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 sustain profitability.
- We may need to raise substantial additional funding which may not be available to us on acceptable terms or at all.
- Our cash flows and the investment of our cash and cash equivalents may be subject to risks which may cause losses and affect the liquidity of these investments.
- We may engage in strategic transactions, including acquisitions, collaborations, licenses or investments in other companies or technologies, and we may not realize the benefits of such transactions.
- We will face significant challenges in successfully commercializing our products and additional product candidates after they are launched.
- The commercial success of our products and product candidates, including in new indications or methods of administration, will depend on the degree of market acceptance.
- We face significant competition for our drug discovery and development efforts.
- Our products, product candidates and new indications for which we have obtained or intend to seek approval as biological products, including for new indications, may face competition sooner than anticipated.
- Enacted and future legislation could impact demand for our products which could impact our business and future results of operations.
- We are subject to government pricing laws, regulation and enforcement.
- We may not obtain or maintain adequate coverage or reimbursement status for our products and product candidates.
- If we fail to obtain orphan drug designation or obtain or maintain orphan drug exclusivity for our products or product candidates, our competitors may sell products to treat the same conditions and our revenue will be reduced.
- We are subject to healthcare laws, regulation and enforcement. The failure to comply with these laws could harm our results of operations and financial conditions.
- All aspects of our business ranging from preclinical, clinical trials, marketing and commercialization are highly regulated and any delay by relevant regulatory authorities could jeopardize our development and approval process or result in other suspensions, refusals or withdrawal of approvals.
- 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.
- Failure to comply with anti-corruption laws and regulations, anti-money laundering laws and regulations, economic sanctions, and/or export control regulations could have an adverse impact on our business.
- We may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities.
- Failure to successfully identify, select and develop efgartigimod in other indications, additional products or product candidates could impair our ability to grow.
- VYVGART for the treatment of generalized myasthenia gravis (***gMG***) is our only product that has obtained regulatory approval in the 27 European Union (***EU***) Member States, Iceland, Norway, Liechtenstein, the United States of America (***U.S.***) and Japan (collectively, ***VYVGART Approved Countries***).
- Our clinical trials may fail.
- Our products and product candidates may have serious adverse, undesirable or unacceptable side effects or even cause death.
- If our target patient population is smaller than excepted, we are unable to successfully enroll and retain patients in our clinical trials, or experience significant delays in doing so, we may not realize the full commercial potential of any products or product candidates.
- We rely, and expect to continue to rely, on third parties to conduct some of our research activities and clinical trials and for parts of the development and commercialization of our existing and future research programs, products and product candidates. If our relationships with such third parties are not successful, our business may be adversely affected.

- Disruptions caused by our reliance on third parties for our manufacturing process may delay or disrupt our business, product development and commercialization efforts.
- Accuracy and timing of our financial reporting is partially dependent on information received from third-party partners, which we do not control.
- We and our third-party manufacturers and suppliers may become exposed to liability, fines, penalties or other sanctions and substantial expenses in connection with environmental compliance or remediation activities.
- Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, or insider trading violations, which could significantly harm our business.
- We may become exposed to costly and damaging liability claims.
- Our business and operations could suffer in the event of system failures or unauthorized or inappropriate use of or access to our systems.
- We are highly dependent on public perception of our products.
- Failure to adequately enforce or protect our intellectual property rights could adversely affect our ability to develop and market our products and product candidates.
- Issued patents could be found invalid or unenforceable if challenged in the applicable patent office or court.
- We may be subject to claims challenging the inventorship or ownership of our intellectual property or be required to make additional payments to secure intellectual property from collaborators.
- Third-party intellectual property rights could adversely affect our ability to commercialize our products and product candidates.
- If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest.
- We may not be able to obtain protection under the Drug Price Competition and Patent Term Restoration Act of 1984 (***Hatch-Waxman Act***) and similar non-U.S. legislation for extending the term of patents covering each of our products and product candidates.
- Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our products.
- We may be unable to protect the confidentiality of our trade secrets and know-how.
- Our future growth and ability to compete depends on retaining our key personnel and recruiting additional qualified personnel.
- Global geo- and socio-political threats and macro-economic uncertainty and other unforeseen political crises could materially and adversely affect our business and financial performance.
- We face risks related to natural disasters and public health issues, such as the COVID-19 pandemic, that could negatively affect our business and financial condition.
- We are exposed to unanticipated changes in tax laws and regulations, adjustments to our tax provisions, exposure to additional tax liabilities, or forfeiture of our tax assets.
- The price of our ADSs and ordinary shares may be volatile and may fluctuate due to factors beyond our control.
- Holders of our ADSs are not treated as holders of our ordinary shares.
- If securities or industry analysts cease coverage of us, or publish inaccurate or unfavorable research about our business, the price of our ADSs or ordinary shares and our trading volume could decline.
- 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.
- Provisions of our articles of association (***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.
- We are not obligated to, and do not comply with, all the best practice provisions of the Dutch Corporate Governance Code 2016 (***DCGC***), which may affect shareholders' rights.
- Claims of U.S. civil liabilities may not be enforceable against us our the members of our management and our board of directors (***Board of Directors***).
- As a foreign private issuer, we are exempt from certain rules under U.S. securities laws and are permitted to file less information with the U.S. Securities and Exchange Commission (***SEC***) than a U.S. company.
- If we were to be classified as a passive foreign investment company (***PFIC***) for U.S. federal income tax purposes, this could result in adverse U.S. tax consequences to certain U.S. holders.

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. [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, including those described below. You should carefully consider all of the information set forth in this Annual Report and in our other filings with 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. 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."

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 sustain profitability.

Since our inception, we have incurred significant operating losses, totaling $2,109.8 million of cumulative losses. To date we have commercialized VYVGART for the treatment of gMG in the VYVGART Approved Countries. We do not currently have any marketing approvals for any other product candidates or VYVGART in other indications. Our losses resulted principally from costs incurred in research and development, preclinical testing and clinical development of our research programs, and from general and administrative costs associated with our operations. We intend to continue to conduct research and development, preclinical testing, clinical trials and regulatory compliance activities as well as the continued commercialization of VYVGART and other products candidates, for current and future indications, and we intend to continue our efforts to expand our sales, marketing and distribution infrastructure. These expenses, together with anticipated general and administrative expenses, may result in incurring further significant losses for the foreseeable future. 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 clinical trials, ambiguous clinical trial results, safety issues or other regulatory challenges.

Although we have generated revenue of $400.7 million from global product net sales of VYVGART in fiscal year 2022, we can provide no assurances that we will be able to achieve or sustain profitability based on sales in that indication alone or that we will be able to receive regulatory approval of and commercialize VYVGART in other indications or in other countries. To become and remain profitable, we must succeed in developing and 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 products and our product candidates, including new indications, discovering and developing additional products and product candidates, including new indications, obtaining regulatory approval for any product candidates that successfully complete clinical trials, establishing manufacturing and marketing capabilities, obtaining funding or reimbursement for our products, and ultimately selling 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.

We may need to raise substantial additional funding which may not be available to us on acceptable terms or at all.

Although we have significant positions of cash and cash equivalents of $800.7 million and other current financial assets of $1,391.8 million as of December 31, 2022, our cash burn increased significantly in 2022 as compared to 2021 and to previous fiscal years, in part due to the commercial launches of VYVGART. We expect to sustain our current cash burn in the near term as we continue to develop new products and new product candidates, and to obtain regulatory approval of our products in additional jurisdictions. Developing products and product candidates, including new indications, and conducting clinical trials is time-intensive, expensive and risky. Our future capital requirements will depend on many factors, including: (i) the success, cost and timing of our development activities, preclinical testing and clinical trials for our product and product candidates, (ii) the time and costs involved in obtaining regulatory approvals and any delays we may encounter, including as we seek regulatory approval in additional jurisdictions or other indications, (iii) commercialization, manufacturing, sales and marketing of products and product candidates, (iv) securing adequate and uninterrupted supply chains, (v) the costs involved in growing our organization to the size needed to allow for the research, development and potential commercialization of our products or product candidates, (vi) the costs involved in filing patent applications and maintaining and enforcing patents or defending against claims or infringements raised by third parties, (vii) the maintenance of our existing collaboration agreements and entry into new collaboration agreements, and (viii) the amount of revenue, if any, we may derive either directly or in the form of royalty payments from future sales of our products or product candidates, if approved.

