## Summary of Risk Factors

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

- We have incurred significant losses since our inception and expect to incur losses for the foreseeable future. We may never achieve or maintain profitability.
- All but one of our products and product candidates are either in preclinical, early-stage clinical or clinical development or market approval has been requested for them, but has not (yet) been granted, and only VYVGART™ for the treatment of generalized myasthenia gravis (***gMG***) has obtained regulatory approval in the U.S. and in Japan. Our trials may fail and even if they succeed we may be unable to commercialize any or all of our products and product candidates due to a lack of, or delay in, regulatory approval or for other reasons.
- We will face significant challenges in successfully commercializing our products.
- Nearly all aspects of our activities are subject to substantial regulation. No assurance can be given that any of our product candidates will fulfill regulatory compliance. Failure to comply with such regulations could result in delays, suspension, refusals and withdrawal of approvals, as well as fines.
- We rely, and expect to continue to rely, on third parties, including independent clinical investigators and contract research organizations (***CROs***), to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our products and product candidates and our business could be substantially harmed.
- We rely on patents and other intellectual property rights to protect our products, product candidates and platform technologies. Failure to enforce or protect these rights adequately could harm our ability to compete and impair our business.
- Our future growth and ability to compete depends on retaining our key personnel and recruiting additional qualified personnel.

## PART I

### ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

### ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

### ITEM 3. KEY INFORMATION

#### A. SELECTED FINANCIAL DATA

[Reserved]

#### B. CAPITALIZATION AND INDEBTEDNESS

Not applicable.

#### C. REASONS FOR THE OFFER AND USE OF PROCEEDS

Not applicable.

#### D. RISK FACTORS

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

**Risk Factors Related to argenx's Financial Position and Need for Additional Capital**

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

We are a commercial-stage biopharmaceutical company with a limited operating history and we have only very recently commenced our transition from clinical-stage to a commercial-stage company. Only VYVGART™ (efgartigimod alfa fcab) for the treatment of gMG has obtained regulatory approval in the U.S. on December 17, 2021 and in Japan on January 20, 2022 and we do not currently have any approvals in any other jurisdictions or for any other product candidates. Since our inception, we have incurred significant operating losses, totaling USD 1,400.2 million of cumulative losses. Our losses resulted principally from costs incurred in research and development, preclinical testing, clinical development of our product and our product candidates as well as costs incurred for research programs, pre-commercial activities and from general and administrative costs associated with our operations. In addition, we expect to continue to incur significant costs associated with our listings in the U.S. and in Europe. In the future, we intend to continue to conduct research and development, preclinical testing, clinical trials and regulatory compliance activities as well as the commercialization of VYVGART™ for the treatment of gMG in the U.S. and in Japan and we intend to continue our efforts to establish and maintain a sales, marketing and distribution infrastructure. These expenses, together with anticipated general and administrative

expenses, will result in incurring further significant losses for at least the next several years. We anticipate that our expenses will increase substantially if and as we execute our strategic objectives and as we experience delays or encounter issues relating thereto, including failed studies, ambiguous trial results, safety issues or other regulatory challenges. If our losses become greater than expected, we may require additional financing than anticipated and such financing may not be available to us on acceptable terms or at all.

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

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

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

Notwithstanding our significant position of cash and cash equivalents of USD 1,334.7 million and current financial assets of USD 1,002.0 million as of December 31, 2021, as disclosed in our consolidated financial statements for the financial year ended December 31, 2021, we expect to require additional funding in the future to sufficiently finance our operations, to advance development of our products and product candidates and to continue our business activities relating to research and development and the commercialization of our products. Our future capital requirements for VYVGART™ and our current or any future product candidates will depend on many factors, including (i) the progress, timing and completion of preclinical testing and clinical trials for our current or any future product candidates, (ii) the number of potential new product candidates we identify and decide to develop, (iii) the time and costs involved in obtaining regulatory approval for our product candidates and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to any of our product candidates, (iv) selling and marketing activities undertaken in connection with the potential commercialization of our current products or product candidates or any future product candidates, if approved, and costs involved in the creation of an effective sales and marketing organization, (v) manufacturing activities undertaken ahead of the potential commercialization of our current products or product candidates or any future product candidates, if approved, and costs involved in the creation of an effective supply chain, (vi) the costs involved in growing our organization to the size needed to allow for the research, development and potential commercialization of our current products or product candidates or any future product candidates, (vii) the costs involved in filing patent applications and maintaining and enforcing patents or defending against claims or infringements raised by third parties, (viii) the maintenance of our existing collaboration agreements and entry into new collaboration agreements, (ix) the amount of revenues, if any, we may derive either directly or in the form of royalty payments from future sales of our current products or product candidates or any future product candidates, if approved, and (x) developments related to COVID-19 and its impact on the costs and timing associated with the conduct of our clinical trials, preclinical programs, manufacturing activities and other related activities.

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

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

Any failure by us to keep the cash burn under control by applying our funds effectively and managing our cash and investments appropriately could result in financial losses that could have a material adverse effect on our business.

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

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

As of December 31, 2021, we had cash and cash equivalents and current financial assets of USD 2,336.7 million. We historically have invested substantially all of our available cash and cash equivalents and current financial assets in either current accounts, savings accounts, term accounts or highly liquid money market funds, pending their use in our business. Any future investments may include term deposits, corporate bonds, commercial paper, certificate of deposit, government securities and money market funds in accordance with our cash management policy. These investments may be subject to general credit, liquidity, and market and interest rate risks. For example, we may realize losses in the fair value of these investments or a complete loss of these investments, which would have a negative effect on our financial condition. In addition, should our investments cease paying or reduce the amount of interest paid to us, our interest income would suffer. The market risks associated with our investment portfolio may have an adverse effect on our results of operations, liquidity and financial condition.

