug

IPAB	Independent Payment Advisory Board
IRB	institutional review board
ITP	immune thrombocytopenic purpura
IVIg	intravenous IgG
Janssen	Janssen Pharmaceuticals, Inc.
JOBS Act	the U.S. Jumpstart Our Business Startups Act of 2012
LEO Pharma	LEO Pharma A/S
Listing	the admission to listing and trading of all new ordinary shares on Euronext Brussels
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
MG	myasthenia gravis
mSWAT	modified SeverityWeighted Assessment Tool
Nasdaq	the Nasdaq Stock Market
NK	natural killer
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 amended by the General Meeting on April 28, 2016
PBMC	peripheral blood lymphocyte
PCT	Patent Cooperation Treaty
PFIC	a passive foreign investment company for U.S. federal income tax purposes
PHSA	the U.S. Public Health Service Act
PIL Code	the 2004 Belgian Code of Private International Law
PIP	pediatric investigation plan
Prospectus Directive	the Directive 2003/71/EC of the European Parliament and of the Council of November 4, 2003, as amended, including by Directive 2010/73/EU
PTCL	peripheral T-cell lymphoma
PwC	PricewaterhouseCoopers N.V.
Record Date	the fourteenth calendar day preceding the date of the General Meeting
redomiciliation	the possible transfer of our corporate seat located in Rotterdam, the Netherlands and our registered office located at Willemstraat 5, 4811 AH, Breda, the Netherlands, to Industriepark Zwijnaarde 7, Building C, 9052 Zwijnaarde (Gent), Belgium
Registration Document	this registration document
REMS	risk evaluation and mitigation strategy
Remuneration Policy	the amended remuneration policy as approved by the shareholders at the General Meeting on November 7, 2017
restructuring	our business restructuring, involving the conversion of argenx N.V. to argenx SE and the transfer of ownership of intellectual property rights to the Belgian BVBA
Roche	F. Hoffman-La Roche AG
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)
Sopartec	Sopartec S.A.
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 Directive 2010/73/EU
Transparency Law	the Belgian law of May 2, 2007 on the disclosure of significant shareholdings in issuers whose securities are admitted to trading on a regulated market and containing various provisions, implementing into Belgian law Directive 2004/109/CE
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 subsidiary, argenx BVBA, argenx US Inc and, as applicable, its former wholly owned subsidiaries

16 INFORMATION INCORPORATED BY REFERENCE

Our consolidated financial statements as of and for the financial years ended December 31, 2018 and 2017 (including the independent auditor's reports thereupon) have been incorporated by reference in this Registration Document. The information so incorporated by reference herein will form an integral part of this Registration Document, save that any statement contained in a document which is incorporated by reference herein, will be modified or superseded for the purpose of this Registration Document to the extent that a statement contained in this Registration Document modifies or supersedes such earlier statement (whether expressly, by implication or otherwise). Any statement so modified or superseded will not, except as so modified or superseded, constitute a part of this Registration Document.

The table below sets out the relevant pages of 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. 4
Consolidated statement of profit and loss and other comprehensive income:	p. 5
Consolidated statement of cash flows:	p. 6
Consolidated statement of changes in equity:	p. 7
Notes to the consolidated financial statements for the year 2018:	p. 8
Independent auditor's report on the consolidated financial statements:	p. 47

The table below sets out the relevant pages of our consolidated financial statements for the financial year ended December 31, 2017, which are incorporated by reference in this Registration Document:

Consolidated statement of financial position:	p. 4
Consolidated statement of profit and loss and other comprehensive income:	p. 5
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Consolidated statement of changes in equity:	p. 7
Notes to the consolidated financial statements for the year 2017:	p. 8
Independent auditor's report on the consolidated financial statements:	p. 66

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*).