To finance our operations, we may need to raise additional capital 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 on acceptable terms or at all will depend on financial, economic and market conditions and other factors, over which we may have no or limited control. If we are unable to raise additional capital if and when needed, or if the terms are not acceptable, our business strategy could be impacted, and we may be forced to delay, reduce or terminate the one or more of our research or development programs or the commercialization of any of our products or product candidates, including new indications, or be unable to expand our operations or otherwise capitalize on our business opportunities, all of which may have a material adverse impact on our business, financial condition and results of operations.

Our assets, earnings and cash flows and 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, 2022, we had cash and cash equivalents and current financial assets of $2,192.5 million compared to $2,336.7 million in December 31, 2021. 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. For example, we have invested in USD denominated cash deposit accounts and in current financial assets with a significant portion of the proceeds from our U.S. public offerings. Any future investments may include term deposits, corporate bonds, commercial paper, certificates of deposit, government securities and money market funds in accordance with our cash management policy. These investments may be subject to general credit, liquidity, market, inflation and interest rate risks and 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. The market risks associated with our cash flows and investment portfolio may adversely affect our results of operations, liquidity and financial condition.

Due to the international scope of our operations, our assets, earnings and cash flows are influenced by movements in exchange rates of several currencies, particularly between the U.S. dollar, our functional currency since

January 1, 2021, and the euro, Swiss francs, Japanese yen and British pounds. Our revenue from outside of the U.S. will increase as our products, whether commercialized by us or our business partners or our collaborators gain marketing approval in such jurisdictions. We do not have any exchange rate hedging arrangements in place. Accordingly, if the U.S. dollar weakens against a specific foreign currency, our revenues will increase, having a positive impact on net income, but our overall expenses will increase, having a negative impact. Conversely, if the U.S. dollar strengthens against a specific foreign currency, our revenues will decrease, having a negative impact on net income, but our overall expenses will decrease, having a positive impact. Continued volatility in foreign exchange rates is likely to impact our operating results and financial condition.

Risk Factors Related to Commercialization of argenx's Products and Product Candidates, Including for New Indications

We will face significant challenges in successfully commercializing our products and additional product candidates after they are launched.

The commercialization of VYVGART in other indications or other approved product candidates, or entrance of any of our products or product candidates into other markets will require us to further expand our sales and marketing organization, enter into collaboration arrangements with third parties, outsource certain functions to third parties, or use some combination of each. We have built, and continue to expand, our sales forces in certain of the VYVGART Approved Countries and plan to further develop our sales and marketing capabilities to promote our products, and product candidates, including new indications, if and when marketing approval has been obtained in other relevant jurisdictions.

Even if we successfully expand our sales and marketing capabilities, either on our own or in collaboration with third parties, we may fail to launch or market our products effectively. Recruiting and training a specialized sales force is expensive and the costs of expanding an independent sales, marketing and/or promotion organization could be greater than we anticipate. We could further encounter difficulties in our sales or marketing, due to regulatory actions, shut-downs, work stoppages or strikes, approval delays, withdrawals, recalls, penalties, supply disruptions, shortages or stock-outs at our facilities or third-party facilities that we rely on, reputational harm, the impact to our facilities due to pandemics or natural or man-made disasters, including as a result of climate change, product liability, and/or unanticipated costs. 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.

We have entered into distribution agreements with Medison Pharma Ltd (***Medison***), Zai Lab Ltd (***Zai Lab***) and Genpharm Services FZ-LLC (***Genpharm***) to perform sales and marketing services in Israel and Central and Eastern Europe, the People's Republic of China (***PRC***) and the Gulf Cooperation Council, comprising Saudi Arabia, Kuwait, the United Arab Emirates, Qatar, Bahrain and Oman (collectively, the ***GCC***), respectively. Under these agreements, our product revenues or the profitability of these product revenues could be lower than if we were to market and sell the products that we develop ourselves. Such distribution agreements may place the commercialization of our products outside of our control, including over the amount or timing of resources that our distribution partners devote to our products. Furthermore, our distributors' willingness or ability to comply with and complete their obligations under our arrangements may be adversely affected by business combinations or significant changes in our distributors' business strategies. In addition, we may not succeed 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.

The commercial success of our products and product candidates, including in new indications or methods of administration, will depend on the degree of market acceptance.

Our products and product candidates, including for new indications or methods of administration, if and when approved and available on the market, may never achieve an adequate level of acceptance by physicians, patients, the

medical community, or healthcare payors for us to be profitable. This will depend on a number of factors, many of which are beyond our control, including, but not limited to:

- the efficacy and safety as demonstrated by clinical trials and subsequent prevalence and severity of any side effects;
- approval may be for indications, dosage and methods of administration or patient populations that are not as broad as intended or desired;
- changes in the standard of care for the targeted indications for any product and product candidate;
- availability of alternative approved therapies;
- sales, marketing and distribution support;
- labeling may require significant use or distribution restrictions or safety warnings;
- potential product liability claims;
- acceptance by physicians, patients and healthcare payors of each product as safe, effective and cost-effective, and any subsequent changes thereof;
- relative convenience, ease of use, including administration, perceived dosing complexity and other perceived advantages over alternative and/or new products;
- patient continued commitment required to receive periodic in-center infusions;
- prevalence and severity of adverse events discovered before or after marketing approval has been received;
- consumer perceptions or publicity regarding the Company or the safety and quality of our product and product candidates, clinical trials for new indications, or any similar products distributed by other companies;
- limitations, precautions or warnings listed in the summary of product characteristics, patient information leaflet, wording of package labeling or instructions for use, and any subsequent changes thereof;
- the cost of treatment with our products in relation to alternative and/or new treatments;
- the extent to which products are approved for inclusion and reimbursed on formularies of hospitals and managed care organizations, and any subsequent changes thereof; and
- whether our products are designated in the label, under physician treatment guidelines or under reimbursement guidelines as a first-line, second-line, third-line or last-line therapy, and any subsequent changes thereof.

In addition, because we are developing our products and product candidates for the treatment of different indications, negative results in a clinical trial evaluating the efficacy and safety of a product or product candidate for one indication could negatively impact the perception of the efficacy and safety of such product or product candidate in a different indication, which could have an adverse effect on our reputation, commercialization efforts and financial condition.

Moreover, efforts to educate the medical community and third-party payors on the benefits of our products may require significant resources and may never be successful. If our product candidates or methods of use of existing products or new indications 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, they may not be able to retain market acceptance and/or the market may prove not to be large enough to allow us to generate significant revenues.

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

The market for pharmaceutical products is highly competitive and characterized by rapidly growing understanding of disease biology, quickly changing technologies, strong intellectual property barriers to entry, and a multitude of companies involved in the creation, development, and commercialization of novel therapeutics. Currently, our only commercial revenue is generated by VYVGART in gMG. We face and expect to continue to face intense competition from other biopharmaceutical companies, who are developing products for the treatment of gMG and other autoimmune diseases, including products that are in the same class as VYVGART, as well as products that are similar to some of our product candidates. Competition for other (potential) future indications is also fierce, with significant development in almost all of the indications we are currently developing or planning to develop for our product or product candidates. For example, we are aware of several neonatal Fc receptor (***FcRn***) inhibitors that are in clinical development. Competitive product launches may erode future sales of our products, including our existing products and those currently under development, or result in unanticipated product obsolescence. Such launches continue to occur, and potentially competitive products are in various stages of development. We could also face competition for use of limited international infusion sites, particularly in new markets as competitors launch new products. We cannot predict with accuracy the timing or impact of the introduction of competitive products that treat diseases and conditions like those treated by our products or product candidates. In addition, our competitors and potential competitors compete with us in recruiting and retaining qualified scientific, clinical research and development and management personnel, establishing clinical trial sites, registering patients for clinical trials, as well as in acquiring technologies complementary to, or necessary for, the development of our products.

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, are more economically attractive, and can be administered more easily than any of our current or future technologies or products.

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.

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

In the U.S., the Biologics Price Competition and Innovation Act (***BPCIA***) created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with a U.S. Food and Drug Administration (***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 biologics license application (***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 competition by biosimilar products sooner than anticipated. Moreover, an interchangeable biosimilar product, once approved, may be substituted under existing state law for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products. Any non-interchangeable biosimilar products may also be substituted by a healthcare provider but, under existing law, will not be automatically substituted at the pharmacy. The extent of the impact of such substitution will depend on a number of marketplace and regulatory factors that are still developing.