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

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

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

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

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

Clinical trials must be conducted in accordance with the EMA, FDA, PMDA and other applicable regulatory authorities' legal requirements and regulations and are subject to oversight by these governmental agencies and IRBs at the medical institutions where the clinical trials are conducted or ethics committees. In addition, clinical trials must be conducted with supplies of our products and product candidates produced under cGMP requirements and other regulations. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance. We depend on our collaborators and on medical

institutions and CROs to conduct our clinical trials in compliance with Good Clinical Practices (***GCP***) requirements. To the extent our collaborators or the CROs or investigators fail to enroll participants for our clinical trials, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays or both, which may harm our business. In addition, clinical trials that are conducted in countries outside the European Union and the U.S. may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non-European Union and non-U.S. CROs, as well as expose us to risks associated with clinical investigators who are unknown to the EMA, FDA, PMDA or other regulatory authorities, and apply different standards of diagnosis, screening and medical care.

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

Even if clinical trials do begin for these preclinical programs, our development efforts may not be successful, and clinical trials that we conduct or that third parties conduct on our behalf may not demonstrate sufficient safety, purity and potency or efficacy to obtain the requisite regulatory approvals for any of our products and product candidates or products and product candidates employing our technology. Many of our clinical trials are blinded, which may cause us to incur significant expenses without any visibility as to the likelihood of successful results. For instance, we expect to receive topline data for the Phase 3 ADVANCE trial of 10 mg/kg efgartigimod for the treatment of primary ITP in the second quarter of 2022. As such study results are blinded, we will not know whether such trial has been successful until we receive the data and cannot assure you that such data will contain positive results. Even if we obtain positive results from preclinical studies or initial clinical trials, we may not achieve the same success in future trials.

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

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

If we are unable to obtain regulatory approval of our products and product candidates on a timely basis or at all, our business will be materially impacted. For instance, we have incurred significant time and expense related to preparation for the build-out of our global commercial infrastructure and drug product inventory ahead of the launch of VYVGART™ for the treatment of gMG. An MAA for efgartigimod for the treatment of gMG is currently under review with the EMA with an anticipated decision in the second half of 2022 and we expect Zai Lab to be able to file for approval in Greater China by mid-2022 and Medison in Israel in the second quarter of 2022. If VYVGART™ is not approved in one or more jurisdictions other than the U.S. and Japan, or if such approvals are significantly delayed, it could have a material adverse effect on our business.

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

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

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

*Operational impacts of COVID-19*

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

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

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

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

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

*Economic impacts of COVID-19*

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

*Impacts of COVID-19 on employees or other stakeholders*

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

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

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

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

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

***Our products and product candidates may have serious adverse, undesirable or unacceptable side effects or even cause death, and we or others may identify undesirable or unacceptable side effects caused by VYVGART™ or any of our product candidates after they receive marketing approval.***

Undesirable side effects that may be caused by our product candidates or by the combination of our product candidates with other medical products could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the EMA, FDA, PMDA or other comparable regulatory authorities. While our preclinical and clinical studies for our product candidates to date show that our product candidates have generally been well tolerated from a risk-benefit perspective, we have observed adverse events and treatment emergent adverse events (***TEAEs***) in our clinical studies to date, and we may see additional adverse events and TEAEs in our ongoing and future trials, which may be more serious than those observed to date, and as a result, our ongoing and future trials may be negatively impacted. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, results of operation and financial condition significantly. Further, because all of our product candidates and preclinical programs, which have not yet received approval by at least one regulatory authority other than VYVGART™ for the treatment of gMG, are based on our SIMPLE Antibody™ platform, any adverse safety or efficacy findings related to any product candidate or preclinical program may adversely impact the viability of our other product candidates or preclinical programs.

Additionally, if we or others identify undesirable or unacceptable side effects caused by VYVGART™ or any of our other product candidates after they receive marketing approval, a number of potentially significant negative consequences could arise, including:

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

Any of these events could prevent us, our collaborators or our potential future partners from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our products. For example, we understand that another company developing a neonatal Fc receptor (***FcRn***) antagonist recently initiated a voluntary pause of its ongoing clinical trials after an observed signal of elevated total cholesterol and low-density lipoprotein (***LDL***) levels in one of its ongoing trials. We have evaluated VYVGART™ in over 600 subjects and patients and to date we have not seen evidence of evaluation in cholesterol markers related to treatment with VYVGART™. However, if we were to observe unexpected adverse events of whatever kind, our trials could be similarly paused and it could have a material adverse effect on our ability to further the advancement of our product candidates. Further, the FDA or the PMDA could require a change of label or even revoke the license, which could harm our reputation and have a material adverse effect on our ability to commercialize VYVGART™.

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

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

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

and products that are equally or more effective or are more economically attractive than any of our current or future technology or product. Competing products or technology platforms may gain faster or greater market acceptance than our products or technology platforms and medical advances or rapid technological development by competitors may result in our products and product candidates or technology platforms becoming non-competitive or obsolete before we are able to recover our research and development and commercialization expenses. If we, our products and product candidates or our technology platforms do not compete effectively, it is likely to have a material adverse effect on our business, financial condition and results of operation.