In the EU, biosimilars are evaluated for marketing authorization pursuant to a set of general and product class-specific guidelines. In addition, in an effort to spur biosimilar utilization and/or increase potential healthcare savings, some EU Member States have adopted, or are considering the adoption of, biosimilar uptake measures such as physician prescribing quotas or automatic pharmacy substitution of biosimilars for the corresponding reference products. Some EU Member States impose automatic price reductions upon market entry of one or more biosimilar competitors. While the degree of competitive effects of biosimilar competition differs among EU Member States and among products, the overall use of biosimilars and the rate at which product sales of innovative products are being affected by biosimilar competition is increasing.

Enacted and future legislation could impact demand for our products which could impact our business and future results of operations.

In the U.S., the United Kingdom (***UK***), the EU and other jurisdictions, there have been a number of legislative and regulatory changes to the healthcare systems that could affect our future results of operations. Governmental regulations that mandate price controls or limitations on patient access to our products or establish prices paid by government entities or programs for our products could impact our business, and our future results of operations could be adversely affected by changes in such regulations or policies.

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 in general and the cost of pharmaceuticals in particular. Healthcare reform initiatives in the U.S. recently culminated in the enactment of the Inflation Reduction Act (***IRA***) in August 2022, which, among other things, will allow Health and Human Services (***HHS***) to negotiate the selling price of certain drugs and biologics that the Centers for Medicare & Medicaid Services (***CMS***) reimburses under Medicare Part B and Part D, although only high-expenditure single-source biologics that have been approved for at least 11 years (7 years for drugs) can be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price. Beginning in October 2022 for Medicare Part D and January 2023 for Medicare Part B, the IRA also penalizes drug manufacturers that increase prices of Medicare Part D and Part B drugs at a rate greater than the rate of inflation. The IRA will also cap out-of-pocket spending for Medicare Part D enrollees and make other Part D benefit design changes beginning in 2024. Beginning in 2025, the IRA eliminates the coverage gap under Medicare Part D by significantly lowering the enrollee maximum out-of-pocket cost to $2,000 and by requiring manufacturers to subsidize, through a newly established manufacturer discount program, 10% of Part D enrollees’ prescription costs for brand drugs below the out-of-pocket maximum, and 20% once the out-of-pocket maximum has been reached (plans will also be required to cover 20% in this case). Although these discounts represent a lower percentage of enrollees’ costs than the current discounts required below the out-of-pocket maximum (that is, in the coverage gap phase of Part D coverage), the new manufacturer contribution required above the out-of-pocket maximum could be considerable for very high-cost patients and the total contributions by manufacturers to a Part D enrollee’s drug expenses may exceed those currently provided. These Part D design changes may also incentivize Part D plans to exclude certain drugs in their formularies, which could affect the supply, demand, and pricing of our product and product candidates.

The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with IRA may be subject to various penalties, including civil monetary penalties. IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in marketplaces in compliance with the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ***ACA***), through plan year 2025. These provisions will take effect

progressively starting in 2023, although they may be subject to legal challenges. The full economic impact of IRA is unknown at this time, but the law's passage is likely to affect the pricing of our products and product candidates. The adoption of restrictive price controls in new jurisdictions, more restrictive controls in existing jurisdictions or the failure to obtain or maintain timely or adequate pricing could also adversely impact revenue. We expect pricing pressures will continue globally.

Further, at the U.S. state level, legislatures are increasingly enacting laws and implementing regulations designed to control pharmaceutical and biological product pricing, including price or reimbursement constraints, discount requirements, marketing cost disclosure and price transparency reporting, and programs designed to encourage importation from other countries and bulk purchasing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, including pharmaceuticals, which could result in reduced demand for our products and product candidates or additional pricing pressures.

We are subject to government pricing laws, regulation and enforcement. These laws affect the prices we may charge the government for our products and the reimbursement our customers may obtain from the government. Our failure to comply with these laws could harm our results of operations and financial conditions.

In the U.S., we are required to participate in various government programs for our products to be reimbursed or purchased by the federal government. We participate in programs such as the Medicaid Drug Rebate Program, the 340B drug discount program, Medicare Part B, Medicare Part D and the U.S. Department of Veterans Affairs Federal Supply Schedule pricing program. The requirements vary by program, but among these and any other programs in which we participate, we are, among other things, required to enter into agreements with and calculate and report prices and other information to certain government agencies, charge no more than statutorily mandated ceiling prices and calculate and pay rebates and refunds for certain products.

The calculations are complex and are often subject to interpretation by us, governmental agencies and the courts. If we determine that the prices we reported were in error, we may be required to restate those prices and pay additional rebates or refunds to the extent we understated the rebate or overcharged the government due to the error. Additionally, there are penalties associated with submission of incorrect pricing or other data. We may incur significant civil monetary penalties if we are found to have knowingly submitted false prices or other information to the government, or to have charged 340B covered entities more than the statutorily mandated ceiling price. Certain failures to timely submit required data also could result in a civil monetary penalty for each day the information is late. We could also become subject to allegations under the False Claims Act and other laws and regulations. In addition, misreporting and failure to timely report data to CMS also can be grounds for CMS to terminate our Medicaid rebate agreement, pursuant to which we participate in the Medicaid Drug Rebate Program. In the event that CMS terminates our rebate agreement, no federal payments would be available under Medicaid or Medicare Part B for our covered outpatient drugs.

Recently enacted legislation in the U.S. has imposed additional rebates under government programs. For example, under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs will be eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in Medicaid rebates than they receive on the sale of products for products that have undergone substantial price increases. In addition, the Infrastructure Investment and Jobs Act, effective January 1, 2023, added a requirement for manufacturers of certain single-source drugs (including biologics and biosimilars) separately paid for under Medicare Part B for at least 18 months and marketed in single-dose containers or packages (known as refundable single-dose containers or single-use package drugs) to provide annual refunds if those portions of the dispensed drug that are unused and discarded exceed an applicable percentage defined by statute or regulation. Manufacturers will be subject to periodic audits and those that fail to pay refunds for their refundable single-dose containers or single-use package drugs shall be subject to civil monetary penalties. We expect that this requirement will apply to VYVGART and potentially other of our products in the future. As a result, we expect that we will owe refunds to CMS starting this year. Although we will evaluate options to reduce the amount of refunds owed, pursuing any such actions will be time-consuming and costly. Even if we invest resources to reduce the amount of refunds owed to CMS, it is possible that we will be delayed or unsuccessful in achieving a reduction worthy of our investment.

Maintaining compliance with these government price reporting and discounting obligations is time-consuming and costly, and a failure to comply can result in substantial fines, penalties, all of which could adversely impact our financial results.

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

Sales of VYVGART for gMG and our product candidates, if approved, will depend, in part, on the extent to which third-party payors, including government health programs in the U.S. (such as Medicare Parts B and D 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. In the U.S., no uniform policy of coverage and reimbursement for products exists among commercial third-party payors. Commercial third-party payors decide which products they will pay for and establish reimbursement levels. Commercial payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidate that we develop through approval will be made on a plan-by-plan basis. One commercial payor's determination to provide coverage for a product does not assure that other commercial payors will also provide coverage and adequate reimbursement for the product. Additionally, a commercial third-party payor's decision to provide coverage for a drug does not imply that an adequate reimbursement rate will be approved. Each plan determines whether or not it will provide coverage for a product, what amount it will pay the manufacturer for the product, on what tier of its formulary the product will be placed and whether to require step therapy. The position of a product on a formulary generally determines the co-payment that a patient will need to make to obtain the product and can strongly influence the adoption of a product by patients and physicians.

Even under U.S. government healthcare programs such as Medicare and Medicaid, coverage and reimbursement policies can vary significantly. Medicare Part D is administered by commercial insurance companies under contract with the CMS. The many Part D plans operated by these companies vary considerably in their coverage and reimbursement policies, much like the commercial plans that these same companies offer, as described above. Medicare Part B and Medicaid coverage and reimbursement rates are more uniform, but even Medicaid programs vary from state to state in their coverage policies and reimbursement rates.

Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Further, from time to time, typically on an annual basis, payment rates are updated and revised by third-party payors. Such updates could impact the demand for our products, to the extent that patients who are prescribed our products, if approved, are not separately reimbursed for the cost of the product.