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

Identifying and qualifying patients to participate in our clinical trials is critical to our success. Patient enrollment depends on many factors, including the size and nature of the patient population, eligibility criteria for the trial, the proximity of patients to clinical sites, the design of the clinical protocol, the availability of competing clinical trials, the availability of new drugs approved for the indication the clinical trial is investigating, and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies. Since some of our product candidates are focused on addressing rare diseases and conditions, there are limited patient pools available to complete our clinical trials in a timely and cost-effective manner. For example, the number of patients suffering from each of MG, ITP, PV, PF, CIDP, T-cell lymphoma (***TCL***) and acute myeloid leukemia (***AML***) is small and has not been established with precision. If the actual number of patients with these disorders is smaller than we anticipate, we may encounter difficulties in enrolling patients in our clinical trials, thereby delaying or preventing development and approval of our drug candidates. Even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials. In addition, a limited number of patients enrolled in our clinical trials are located in Russia or Ukraine. The conflict between Russia and Ukraine, see "Global economic uncertainty and weakening product demand caused by political instability, changes in trade agreements and conflicts, such as the conflict between Russia and Ukraine, could adversely affect our business and financial performance." may prevent their continued participation in such trials and may prevent us from enrolling new patients from such countries which, in turn, may cause delays in certain ongoing clinical trials. For example, a relevant minority of the patients in the ADDRESS trial of SC efgartigimod for PF and PV are participating in studies conducted in Ukraine or Russia. Accordingly, we expect that the conflict between Russia and Ukraine will delay our ADDRESS trials, with the timing of topline data for the ADDRESS trial of SC efgartigimod for PF and PV currently under review.

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

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

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

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

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. Currently, we have only VYVGART™ has been approved in the U.S. and in Japan for commercial sale for the treatment of gMG; however, the current and future use of product candidates by us and our collaborators in clinical trials, and the sale of any approved products, may expose us to liability claims. These claims might be made by patients who use the product, healthcare providers, pharmaceutical companies, our collaborators or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially adversely affect the market for our products and product candidates or any prospects for commercialization of our products and product candidates. Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products due to negative public perception;
- damage to our reputation;
- withdrawal of clinical trial participants or difficulties in recruiting new trial participants;
- initiation of investigations by regulators;
- costs to defend or settle the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to trial participants or patients;

- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenues from product sales; and
- the inability to commercialize any of our product candidates, if approved.

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

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

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

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

We are in the process of continuing to setup our sales and marketing infrastructure, have limited experience in the sale or marketing of pharmaceutical products and may not or not timely have the appropriate infrastructure in place (including, such as information technology, enterprise resource planning and forecasting). To achieve commercial success for any approved product, we must develop or acquire a sales and marketing organization, outsource these functions to third parties or enter into collaboration arrangements with third parties. While we have established our own sales force in the U.S. and in Japan for VYVGART™ for the treatment of gMG, we plan to expand our own sales and marketing capabilities and promote our products and product candidates if and when regulatory approval has been obtained in the relevant jurisdictions and/or for other product candidates or other indications. There are risks involved should we decide to expand our own sales and marketing capabilities or enter into arrangements with third parties to perform these services. Even if we have established or expanded our own sales and marketing capabilities, we may fail to launch our products effectively or to market our products effectively. Recruiting and training a sales force is expensive and costs of creating an independent sales and marketing organization and of marketing and promotion could be above those anticipated by us. In addition, recruiting and training a sales force is time consuming and could delay any product launch. In the event that any such launch is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

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

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

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

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

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

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

***Our products and product candidates for which we have obtained or intend to seek approval as biological products may face competition sooner than anticipated.***

The Biologics Price Competition and Innovation Act (***BPCIA***) created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until twelve years from the date on which the reference product was first licensed. During this twelve-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing

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

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

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

In the U.S., the European Union and other foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. If such legislative and/or regulatory initiatives and changes would lead to increased restrictions on marketing our products, or lead to limiting the funds available for healthcare in jurisdictions relevant to us which may reduce reimbursement levels and is likely to affect the prices we may set, we would be negatively impacted in our ability to successfully and profitably market our products and product candidates. See section titled "*Information on Company, Business Section, Coverage, Pricing, and Reimbursement*."

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. If we or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or our collaborators are not able to maintain regulatory compliance, our products and product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business. See section titled "*Information on Company – Business Section – Coverage, Pricing, and Reimbursement*."

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

Our ability to successfully commercialize VYVGART™ or any other products and product candidate approved for commercialization will depend, in part, on the extent to which third-party payors, including government health programs in the United States (such as Medicare and Medicaid) and other countries, commercial health insurers, and managed care organizations, provide coverage and establish adequate reimbursement levels for such products and product candidates. Moreover, increasing efforts by governmental and third-party payors in the European Union, the U.S., China and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for VYVGART™ or any other of our products and product candidates approved for commercialization. Limitations on reimbursement and reimbursement levels may diminish or prevent altogether any significant demand for VYVGART™ or our other product candidates once approved and/or may prevent us entirely from entering certain markets, which would prevent us from generating significant revenues or becoming profitable, which would adversely affect our business, financials and results of operations.

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

Our current and future operations may be directly, or indirectly through our customers and third-party payors, subject to various U.S. federal and state, European, Japanese and Chinese healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute. Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. These laws may impact, among other things, our proposed sales, marketing and education programs and constrain our business and financial arrangements and relationships with third-party payors, healthcare professionals who participate in our clinical research program, healthcare professionals and others who recommend, purchase, or provide our approved products, and other parties through which we market, sell and distribute our products for which we obtain marketing approval. In addition, we may be subject to patient data privacy and security regulation by both the U.S. federal government and the other states and countries in which we conduct our business. Finally, our current and future operations are subject to additional healthcare-related statutory and regulatory requirements and enforcement by regulatory authorities in jurisdictions in which we conduct our business. For example, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is generally not permitted in the countries that form part of the European Union. Some EU member states have enacted laws explicitly prohibiting the provision of these types of benefits and advantages to induce or reward improper performance generally, and the United Kingdom has enacted such laws through the Bribery Act 2010. Infringements of these laws can result in substantial fines and imprisonment. EU Directive 2001/83/EC, which is the EU directive governing medicinal products for human use, further provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision has been transposed into the Human Medicines Regulations 2012 and remains applicable in the United Kingdom. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. See section titled "*Information on Company – Business Section – Healthcare Law and Regulation*."

The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements. We have limited experience in the sale or marketing of pharmaceutical products and we are building and, in light of any future approval and commercialization, will need to continue building an internal program to ensure compliance with the different health care laws and regulations. The establishment, expansion and maintenance of an internal compliance program will involve substantial costs and the program may not be successful in complying with the different reporting requirements.

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

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time and resource consuming and can divert a company's attention from the business. See section titled "*Information on Company – Business Section – Healthcare Reform.*

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

In addition, in the United States, the European Union and other foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs, including the cost of prescription drugs, and improve the quality of healthcare. If such legislative and/or regulatory initiatives and changes would lead to increased restrictions on the marketing of VYVGART™ or any of our products and product candidates approved for commercialization, or lead to limiting the funds available for healthcare in jurisdictions relevant to us which may reduce reimbursement levels and is likely to affect the prices we may set, we would be negatively impacted in our ability to successfully and profitably market VYVGART™ or any of our products and product candidates approved for commercialization.

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

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

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

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

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

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

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

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

We may from time to time seek orphan drug designation in the U.S. or Europe for certain indications addressed by our products and product candidates. For example, in September 2017, the FDA granted orphan drug designation for the use of VYVGART™ for gMG, in January 2019, the FDA granted orphan drug designation for the use of efgartigimod for the treatment of ITP and for the use of cusatuzumab for the treatment of AML and in August 2021, the FDA granted orphan drug designation for the use of efgartigimod co-formulated with rHuPH20 for the treatment of CIDP. Even if we are able to obtain orphan designation, we may not be the first to obtain marketing approval for such indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the U.S. may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for

a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan drug is approved, the FDA or the EMA can subsequently approve the same drug with the same active moiety for the same condition if the FDA or the EMA concludes that the later drug is safer, more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

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

Even when and if our products and product candidates are approved for marketing, sales of such products and product candidates will depend, in part, on the extent to which third-party payors, including government health programs in the U.S. (such as Medicare and Medicaid) and other countries, commercial health insurers, and managed care organizations, provide coverage and establish adequate reimbursement levels for such products and product candidates. Moreover, increasing efforts by governmental and third-party payors in the European Union, the U.S., China and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our products and product candidates. For instance, access to VYVGART™ for the treatment of gMG may be restricted by limited payer coverage due to treatment criteria, which may prevent us from realizing its full commercial potential.

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

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

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

We will be required to spend substantial time and money to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations. Recent healthcare reform legislation has strengthened these federal and state healthcare laws. Violations of these laws can subject us to criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment and exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm, and the required curtailment or restructuring of our operations. Moreover, we expect that there will continue to be federal and state laws and regulations, proposed and implemented, that could impact our business, financial condition and results of operations.

**Risk Factors Related to argenx's Business and Industry**

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

The international biopharmaceutical and medical technology industries are subject to a high level of regulation by the FDA, the EMA, the PMDA and other comparable regulatory authorities and by other national or supra-national regulatory authorities. Applicable regulations impose substantial requirements covering nearly all

aspects of our activities and the activities of our partners and licensees, notably on research and development, manufacturing, preclinical tests, clinical trials, labeling, marketing, sales, storage, record keeping, promotion and pricing of our products and product candidates.

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

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

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

The FDA, EMA, PMDA and other comparable regulatory authorities have substantial discretion in the approval process and determining when or whether regulatory approval will be obtained for any of our product candidates. Any of the FDA, EMA, PMDA and other comparable regulatory authorities may disagree with our interpretation of data submitted for their review. Even if we believe the data collected from clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA, EMA, PMDA or any other regulatory authority. For instance, we have submitted a request for approval of VYVGART™ in gMG to the EMA and anticipate receipt of such approval in the first quarter of 2022 and the second half of 2022, respectively, but can provide no assurances that such approval will be obtained on the timeline that we expect or at all. In addition, we anticipate to file requests for approval of VYVGART™ in new indications, but can provide no assurances that such requests will be accepted or that approval will be obtained on the timeline that we expect or at all. Furthermore, the FDA has resumed inspections of certain domestic clinical trial operations and trial sites. We cannot be sure to be ready for such an inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities in view of the substantial time and attention devoted by our personnel to the commercial launch of VYVGART™ for the treatment of gMG.

We and our collaborative partners are, or may become subject to, numerous ongoing other regulatory obligations, such as data protection, environmental, health and safety laws and restrictions on the experimental use

of animals. The costs of compliance with such applicable regulations, requirements or guidelines could be substantial, and failure to comply could result in sanctions, including fines, injunctions, civil penalties, denial of applications for marketing authorization of our products, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly increase our or our collaborative partners' costs or delay the development and commercialization of our product candidates.