The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Even if we do obtain adequate levels of reimbursement, third-party payors, such as government or private healthcare insurers, carefully review and increasingly question the coverage of, and challenge the prices charged for, products. Increasingly, third-party payors are requiring that biopharmaceutical companies provide them with predetermined discounts from list prices and are challenging the prices charged for products. We may also be required to conduct expensive pharmacoeconomic studies to justify the coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be.

Moreover, coverage policies and third-party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained for one or more products for which we receive marketing approval in one or more indications, less favorable coverage policies and reimbursement rates may be implemented in the future. For instance, even though favorable coverage and reimbursement status has been attained for VYVGART for the treatment of gMG in the U.S., access to VYVGART for the treatment of gMG or for any other indication may be reduced or restricted by limited payer coverage due to treatment criteria, which may prevent us from realizing its full commercial potential. In addition, the coverage and reimbursement levels for our products for the

treatment in one indication may have an adverse impact on the coverage and reimbursement levels of such products or product candidates in other indications for which marketing approval has previously been or may subsequently be obtained. Inadequate coverage or reimbursement may diminish or prevent altogether any significant demand for our products and/or may prevent us entirely from entering certain markets or indications, which would prevent us from generating significant revenues or becoming profitable, which would adversely affect our business, financials and results of operations.

If we fail to obtain orphan drug designation or obtain or maintain orphan drug exclusivity for our products or product candidates, 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 EU, after a recommendation from the European Medicines Agency (***EMA***)'s Committee for Orphan Medicinal Products (***COMP***), the EU 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 EU or when, without incentives, it is unlikely that sales of the drug in the EU 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 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 submitted by another applicant to market a same or similar biological product for the same indication for a period of seven years, except in limited circumstances. Whether a biological product is the same as another product is based on whether the two products have the same principal molecular structural features. Orphan designation does not, however, truncate the duration of the regulatory review and approval process.

In the EU, 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 including from biosimilars. Similar considerations apply in the UK.

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 efgartigimod for gMG, and upon approval of VYVGART, the FDA granted seven years of orphan drug exclusivity for VYVGART for the treatment of gMG in adult patients who are anti-acetylcholine receptor antibody positive (***AChR-AB+***). In July 2022, the FDA granted orphan drug designation for the use of efgartigimod co-formulated with rHuPH20 for the treatment of gMG, and we expect to obtain orphan drug exclusivity for this product with this use if our BLA is approved. In January 2019, the FDA granted orphan drug designation for the use of efgartigimod for the treatment of immune thrombocytopenia (***ITP***) and for the use of cusatuzumab for the treatment of acute myeloid leukemia (***AML***), and in August 2021, the FDA granted orphan drug designation for the use of efgartigimod co-formulated with rHuPH20 for the treatment of chronic inflammatory demyelinating polyneuropathy (***CIDP***). In December 2022, Japan's Ministry of Health, Labour and Welfare (***MHLW***) granted orphan drug designation for the use of efgartigimod for the treatment of ITP. With regard to these designations or future designations we may obtain, we may not be the first to obtain marketing approval of these drugs for such indication due to the uncertainties associated with developing therapeutic products, and we may not obtain orphan designation upon approval. 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 we

are 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 or different principal molecular structural features can be approved for the same condition. Even after an orphan drug is approved, the FDA, EMA or other foreign regulator can subsequently approve the same drug with the same principal molecular structural features for the same condition if the regulator concludes that the later drug is safer, more effective, or makes a major contribution to patient care.

Risk Factors Related to Other Government Regulations

We are 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, EU, Japanese, Chinese, UK, Canadian and other jurisdictions' healthcare laws including anti-kickback statutes, anti-bribery, anti-corruption provisions, false claims acts, including the U.S. federal Anti-Kickback Statute (***AKS***), Food, Drug & Cosmetic Act, False Claims Act and more. 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 with third-party payors, healthcare professionals who participate in our clinical research programs, 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, our current and future operations are subject to other 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 medical products is generally not permitted in the countries that form part of the EU. 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 UK has enacted similar restrictions through the Bribery Act 2010. Infringements of these laws can result in substantial fines and imprisonment, as well as associated reputational harm. We are also subject to EU Directive 2001/83/EC and the UK Human Medicines Regulations 2012. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

The shifting compliance environment and the need to maintain robust and expandable systems to comply with multiple jurisdictions with different compliance or reporting requirements increases the possibility that we or our collaborative partners may run afoul of one or more of the requirements. We continue to expand, enhance and refine our internal ethics and compliance function and program to ensure compliance with the different healthcare laws and regulations. The expansion and maintenance of an internal compliance program involves substantial costs and, notwithstanding our investment, mechanisms put in place to ensure compliance with applicable laws and regulations and our best efforts, the program may not be fully successful as there can be no assurance that our policies and procedures will be followed at all times or will effectively detect and/or prevent all compliance violations by our employees, consultants, subcontractors, agents and partners.

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 investigations, penalties, damages, fines, disgorgement, imprisonment, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid in the U.S., 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. Managing such investigations and defending against or appealing any such actions or penalties can be costly and time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in managing any such governmental investigations and/or defending

against or appealing any such actions or penalties that may be brought against or imposed upon 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. Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations also involves substantial costs.

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.

All aspects of our business ranging from preclinical, clinical trials, marketing and commercialization are highly regulated and any delay by relevant regulatory authorities could jeopardize our development and approval process or result in other suspensions, refusals or withdrawal of approvals.

Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned investigational new drug (***IND***) applications in the U.S. or Japan, or our clinical trial applications (***CTAs***) in the UK or in the EU, or a comparable application in other jurisdictions. 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. We also cannot guarantee that submission of INDs or CTAs or comparable applications will result in the UK Medicines and Healthcare Products Regulatory Agency (***MHRA***), EMA, FDA, MHLW (collectively, ***Relevant Regulatory Authorities***) or other regulatory authorities allowing clinical trials to even begin.

Clinical trials must be conducted in accordance with Relevant Regulatory Authorities and other applicable regulatory authorities' legal requirements and regulations and are subject to oversight by these governmental agencies and institutional review boards (***IRBs***) and ethics committees at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted in compliance with good clinical practices (***GCPs***) and with supplies of our products and product candidates produced under current good manufacturing practices (***cGMPs***) and other regulations. We could encounter delays if a clinical trial is suspended or terminated, by us, by the IRBs or ethics committees of the institutions in which such clinical trials are being conducted, by the data review committee or data safety monitoring board for such clinical trial by the Relevant Regulatory Authorities or other comparable 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 clinical trial site by the Relevant Regulatory Authorities or other applicable 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 the product or product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

If we experience delays in the completion of, or termination of, any clinical trial of our products or product candidates, the costs to our clinical trials will increase, the commercial prospects of our products and product candidates may be harmed, our ability to generate product revenues from any of these products and product candidates will be delayed and our product candidate development and approval process may be jeopardized. 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.

Moreover, we must obtain separate regulatory approvals in each jurisdiction where we want to market and approval by one regulatory authority does not ensure approval by any other regulatory authority. As approval procedures can vary among countries and may change over time, this can require additional clinical testing and the time required to obtain approval may differ. For instance, only VYVGART for the treatment of gMG has obtained regulatory approval in the VYVGART Approved Countries. Efgartigimod was recently awarded a positive scientific opinion under the Early Access to Schemes program by the MHRA. Zai Lab and Medison have submitted a request for approval of VYVGART

in gMG in the PRC and Israel, respectively. We 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 we will receive approval on our anticipated timeline, or at all.

If VYVGART™ or any new formulations of VYVGART are not approved in one or more jurisdictions including beyond the VYVGART Approved Countries, or if such approvals are significantly delayed, it could have a material adverse effect on our business. 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.

Further, Relevant Regulatory Authorities may impose extensive and ongoing unique regulatory requirements, for example, they:

- may withdraw 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 another comparable foreign authority;
- may approve a product candidate for fewer or more limited indications or patient sub-segments than requested; or
- may grant approval contingent on the performance of costly post-marketing clinical trials, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate; 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.

The costs of compliance with all Relevant Regulatory Authorities and applicable authorities 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 collaborative partners' costs or delay the development and commercialization of our product candidates. 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.

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.

Privacy laws, regulation and potential enforcement are particularly relevant to our business as we collect, store and process patient data, including sensitive health data as well as human biological samples such as blood or tissue, in the context of our clinical development activities, post-marketing approval monitoring obligations, and associated activities. We also collaborate on a regular basis with third parties where we may seek to use data collected by third parties on our or their behalf, or we may seek to share data collected by us with such third parties to further our research or commercial initiatives.