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

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

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

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

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

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

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, consultants, vendors and collaboration partners may engage in fraudulent conduct or other illegal activities. Misconduct by these parties could include intentional, reckless and negligent conduct, data manipulation (scientific fraud) or unauthorized activities that violate: (i) the regulations of the FDA, EMA, PMDA and other comparable regulatory authorities, including those laws that require the reporting of true, complete and accurate information to such authorities; (ii) manufacturing standards; (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the U.S. and in other countries; or (iv) laws that require the reporting of true, complete and accurate financial information and data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit

a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, results of operations and financial condition, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other U.S. or international healthcare programs, individual imprisonment, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, other sanctions, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. These risks may be particularly heightened given our lack of experience with commercialization and the rapid growth of our sales and marketing function. Furthermore, due to the highly regulated environment in which we operate and our heavy reliance on approval of our products by governmental entities and healthcare providers, reputational risks related to the misconduct or other improper behavior as described above are likely to have a bigger impact on us than on most companies operating in other industries.

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

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

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

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

Despite the implementation of security measures, our internal computer systems and those of our third-party service providers are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failure. Cyber-attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyber-attacks have been threatened by state actors and private citizens as a method of potential international sabotage in furtherance of national or political goals. Cyber-attacks could include the deployment of harmful malware, ransom-ware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. Cyber-attacks also could include phishing attempts or e-mail fraud to cause payments or information to be transmitted to an unintended recipient.

Any system failure, accident or security breach that causes interruptions in our own or in third-party service vendors' operations could result in a material disruption of our product development programs. For

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

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

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

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

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

Also, certain raw materials or other products necessary for the manufacture and formulation of our products and product candidates, some of which are difficult to source, are provided by single-source unaffiliated third-party suppliers. In addition, we rely on certain third parties to perform filling, finishing, distribution, laboratory testing and other services related to the manufacture of our products and product candidates, and to supply various raw materials and other products. We would be unable to obtain these raw materials, other products, or services for an indeterminate period of time if any of these third parties were to cease or interrupt production or otherwise fail to supply these materials, products, or services to us for any reason, including due to regulatory

requirements or actions (including recalls), adverse financial developments at or affecting the supplier, failure by the supplier to comply with cGMPs, contamination, business interruptions, or labor shortages or disputes. Interruptions in the supply of these materials, products or services may result from international conflict, trade disputes or economic sanctions enacted by, or imposed on, the U.S., the European Union or any other country. In any such circumstances, we may not be able to engage a backup or alternative supplier or service provider in a timely manner or at all. This, in turn, could materially and adversely affect our ability to supply products and product candidates, which could materially and adversely affect our business, financial condition and results of operations.

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

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

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

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

**Risk Factors Related to argenx's Dependence on Third Parties**

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

We have relied upon and plan to continue to rely upon third parties, including licensees, independent clinical investigators and third-party CROs, to conduct our preclinical studies and clinical trials and to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on these third parties does not relieve

us of our regulatory responsibilities. We and our partners, third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, EMA, PMDA and comparable regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we, our investigators or any of our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA, PMDA or comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Upon inspection by a given regulatory authority, such regulatory authority may determine that our clinical trials do not fully comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

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

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

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

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

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

We are, and expect to continue to be, dependent on partnerships with partners relating to the development and commercialization of our existing and future research programs and product candidates. We currently have collaborative research relationships with various pharmaceutical companies such as AbbVie S.Á.R.L. (***AbbVie***), Shire AG (***Shire***, now knows as Shire International GmbH), Zai Lab Limited (***Zai Lab***) and with various academic and research institutions worldwide, for the development of product candidates resulting from such collaborations. We had, have and will continue to have discussions on potential partnering opportunities with various pharmaceutical companies. If we fail to enter into or maintain collaborations on reasonable terms or at all, our ability to develop our existing or future research programs and product candidates could be delayed, the

commercial potential of our products could change and our costs of development and commercialization could increase.

Our dependence on collaborative partners subjects us to a number of risks, including, but not limited to the termination of the collaboration agreements with all its consequences, disagreement on the interpretation of contractual terms or no adherence or uncertainties as part of the ongoing collaboration. In addition, we may not be able to control our collaborative partners' compliance with all applicable requirements for the commercialization of our products, which could adversely affect such commercializing and the profitability of such products.

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

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

We do not currently have, nor do we plan to acquire, the infrastructure or capability internally to manufacture our products or product candidates for use in the conduct of our clinical studies or for commercial supply, when and if our products are approved. Instead, we rely on, and expect to continue to rely on contract manufacturing organizations (*CMOs*). We are forced to rely on limited and single sources of manufacturing. We currently rely mainly on Lonza for the manufacturing of the drug substance of all our products. Furthermore, we use Vetter Pharma International GmbH's fill and finish services for our products. Reliance on third-party providers may expose us to more risk than if we were to manufacture our products and product candidates ourselves. We do not control the manufacturing processes of the CMOs we contract with and are dependent on those third parties for the production of our products and product candidates in accordance with relevant regulations (such as cGMP), which includes, among other things, quality control, quality assurance and the maintenance of records and documentation.

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

We and our third-party suppliers may also be subject to audits by the FDA, EMA, PMDA or other comparable regulatory authorities. If any of our third-party suppliers fails to comply with cGMP or other applicable manufacturing regulations, our ability to develop and commercialize the products could suffer significant interruptions. We face risks inherent in relying on a single CMO, as any disruption, such as a fire, pandemic, natural hazards or vandalism at the CMO could significantly interrupt our manufacturing capability. Alternative production plans in place or disaster-recovery facilities available to us may not be sufficient. In case of a

disruption, we may have to establish additional alternative manufacturing sources. This would require substantial investment on our part, which we may not be able to obtain on commercially acceptable terms or at all. Additionally, we may experience significant manufacturing delays as we build or locate replacement facilities and seek and obtain necessary regulatory approvals. If this occurs, we will be unable to satisfy manufacturing needs on a timely basis, if at all. Also, operating any new facilities may be more expensive than operating our current facilities. Further, business interruption insurance may not adequately compensate us for any losses that may occur, and we would have to bear the additional cost of any disruption. For these reasons, a significant disruptive event of the manufacturing facility could have drastic consequences, including placing our financial stability at risk.