The EU General Data Protection Regulation (***GDPR***) imposes a broad range of strict requirements on companies, including with respect to cross-border transfers of personal data. The GDPR allows the imposition of substantial penalties in the event of non-compliance, including fines of up to €10,000,000 or up to 2% of total worldwide annual turnover for certain comparatively minor offenses, or up to €20,000,000 or up to 4% of 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 addition, national laws of EU Member States may partially deviate from the GDPR and impose different obligations from country to country, so that we do not 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 national laws have historically differed quite substantially in this field, leading to additional uncertainty.

Following its departure from the EU, the UK has maintained in force substantially equivalent provisions to the GDPR (***UK GDPR***). Similar concerns as those described above apply to our compliance with the UK GDPR.

Privacy laws continue to evolve and expand in Europe. For example, Directive 2002/58/EC of the European Parliament and of the Council of July 12, 2002 (as amended, the ***e-Privacy Directive***) required the EU Member States to implement laws to meet strict privacy requirements related to electronic communications, cookies and online monitoring, and other digital privacy. Violations of these requirements can result in administrative measures, including fines, or criminal sanctions. The EU is in the process of developing a new e-Privacy Regulation to replace the e-Privacy Directive, and the new e-Privacy Regulation may impose additional obligations and risk for our business.

Beyond the EU and UK, privacy and data protection laws and regulations continue to develop and expand around the world, including in other jurisdictions in which we operate, such as the U.S., Japan, and Canada. Such laws and regulations impose increasing restrictions and obligations on the processing of personal data, including sensitive personal data such as genetic data. For example, in the U.S., the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information and the California Consumer Privacy Act of 2018 imposes obligations on covered businesses, including, but not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. If we are investigated by a data protection authority, we may face fines and other penalties. Any such investigation or charges by such 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 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. 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 harm our business, prospects, financial condition and results of operations.

Failure to comply with anti-corruption laws and regulations, anti-money laundering laws and regulations, economic sanctions, and/or export control regulations could have an adverse impact on our business.

We are subject to various federal and foreign laws and regulations regarding anti-corruption, anti-money laundering, economic sanctions, and export control regulations. These include the UK Bribery Act 2010 and the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, payments, offers, or promises made for the purpose of improperly influencing any act or decision of a foreign official. The nature of our business means that we engage in significant interactions with foreign officials. We are also subject to economic sanctions and export controls rules and regulations imposed by, amongst others, the U.S. Department of the Treasury's Office of Foreign Assets Control, other agencies of the U.S. government, HM Treasury and other agencies of the UK government, the EU, and the United Nations. Any change in export or import regulations, economic sanctions regulations or related legislation, shift in the enforcement or scope of existing regulations, or change in the countries, governments, persons or technologies targeted by such regulations, could decrease our ability to export or sell our products internationally. Any limitation on our ability to export or sell our products could adversely affect our business.

We have mechanisms in place to ensure compliance with applicable anti-corruption, anti-money laundering, and economic sanctions rules and regulations. However, there can be no assurance that our policies and procedures will

be followed at all times or will effectively detect and/or prevent violations of applicable compliance regimes by our employees, consultants, sub-contractors, agents and partners. As a result, in the event of non-compliance, we could be subject to substantial civil or criminal penalties, including economic sanctions against us, incarceration for responsible employees and managers, the possible loss of export or import privileges, reputational harm, and resulting loss of revenue and profits, which could have a material adverse impact on our business, financial conditions and operations.

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 third-party manufacturing activities, are subject to numerous environmental, health and safety laws and regulations and for which we may become liable.

If we or one of our contract manufacturing organizations (***CMOs***) or other third-party distributors, manufacturers, licensees or co-marketers fail to comply with such laws and regulations, such failure could result in substantial fines, penalties or other sanctions which could also bring significant reputational loss to our business.

Furthermore, environmental, health and safety laws and regulations are becoming more stringent. Our CMOs 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.

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

Failure to successfully identify, select and develop efgartigimod in other indications, additional products or product candidates could impair our ability to grow.

Our long-term growth strategy entails developing and marketing additional products and product candidates, including efgartigimod in new indications, which requires substantial resources, whether or not any product candidates or new indications are ultimately identified. The success of this strategy depends partly upon our ability to identify, select, develop, and ultimately, commercialize promising product candidates. We are heavily dependent on precise, accurate and reliable scientific data to identify, select and develop promising 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 and product candidates, could impair our ability to grow. Even with accurate scientific data, our technology platforms may fail to discover and to generate additional products and products candidates, that are suitable for further development.

Even if we identify additional product candidates, they may not be suitable for clinical development as a result of harmful side effects, limited efficacy or other characteristics that indicate that it is unlikely to be a product that will receive approval by the Relevant Regulatory Authorities and other comparable regulatory authorities or achieve market acceptance. If we do not successfully identify, develop and commercialize product candidates and efgartigimod in new indications based upon our technological approach, we may not be able to obtain product or collaboration revenues in future periods.

VYVGART for the treatment of gMG is our only product that has obtained regulatory approval in the VYVGART Approved Countries. Our other products and product candidates – including additional indications or methods of use for efgartigimod, ARGX-117 and ARGX-119 – are either in preclinical or clinical development or are pending marketing approval.

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 that our products are safe, pure, and effective in humans. Clinical trials are expensive and can take many years to complete, and their outcome is inherently uncertain. Further, success in early clinical trials or in one indication does not guarantee success in later clinical trials or in other indications.

The time required to obtain approval by the Relevant 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 for new indications. We may experience delays in our ongoing or planned clinical trials, for a large variety of reasons outside our control in complying with regulatory approvals which can adversely affect the timing of trials, including as described in the header "*–All aspects of our business ranging from preclinical, clinical trials, marketing and commercialization are highly regulated and any delay by relevant regulatory authorities could jeopardize our development and approval process or result in other suspensions, refusals or withdrawal of approvals*."

If we are unable to obtain regulatory approval of our products and product candidates on a timely basis or at all, our business may be impacted.

Our clinical trials may fail, and even if they succeed, we may not obtain regulatory approval for our products and product candidates or regulatory approval may be delayed.

Even if clinical trials are initiated, our development efforts may not be successful. 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. Even if we obtain positive results from preclinical studies or initial clinical trials, we may not achieve the same success in future trials.

Regulatory approval of our products or product candidates may be delayed or refused for many reasons, including:

- the Relevant Regulatory Authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate, to the satisfaction of the FDA or comparable foreign regulatory authorities, that our product candidates are safe, pure, potent and effective for any of their proposed indications;
- we may be unable to demonstrate our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA may determine that clinical trial results are not generalizable to the U.S. population and/or U.S. medical practice based on the proportion and results of subjects outside of the U.S. where differences in patient management might affect the treatment response;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- the chemistry, manufacturing and controls information submitted in a marketing application is insufficient; and
- the facilities of third-party manufacturers with which we contract for the manufacture of our product candidates are not adequate to support approval of our product candidates.

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

We could also experience operational challenges as we undertake an increasing number of clinical trials, including those conducted in countries outside the EU and the U.S. that may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non-EU and non-U.S. contract research organizations (***CROs***), as well as expose us to risks associated with clinical investigators who are unknown to the Relevant Regulatory Authorities, and apply different standards of diagnosis, screening and medical care.

If we experience delays in the completion of, or termination of, any clinical trial of our products or product candidates, our commercial prospects may be harmed. Any delays in completing our clinical trials may increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence

product sales and generate revenues. 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. 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.

If we decide to pursue accelerated approval for any of our product candidates, it may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval. If we are unable to obtain approval under an accelerated pathway, we may be required to conduct additional clinical trials beyond those that we contemplate, which could increase the expense of obtaining, reduce the likelihood of obtaining, and/or delay the timing of obtaining, necessary marketing approvals.