The manufacturing of all of our products and product candidates requires using cells which are stored in a cell bank. We have one master cell bank for each product manufactured in accordance with cGMP. Half of each master cell bank is stored at a separate site so that in case of a catastrophic event at one site we believe sufficient vials of the master cell banks are left at the alternative storage site to continue manufacturing. We believe sufficient working cell banks could be produced from the vials of the master cell bank stored at a given site to assure product supply for the future. However, it is possible that we could lose multiple cell banks and have our manufacturing significantly impacted by the need to replace these cell banks, which could materially adversely affect our business, prospects, financial condition and results of operations.

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

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

**Risk Factors Related to argenx’s Intellectual Property**

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

Our commercial success depends in part on obtaining and maintaining patents and other forms of intellectual property rights for our products and product candidates, methods used to manufacture those products and the methods for treating patients using those products, or on licensing in such rights. Specifically, we are materially dependent on patent and other proprietary protection related to our core platform technologies and our products and product candidates. Failure to protect or to obtain, maintain or extend adequate patent and other intellectual property rights could materially adversely affect our ability to develop and market our products and product candidates. The enforcement, defense and maintenance of such patents and other intellectual property rights may be challenging and costly.

We cannot be certain that patents will be issued or granted with respect to applications that are currently pending. As a biopharmaceutical company our patent position is uncertain because it involves complex legal and factual considerations. The standards applied by the European Patent Office, the U.S. Patent and Trademark Office (***USPTO***) and foreign patent offices in granting patents are not always applied uniformly or predictably. For

example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biopharmaceutical patents. Consequently, patents may not issue from our pending patent applications. As such, we do not know the degree of future protection that we will have on our proprietary products and technology. The scope of patent protection that the European Patent Office and the USPTO will grant with respect to the antibodies in our antibodies product pipeline is uncertain. It is possible that the European Patent Office and the USPTO will not allow broad antibody claims that cover antibodies closely related to our products and product candidates as well as the specific antibody. As a result, upon receipt of EMA or FDA approval, competitors may be free to market antibodies almost identical to ours, including biosimilar antibodies, thereby decreasing our market potential. However, a competitor cannot submit to the FDA an application for a biosimilar product based on one of our products until four years following the date of approval of our “reference product,” and the FDA may not approve such a biosimilar product until twelve years from the date on which the reference product was approved.

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

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

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

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

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

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

Our competitive position may suffer if patents issued to third parties or other third-party intellectual property rights cover our products or elements thereof, our manufacture or uses relevant to our development plans, the targets of our products and product candidates, or other attributes of our products and product candidates or our technology. In such cases, we may not be in a position to develop or commercialize products or product candidates unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned, or enter into a license agreement with the intellectual property right holder, if available on commercially reasonable terms. We are aware of certain U.S. issued patents held by third parties that some may argue cover certain aspects of our product candidates, including cusatuzumab. One such third party patent family of potential relevance to cusatuzumab is scheduled to expire in 2028. In the event that a patent has not expired at the time of approval of such product candidate and the patent owner were to bring an infringement action against us, we may have to argue that our product, its manufacture or use does not infringe a valid claim of the patent in question. Alternatively, if we were to challenge the validity of any issued U.S. patent in court, we would need to overcome a statutory presumption of validity that attaches to every U.S. patent. This means that in order to prevail, we would need to present clear and convincing evidence as to the invalidity of the patent's claims. There is no assurance that a court would find in our favor on questions of infringement or validity. In the event that a patent is successfully asserted against us such that the patent is found to be valid and enforceable and infringed by our product, unless we obtain a

license to such a patent, which may not be available on commercially reasonable terms or at all, we could be prevented from continuing to develop or commercialize our product. Similarly, the targets for certain of our products and product candidates have also been the subject of research by other companies, which have filed patent applications or have patents on aspects of the targets or their uses. There can be no assurance any such patents will not be asserted against us or that we will not need to seek licenses from such third parties. We may not be able to secure such licenses on acceptable terms, if at all, and any such litigation would be costly and time-consuming.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

while granted by others. It is also quite common that depending on the country, the scope of patent protection may vary for the same products or product candidate or technology.

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

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

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

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

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

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

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

defendant in a district court action. The AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

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

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

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

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

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

In addition to patent protection, we also rely on trade secret protection for our proprietary information that is not amenable to, or that we do not consider appropriate for, patent protection, including, for example, certain aspects of our llama immunization and antibody affinity maturation approaches. However, trade secrets are difficult to protect, and we have limited control over the protection of trade secrets used by our licensors, collaborators and suppliers.

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

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

**Risk Factors Related to argenx's Organization and Operations**

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

Our success depends upon the continued contributions of our key management, scientific and technical personnel, many of whom have been instrumental for us and have substantial experience with our therapies and related technologies. These key management individuals include the members of our Board of Directors and senior management.

The loss of key managers and senior scientists could delay our research and development activities. In addition, our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified management, scientific and medical personnel. Many other biotechnology and pharmaceutical companies and academic institutions that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. Therefore, we might not be able to attract or retain these key persons on conditions that are economically acceptable.

Furthermore, we will need to recruit new managers and qualified scientific, commercial, regulatory and financial personnel to develop our business if we expand into fields that will require additional skills. Our inability to attract and retain these key persons could prevent us from achieving our objectives and implementing our business strategy, which could have a material adverse effect on our business and prospects.