In the future, we may decide to pursue accelerated approval for one or more of our product candidates. Under the FDA's accelerated approval program, the FDA may approve a drug or biological product for a serious or life-threatening disease or condition that provides a meaningful advantage over available therapies based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. For products granted accelerated approval, post-marketing confirmatory trials are required to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. These confirmatory trials must be completed with due diligence, and the FDA may require that the trial be designed, initiated, and/or fully enrolled prior to approval. If we were to pursue accelerated approval for a product candidate for a disease or condition, we would do so on the basis that there is no available therapy for that disease or condition. If standard of care were to evolve or if any of our competitors were to receive full approval on the basis of a confirmatory trial for a drug or biological product for a disease or condition for which we are seeking accelerated approval before we receive accelerated approval, the disease or condition may no longer qualify as one for which there is no available therapy, and accelerated approval of our product candidate may not occur.

Moreover, the FDA may withdraw approval of any product candidate approved under the accelerated approval pathway if, for example:

- the trial or trials required to verify the predicted clinical benefit of our product candidate fail to verify such benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with such product;
- other evidence demonstrates that our product candidate is not shown to be safe or effective under the conditions of use;
- we fail to conduct any required post-approval trial of our product candidate with due diligence; or
- we disseminate false or misleading promotional materials relating to the relevant product candidate.

Recently, the accelerated approval pathway has come under scrutiny within the FDA and by Congress. The FDA has put increased focus on ensuring that confirmatory studies are conducted with diligence and, ultimately, that such studies confirm the benefit. The Food and Drug Omnibus Reform Act (***FDORA***) was recently enacted, which included provisions related to the accelerated approval pathway. Pursuant to FDORA, the FDA is authorized to require a post-approval study to be underway prior to approval or within a specified time period following approval. FDORA also requires the FDA to specify conditions of any required post-approval study and requires sponsors to submit progress reports for required post-approval studies. FDORA enables the FDA to initiate enforcement action for the failure to conduct with due diligence a required post-approval study, including a failure to meet any required conditions specified by the FDA or to submit timely reports.

Failure to obtain accelerated approval for our product candidates could result in a longer time period to commercialization of such product candidate, if any, and could increase the cost of development of such product candidate and harm our competitive position in the marketplace.

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 products or product candidates after they have received 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 more restrictive labeling or the delay or denial of regulatory approval by the Relevant Regulatory Authorities. While our preclinical studies and clinical trials 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 trials to date, and we may see additional adverse events and TEAEs in our ongoing and future clinical trials. Such side effects may be more serious than those observed to date, and as a result, our ongoing and future clinical trials may be negatively impacted. Moreover, as we seek to develop product candidates, including products in new indications, patients may experience new or more serious effects. Drug-related side effects could affect patient recruitment, the ability of enrolled patients to complete the clinical trial, result in potential product liability claims, damage sales of our existing products, result in significant reputational damage for us and our product development, and other issues including the delay of other 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 negatively impact us, our collaborators or our potential future partners. Further, we are developing a subcutaneous (***SC***) formulation of efgartigimod co-formulated with rHuPH20, an SC drug delivery technology, for the treatment of gMG and other indications, and side effects or adverse events associated with rHuPH20, may affect multiple of our products, and our product candidates. Further, the Relevant Regulatory Authorities 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.

If our target patient population is smaller than expected, we are unable to successfully enroll and retain patients in our clinical trials, or experience significant delays in doing so, we may not realize the full commercial potential of any products or product candidates.

Currently, we mainly develop products or product candidates for the treatment of rare diseases for which the target patient population can be small. If the actual number of patients with these disorders is smaller than we expected, we may encounter difficulties in enrolling sufficient patients in our clinical trials, thereby delaying or preventing development and approval of our products or product candidates. Physicians, who are an important source of referral of patients for clinical trials, may also be less familiar with these rare diseases and may therefore fail to identify these conditions in their patients and therefore may not refer them to our clinical trials.

Patient enrollment, a significant factor in the timing of clinical trials, depends on many factors, including the size and nature of the patient population, eligibility criteria for the clinical trial, the proximity of patients to clinical sites, competition for patient recruitment from competing clinical trials, the design of the clinical protocol, the eligibility criteria for the clinical trials, the availability of alternate approved therapies 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. We compete with other companies to enroll target patient populations, as set forth in the risk factor *"—We face significant competition for our drug discovery and development efforts."* Even if product candidates obtain significant market share for their approved indications, because certain potential target populations are small, we may never recoup our investment in such product candidate without obtaining regulatory approval for additional indications for such product candidates.

Even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our clinical trials. In addition, any negative results we may report in clinical trials of our drug candidates 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.

In addition, certain of patients enrolled in our clinical trials are located in areas subject to conflict, hostilities or war, or countries that continue to be impacted by COVID-19. See the risk factors under the headers "—*Global geo- and socio-political threats and macro-economic uncertainty and other unforeseen political crises could materially and adversely affect our business and financial performance*" and "—*We face risks related to natural disasters and public health issues, such as the COVID-19 pandemic, that could negatively affect our business and financial condition.*"

Risk Factors Related to argenx's Dependence on Third Parties

We rely, and expect to continue to rely, on third parties to conduct some of our research activities and clinical trials and for parts of the development and commercialization of our existing and future research programs, products and product candidates. If our relationships with such third parties are not successful, our business may be adversely affected.

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators, CROs, CMOs and other third-party service providers, to assist us in the conduct of certain of our research activities and clinical trials and to monitor and manage data for our ongoing preclinical studies and clinical trials. We also depend on our collaborators and on medical institutions and CROs to conduct our research activities and clinical trials in compliance with regulatory and legal requirements, including GCPs or GMPs, our standard operating procedures and our applicable protocols. Nevertheless, we are responsible for ensuring that each of our studies and clinical 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. To the extent our collaborators or the CROs or investigators fail to enroll participants for our clinical trials, fail to conduct the clinical trial to GCP standards or in full compliance with legal and regulatory requirements or are delayed for a significant time in the execution of

clinical trials, including achieving full enrollment, we may be affected by increased costs, program delays or both, which may harm our business.

In addition, we are, and expect to continue to be, dependent on partnerships with partners and licensees relating to the development and commercialization of our existing and future research programs, products and product candidates. We currently have collaborative research relationships with various pharmaceutical companies such as AbbVie SARL (***AbbVie***), Zai Lab and with various academic and research institutions worldwide for the development of product candidates resulting from such collaborations. We also have distribution agreements with Medison and Genpharm for the distribution of VYVGART. 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 and to commercialize our existing or future products could be delayed, the commercial potential of our products could change and our costs of development and commercialization could increase.

While we have agreements governing our relationships with these third parties, we have limited influence over their actual performance and control only certain aspects of their activities. If independent investigators, third-party service providers 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, 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 Relevant Regulatory Authorities 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, which may require us to repeat clinical trials and delay the regulatory approval process. Our collaborative partners may not adhere or terminate collaboration agreements with all associated consequences or disagree on the interpretation of contractual terms. 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 commercialization and the profitability of such products. Failures by our collaborative partners to meet their contractual, regulatory, or other obligations to us or any disruption in the relationships between us and our collaborative partners, could have a material adverse effect on our product pipeline and business.

We face significant competition in establishing successful relationships with third-party service providers and appropriate collaborative partners. These third-party service providers may have contractual relationships with other entities, some of which may be our competitors, which may draw their time and resources away from our programs. In addition, some of our third-party service providers or CROs have the ability to terminate their respective agreements with us, and if such agreements terminate, we may not be able to enter into arrangements with alternative CROs or investigators or to do so on commercially reasonable terms. In addition, we may not be able to find appropriate collaboration 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.

Disruptions caused by our reliance on third parties for our manufacturing process may delay or disrupt our business, product development and commercialization efforts.

We do not have the ability to internally source the raw materials necessary to produce our product or product candidates, and do not currently have, nor do we plan to acquire, the infrastructure or capability internally to manufacture our products or product candidates and depend on a worldwide supply chain and third parties for both.

Disruptions caused by our reliance on such third-party suppliers, service providers and manufacturers may delay or disrupt our business, product development and commercialization efforts.

Reliance on Third-Party Suppliers and Service Providers

For some of our raw materials, we rely on a single source of supply and there are limited supplies of the raw materials. 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, including for example if VYVGART is approved for additional indications, we could experience delays in our research or planned clinical trials or risk shortages in commercial supply which could materially impact our revenue potential. These issues could be made worse during a pandemic or due to geopolitical events, including trade disputes or economic sanctions enacted as a result of international conflict.

Additionally, 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 including rigorous testing requirements, which could limit or delay production. If there are changes in the regulation requirements that our suppliers are unable to meet, our clinical development or commercial activities may be delayed or interrupted.