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

We have grown significantly in number of employees and scope of operations over the recent years and expect to experience significant growth in the number of our employees and the scope of our operations also in the near future, particularly in the areas of drug research, drug development, regulatory affairs and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. For example, we are currently outsourcing certain development areas which we cannot cover ourselves due to limited personnel capacities, for example to Zai Lab in relation to proof-of-concept trials in two kidney indications, LN and MN or to IQVIA in relation to proof-of-concept trials in primary SjS and COVID-19-mediated POTS. As a result of our limited financial, manufacturing and management recourses, we may forgo or delay pursuit of opportunities with potential product candidates that later prove to have greater market potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Further, we may relinquish rights to such product candidates through collaborations, licensing or royalty arrangements in circumstances where it would have been more advantageous for us to retain sole development and commercialization rights.

The expansion of our operations may lead to significant costs and may divert our management and business development resources and may dilute our corporate culture, which in turn may make it more difficult to attract and retain employees. Any inability to manage growth could delay the execution of our strategic objectives or disrupt our operations, which in turn could materially harm our business and prospects.

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

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

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

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

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

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

***We have obtained significant funding from agencies of the government of the Flemish region of Belgium and have benefited from certain research and development incentives, which may be re-evaluated if our shareholder base changes significantly. The tax authorities may challenge our eligibility for or our calculation of such incentives.***

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

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

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

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

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

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

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

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

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

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

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

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

In addition, we may not be able to use, or changes in tax regulations may affect the use of, certain unrecognized tax assets or credits that we have built over the years. For instance, as of December 31, 2021, we had $815.3 million of consolidated tax loss carry forwards. In general, some of these tax losses carry forwards may be forfeited in whole, or in part, as a result of various transactions, or their utilization may be restricted by statutory law in the relevant jurisdiction. Any corporate reorganization by us or any transaction relating to our shareholding structure may result in partial or complete forfeiture of tax loss carry forwards. For instance, under Belgian law, argenx BV may lose its tax loss carry forwards and other tax incentives in case of a change of control, through an acquisition or otherwise, not meeting legitimate financial or economic needs as well as in case of a tax neutral reorganization, such as a merger or a demerger, involving argenx BV. The tax burden would increase if profits, if any, could not be offset against tax loss carry forwards.

**Risks Related to the ADSs**

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

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

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

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

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

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

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

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

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

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

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

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

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

result of fluctuations in the exchange rate between the USD and the euro, the USD equivalent of the proceeds that a holder of the ADSs would receive upon the sale on Euronext Brussels of any ordinary shares withdrawn from the depositary and the USD equivalent of any cash dividends paid in euros on our shares represented by the ADSs could also decline.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 (Section 404), we are required to furnish a report by our board of directors on our internal control over financial reporting. We are also required to include an attestation report on internal control over financial reporting issued by our independent registered public

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

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

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

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

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

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

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

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

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

As a Dutch European public company with limited liability (*Societas Europaea* or *SE*), we are subject to the Dutch Corporate Governance Code (the ***DCGC***). The DCGC contains both principles and best practice provisions for board of directors, management boards, supervisory boards, shareholders and general meetings of shareholders, financial reporting, auditors, disclosure, compliance and enforcement standards. The DCGC applies to all Dutch companies listed on a regulated market, including Euronext Brussels. The principles and best practice provisions apply to our board of directors (in relation to role and composition, conflicts of interest and independency requirements, board committees and remuneration), shareholders and the General Meeting (for example, regarding anti-takeover protection and our obligations to provide information to our shareholders) and financial reporting (such as external auditor and internal audit requirements). We do not comply with all the best practice provisions of the DCGC. As a Dutch company, we are required to disclose in our Annual Report, filed in the Netherlands, whether we comply with the provisions of the DCGC. If we do not comply with the provisions of the DCGC (for example, because of a conflicting Nasdaq requirement or otherwise), we must list the reasons for any deviation from the DCGC in our Annual Report. See “Item 16.G.—Corporate Governance.”

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

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

The United States currently does not have a treaty with either the Netherlands or Belgium providing for the reciprocal recognition and enforcement of judgments, other than arbitration awards, in civil and commercial matters. Consequently, a final judgment for payment given by a court in the United States, whether or not predicated solely upon U.S. securities laws, would not automatically be recognized or enforceable in the Netherlands or be enforceable in Belgium. This will depend on the applicable Dutch or Belgian national rules.

In order to obtain a judgment which is enforceable in the Netherlands, the party in whose favor a final and conclusive judgment of the U.S. court has been rendered will be required to file its claim with a court of competent jurisdiction in the Netherlands. Such party may submit to the Dutch court the final judgment rendered by the U.S. court. If and to the extent that the Dutch court finds that the jurisdiction of the U.S. court has been based on grounds which are internationally acceptable and that proper legal procedures have been observed, the court of the Netherlands will, in principle, give binding effect to the judgment of the U.S. court, unless such judgment contravenes principles of public policy of the Netherlands. Dutch courts may deny the recognition and enforcement of punitive damages or other awards. Moreover, a Dutch court may reduce the amount of damages granted by a U.S. court and recognize damages only to the extent that they are necessary to compensate actual losses or damages. Enforcement and recognition of judgments of U.S. courts in the Netherlands are solely governed by the provisions of the Dutch Code of Civil Procedure (*Wetboek van Burgerlijke Rechtsvordering*).