We may not be able to engage a back-up or alternative supplier or service provider in a timely manner or at all 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 reasons, 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 also result from international conflict, trade disputes or economic sanctions enacted by, or imposed on, the U.S., the UK, the EU or any other country or region.

Reliance on Third-Party Manufacturing

We rely on and expect to continue to rely on CMOs. We also 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.

Although we do not control the manufacturing process at our CMOs and are completely dependent on them for the production of our products and product candidates in accordance with relevant regulations (such as cGMPs), we are responsible for ensuring that our products comply with regulatory requirements. If our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the Relevant Regulatory Authorities or other comparable regulatory authorities, our business could be adversely affected in a number of ways, including an inability to initiate or continue clinical trials of product candidates under development, delay in submitting regulatory applications, or receiving regulatory approvals for product candidates, including new indications, subjecting third-party manufacturing facilities to additional inspections by regulatory authorities, requirements to cease distribution or to recall batches of our products or product candidates and an inability to meet commercial demands for our marketed products.

We contract with Lonza Sales AG (***Lonza***) based in Slough, UK, Portsmouth, U.S. and Singapore and FUJIFILM Diosynth Biotechnologies Denmark ApS (***Fujifilm***) for activities relating to the development of cell banks, development of our manufacturing processes and the manufacturing of drug substance, and use additional contract manufacturers to fill, test, label, package, store and distribute our (investigational) drug products. Our products and product candidates are biologics and require multiple processing steps that are more difficult than those required for most small molecule chemical pharmaceuticals. 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.

We face risks inherent in relying on limited CMOs, as any failure in their ability to successfully manufacture our products or product candidates as described above or 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 at 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.

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, including distributor and licensing partners, on certain product candidates. 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 inaccurate, it would adversely impact the timing and accuracy of our own financial reporting. Any inaccuracy in our financial reporting could cause investors to lose confidence in our financial reporting. This in turn may lead to reputational damage or affect our ability to obtain, and the terms of, any future financing, which may harm our business.

We and our third-party manufacturers and suppliers may become exposed to liability, fines, penalties or other sanctions and substantial expenses in connection with environmental compliance or remediation activities.

Our and our third-party manufacturers and suppliers operations, including 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, laboratory procedures and exposure to pathogens. We do not have control over our manufacturers’ or suppliers’ compliance with environmental, health and safety laws and regulations. If we, or they fail to comply with such laws and regulations, we could be subject to liability, fines, penalties or other sanctions and incur substantial expenses to comply or remediate the activities.

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.

Risk Factors Related to argenx’s Business and Industry

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, or insider trading violations, which could significantly harm our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with governmental regulations, comply with healthcare fraud and abuse and anti-kickback laws and regulations in the U.S. and other markets, or failure to report financial information or data accurately or disclose unauthorized activities to us. In particular, 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. Employee misconduct could also involve the improper use of, including improper trading based upon, information obtained in the course of clinical studies, which could result in regulatory sanctions and serious harm to our reputation. We maintain a global

compliance program and remain focused on its evolution and enhancement. Our program includes efforts such as risk assessment and monitoring, fostering a culture encouraging employees and third parties to raise good faith questions or concerns, and defined processes and systems for reviewing and remediating allegations and identified potential concerns. It is not always possible, however, to identify and deter employee misconduct, 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 these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

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 and marketing of human therapeutic products. The current and future use of products and product candidates by us and our collaborators in clinical trials and the sale of any approved products may further expose us to liability claims. If any of our products or 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. These claims might be made by patients who use the product, healthcare providers, pharmaceutical companies, physicians, payors, caregivers, investors, employees, government agencies, or our collaborators or others selling such products. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. 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. Any such claims, regardless of their merit, could also adversely affect our reputation and the trust that physician and patients place in our products.

Regardless of the merits or eventual outcome litigation or 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 clinical 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 clinical trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenues from product sales; and
- the inability to successfully commercialize VYVGART and any of our other product candidates, if approved.

Although we maintain product liability insurance, we may not be able to maintain insurance coverage at a reasonable cost or to obtain adequate insurance coverage to satisfy any liability that may arise. Product liability claims could delay or prevent completion of our clinical development programs. In addition, claims made by patients, healthcare professionals or others might not be fully covered by product liability insurance and could result in investigations of the safety of our products or product candidates or may result in recalls. 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, financial condition and results of operations would be adversely affected.

We may engage in strategic transactions, including acquisitions, collaborations, licenses or investments in other companies or technologies, and we may not realize the benefits of such transactions.

We may enter into strategic transactions, including acquisitions, collaborations, licenses or investments for or in other companies or technologies that complement or augment our existing business and facilitate our access to new products, research projects or geographical areas. However, we may not be able to identify appropriate targets or enter into such transactions under satisfactory conditions. In addition, we may need additional funding to finance these transactions including through issuances of public or private equity or convertible debt securities, which could be dilutive to our shareholders and ADS holders.

Integrating any newly acquired companies, business, technologies or products could be expensive, time-consuming, and may never be successful. Integration efforts often take a significant amount of time, place a significant strain on managerial, operational and financial resources, result in loss of key personnel and could prove to be more difficult or expensive than we predict. The diversion of our management's attention and any delay or difficulties encountered in connection with any future transactions we may consummate could result in the disruption of our ongoing business or inconsistencies in standards and controls that could negatively affect our ability to maintain third-party relationships. We cannot assure that we will achieve the expected synergies to justify any such transaction, which could have a material adverse effect on our business, financial condition, results of operations and future growth prospects and our investors' ability to realize on their investment.

Our business and operations could suffer in the event of system failures or unauthorized or inappropriate use of or access to our systems.

We are increasingly dependent on our information technology systems and infrastructure for our business. We collect, store and transmit sensitive information including intellectual property, proprietary business information, including highly sensitive clinical trial data, and personal information in connection with business operations. The secure maintenance of this information is critical to our operations and business strategy. Some of this information could be an attractive target of criminal attack or unauthorized access and use by third parties with a wide range of motives and expertise, including organized criminal groups, "hacktivists," patient groups, disgruntled current or former employees and others. Cyber-attacks are of ever-increasing levels of sophistication, and despite our security measures, our information technology and infrastructure may be vulnerable to such attacks or may be breached, including due to employee error or malfeasance.

The pervasiveness of cybersecurity incidents in general and the risks of cyber-crime are complex and continue to evolve. Although we are making significant efforts to maintain the security and integrity of our information systems and are exploring various measures to manage the risk of a security breach or disruption, there can be no assurance that our security efforts and measures will be effective or that attempted security breaches or disruptions would not be successful or damaging. Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage or interruption from computer viruses, unauthorized or inappropriate access or use, natural disasters, pandemics (including COVID-19), terrorism, war (including the ongoing conflict in Ukraine), and telecommunication and electrical failures. Such events could cause interruption of our operations. For example, the loss of pre-clinical trial data or data from completed or ongoing clinical trials for our product candidates could result in delays in our regulatory filings and development efforts, as well as delays in the commercialization of our products, and significantly increase our costs. To the extent that any disruption, security breach or unauthorized or inappropriate use or access to our systems were to result in a loss of or damage to our data, or inappropriate disclosure of confidential or proprietary information, including but not limited to patient, employee or vendor information, we could incur notification obligations to affected individuals and government agencies, liability, including potential lawsuits from patients, collaborators, employees, stockholders or other third parties and liability under foreign, federal and state laws that protect the privacy and security of personal information, and the development and potential commercialization of our product candidates could be delayed.

We are highly dependent on public perception of our products.

We are highly dependent upon consumer perceptions of the safety and quality of our products. We could be adversely affected if we, or any of our collaborators, are 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, or for example, be deemed cruel to animals. 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.

Risk Factors Related to argenx's Intellectual Property

Failure to adequately enforce or protect our intellectual property rights in products, product candidates and platform technologies could adversely affect our ability to develop and market our products and product candidates.

Our commercial success depends in part on obtaining and maintaining patents and other forms of intellectual property rights for our products, product candidates and platform technologies. Failure to protect or to obtain, maintain or extend adequate patent and other intellectual property rights, which may be challenging and costly, could adversely affect our ability to develop and market our products and product candidates and erode or negate any competitive advantage we may have.

We cannot be certain that patents will be issued or granted with respect to applications that are currently pending. The scope of patent protection that the European Patent Office and the U.S. Patent and Trademark Office (***USPTO***) will grant with respect to the antibodies in our product pipeline is uncertain and may vary by jurisdiction. 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 thereby decreasing our market potential.