In order to obtain the enforceability in Belgium of a U.S. final and conclusive judgment, a declaration of enforceability by a Belgian judge will have to be obtained via a specific court procedure. A U.S. judgment will not be declared enforceable in Belgium if it infringes upon one or more of the grounds for refusal listed in the 2004 Belgian Code of Private International Law (the ***PIL Code***). Based on the same grounds for refusal, the recognition and enforcement of a U.S. judgment may be challenged before the Belgian judge. Notably, enforcement and recognition need to be refused if (a) due process has not been observed, (b) the Belgian courts have exclusive jurisdiction to determine the matter or (c) the effect of recognizing this judgment or declaring it enforceable would be manifestly incompatible with Belgium's (international) public policy principles. Punitive damages awards for example may be denied recognition and enforcement under the latter refusal ground. In the review of the request for enforcement or the challenge of the recognition of a U.S. judgment, the Belgian judge will not, however, review

the merits of the case, nor does any reciprocity requirement apply. Enforcement and recognition of judgments of U.S. courts in Belgium are solely governed by the provisions of the PIL Code.

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

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

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

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

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

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

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

We qualify as a foreign private issuer. As a result, in accordance with the listing requirements of Nasdaq, we rely on home country governance requirements and certain exemptions thereunder rather than relying on the corporate governance requirements of Nasdaq. In accordance with Dutch law and generally accepted business practices, our Articles of Association do not provide quorum requirements generally applicable to General Meetings. To this extent, our practice varies from the requirement of Nasdaq Listing Rule 5620(c), which requires an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting stock. Although we must provide shareholders with an agenda and other relevant documents for the General Meeting, Dutch law does not have a regulatory regime for the solicitation of proxies and the solicitation of proxies is not a generally accepted business practice in the Netherlands, thus our practice will vary from the requirement of Nasdaq Listing Rule 5620(b). In addition, we have opted out of certain

Dutch shareholder approval requirements for the issuance of securities in connection with certain events such as the acquisition of stock or assets of another company, the establishment of or amendments to equity-based compensation plans for employees, a change of control of us and certain private placements. To this extent, our practice varies from the requirements of Nasdaq Rule 5635, which generally requires an issuer to obtain shareholder approval for the issuance of securities in connection with such events. For an overview of our corporate governance principles, see "Item 16G.—Corporate Governance." Accordingly, you may not have the same protections afforded to shareholders of companies that are subject to these Nasdaq requirements.

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

We are a foreign private issuer, and therefore we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers. We may no longer be a foreign private issuer as of June 30, 2022 (the end of our second fiscal quarter), which would require us to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers as of January 1, 2023 and would also trigger a 10-K filing for the year ended December 31, 2022. In order to maintain our current status as a foreign private issuer, either (a) a majority of our ordinary shares must be either directly or indirectly owned of record by non-residents of the United States or (b)(i) a majority of our executive officers or directors may not be U.S. citizens or residents, (ii) more than 50% of our assets cannot be located in the United States and (iii) our business must be administered principally outside the United States. As of March 16, 2022, we believe at least 50% of our outstanding ordinary shares were held by U.S. residents (assuming that all our ordinary shares represented by ADSs were held by residents of the United States). If we lose this status, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC and Nasdaq rules. The regulatory and compliance costs to us under U.S. securities laws if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be significantly higher than the cost we would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities highly time consuming and costly. We also expect that if we were required to comply with the rules and regulations applicable to U.S. domestic issuers, it would make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our board of directors.

***If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of the ADSs.***

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

Our management is required to assess the effectiveness of our internal controls and procedures annually and is required to issue an Annual Report on internal control over financial reporting, and our independent registered public accounting firm is required to undertake an assessment of our internal control over financial reporting, which could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the

expense of remediation. The rules governing the standards that must be met for our management to assess our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act are complex and require significant documentation, testing and possible remediation. These stringent standards require that our audit and compliance committee be advised and regularly updated on management's review of internal control over financial reporting in connection with issuing our consolidated financial statements as of and for the year ended December 31, 2021.

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

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

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

***We believe that we were not classified as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes for the 2021 taxable year, and do not anticipate being classified as a PFIC for U.S. federal income tax purposes for the 2022 taxable year, but this conclusion is a factual determination that is made annually and thus is subject to change. If we were to be classified as a PFIC, this could result in adverse U.S. tax consequences to certain U.S. holders.***

Generally, if, for any taxable year, at least 75% of our gross income is passive income, or at least 50% of the value of our assets is attributable to assets that produce passive income or are held for the production of passive income, including cash, we would be characterized as a passive foreign investment company (***PFIC***), for U.S. federal income tax purposes. For purposes of these tests, passive income includes dividends, interest, and gains from the sale or exchange of investment property and rents and royalties other than rents and royalties which are received from unrelated parties in connection with the active conduct of a trade or business. Our status as a PFIC depends on the composition of our income and the composition and value of our assets (for which purpose the total value of our assets may be determined in part by the market value of our ordinary shares and the ADSs, which are subject to change) from time to time. If we are characterized as a PFIC, U.S. holders of ADSs may suffer adverse tax consequences, including having gains realized on the sale of ADSs treated as ordinary income, rather than capital gain, the loss of the preferential rate applicable to dividends received on ADSs by individuals who are U.S. holders, and having interest charges apply to distributions by us and the proceeds of sales of ADSs. See "Item 10.E—Taxation—Certain Material U.S. Federal Income Tax Considerations to U.S. Holders—Passive Foreign Investment Company Considerations."

We do not believe that we were classified as a PFIC for the 2021 taxable year and, based upon the expected value of our assets, including any goodwill, and the expected composition of our income and assets, we do not anticipate being classified as a PFIC with respect to the 2022 taxable year. However, our status as a PFIC is