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. 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. Moreover, in some circumstances, we may need to rely on patent procurement activities of our licensors, licensees or collaboration partners or obtain additional costly licenses. Such parties may not fully comply with applicable patent rules or disagree with us as to the prosecution, maintenance or enforcement of any patent rights. Even if patents do issue and such patents cover our products and product candidates, third parties may initiate proceedings challenging the validity, enforceability or scope of such patents, which may result in the patent claims being narrowed or invalidated. Our and our licensors', licensees' or collaboration partners' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology.

Furthermore, 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 and product candidate. 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.

We enjoy only limited geographical protection with respect to certain patents and may face difficulties in certain 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 are usually filed within twelve months after the priority filing. We have so far not filed for patent protection in all national and

regional jurisdictions where such protection may be available. If we fail to timely file a patent application in any such country or major market, we may be precluded from doing so at a later date. In addition, the grant proceeding of each national/regional patent may lead to situations in which applications might in some jurisdictions be refused by the relevant patent offices, while granted by others. Furthermore, 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., UK and the EU. Finally, some countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties, and other 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.

Issued patents could be found invalid or unenforceable if challenged in the applicable patent office or court.

Once granted, patents may remain open to invalidity challenges for a given period after allowance or grant, during which time third parties can raise objections against such granted patent. In the course of such proceedings, the patent owner may be compelled to limit the scope of the allowed or granted claims thus challenged or may lose the allowed or granted claims altogether.

To protect our competitive position, we may from time to time need to resort to litigation in order to enforce or defend any intellectual property rights owned by or licensed to us, or to determine or challenge the scope or validity of 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. In addition, litigation involving our patents carries the risk that one or more of our patents will be held invalid or held unenforceable. Such an adverse court ruling could allow third parties to commercialize our products or use our platform technologies, and then compete directly with us, without payment to us.

We may be subject to claims challenging the inventorship or ownership of our intellectual property or be required to make additional payments to secure intellectual property from collaborators.

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 of any such consultant's or employee's former employer or have breached their non-competition agreement. Additionally, many of our collaborators do not commit to assigning all intellectual property arising out of the collaboration to us and, instead, grant us options to acquire intellectual property or commit to making such intellectual property available to us at a fair price. As such, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our products and product candidates.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with such party. Our and their assignment agreements may not be self-executing or may be breached and we may be forced to bring claims against third parties or defend claims they may bring against us to determine the ownership of what we regard as our intellectual property.

There is no guarantee we will be successful in defending such claims, which would result in us paying monetary damages, or lose valuable personnel or intellectual property rights.

Third-party intellectual property rights could adversely affect our ability to commercialize our products and product candidates.

Our competitive position may suffer if third-party intellectual property rights cover our products or product candidates or our manufacture or uses relevant to our development plans. In such cases, we may not be in a position to develop or commercialize products or product candidates unless we successfully pursue costly and time-consuming litigation to nullify or invalidate the third-party intellectual property right concerned or enter into a license agreement with the intellectual property right holder. We are aware of certain U.S. issued patents held by third parties that arguably 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. 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, we could be prevented from continuing to develop or commercialize our product. Similarly, other companies have filed patent applications or have patents on the targets for certain of our products 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.

It is also possible that we are unaware of relevant patents or applications or of relevant scientific discoveries. 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. Additionally, publications of discoveries in scientific literature often lag behind the actual discoveries. Therefore, patent applications covering our products, product candidates or platform technology could have been filed by others and relevant discoveries may have been made without our knowledge. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our products or platform technologies.

Third-party intellectual property right holders, including our competitors, may actively bring infringement claims against us that we may not be able to successfully settle or otherwise resolve.

If we fail in any such dispute, 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, thereby giving our competitors access to the same technologies licensed to us or our licensors or collaboration partners. 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 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.

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

We may be unable to acquire or in-license third-party intellectual property rights that we identify as an appropriate strategic fit for our Company and necessary for our product candidates and technology. A number of more established companies with greater resources may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive.

We sometimes collaborate with U.S. and non-U.S. academic institutions to accelerate our preclinical research or development. 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, in which case 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, in which case we may have to abandon development of that product candidate or program.

Existing license agreements impose various development, payment and other obligations. If we fail to comply with our obligations under these agreements, the licensor may have the right to terminate the license. Several of our existing license agreements are sub-licenses from third parties who are not the original licensors of the intellectual property at issue. 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, causing us to lose our rights to the applicable intellectual property if we are unable to secure our own direct license with the owner of the relevant rights on reasonable terms.

Further, if disputes over intellectual property that we have licensed or our associated obligations 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, we may not be able to build name recognition in our markets of interest.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. Third parties may oppose or attempt to cancel our trademark applications or trademarks or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we may not be able to use these trademarks to market our products in those countries and could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks. If we attempt to enforce our trademarks and assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. Over the long term, if we are unable to establish name recognition, we may not be able to compete effectively. 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.

We may not be able to obtain protection under the Hatch-Waxman Act and similar non-U.S. legislation for extending the term of patents covering each of our products and product candidates.

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 Hatch-Waxman Act and similar legislation in the EU and the Asia Pacific region. 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 or 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.

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

Changes in patent law and regulations in the various countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces them may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. For example, 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. Such changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

We may be unable to protect the confidentiality of our trade secrets and know-how.

In addition to patent protection, we rely on trade secret protection for our proprietary information, 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 numerous licensors, collaborators and suppliers.

We 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, advisors and potential collaborators may unintentionally or willfully disclose our confidential information to competitors despite these procedures or in violation of our confidentiality agreements. In addition, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known to our competitors or inadvertently incorporated into the technology of others. Any disclosure, either intentional or unintentional, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements.

Enforcing a claim that a third party illegally obtained 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.

As a global organization in a highly competitive and specialized industry, our success depends upon the continued contributions of our key management, scientific, medical and technical personnel, many of whom have been instrumental for us and have substantial experience with our product and related technologies. These key management individuals include the members of our Board of Directors and senior management team. Difficulties in recruiting or the loss of key managers, scientific, medical or technical personnel could delay our research and development activities. In addition, it may be difficult to attract and retain highly qualified management, scientific and medical personnel, particularly if we expand into fields that will require additional skills.

As a Dutch company listed on Euronext Brussels in addition to the Nasdaq Global Select Market (***Nasdaq***), our remuneration practices and policies may be limited by local governance rules or shareholder guidance for EU companies. Such limitations may make it more difficult to successfully compete for key talent in a number of markets that have differing remuneration practices and policies as we are bound by more restrictive remuneration practices than our competitors. For example, the DCGC places certain limitations on the ability to grant equity incentives to non-executive directors, while Belgian law requires non-executive directors to receive part of their remuneration in the forms

of shares, but not stock options. The DCGC also places limitations on amount of severance payment permitted in the event of dismissal. In addition, the U.S. has proposed legislation that imposes restrictions on our ability to prevent departing employees from competing with us following their departure. If finalized, such legislation could also adversely affect our ability to retain employees who may go to competitors with more resources than us and who are not bound by similar remuneration policies.

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. Additionally, an inflationary environment, combined with the tight labor market for the recruitment and retention of skilled workers, 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. Therefore, we might not be able to attract or retain these key persons on conditions that are economically acceptable.

Global geo- and socio-political threats and macro-economic uncertainty and other unforeseen political crises could materially and adversely affect our business and financial performance.

Many geo- and socio-political threats and macro-economic uncertainties are outside of our control, including general economic and market conditions, consumer and commercial credit availability, inflation, interest rates, unemployment, consumer debt levels, political crises, such as terrorist attacks, war and other political instability, economic sanctions and other challenges affecting the global economy, including the Russia-Ukraine conflict, disruptions in supply chains, and changes in trade agreements which could adversely affect consumer confidence and disposable income levels, increase difficulty in forecasting our financial results and have other impacts on our business and financial performance.

Due to our international operations and the fact that we run clinical trials in a large number of jurisdictions, the eruption of global conflicts, such as the continuing conflict between Russia and Ukraine may negatively impact our ability to conduct or complete clinical trials in the affected regions, which could adversely affect our business and financial performance. For example, a relevant minority of the patients in the ADDRESS trial of SC efgartigimod for pemphigus vulgaris (***PF***) and pemphigus foliaceus (***PV***) are participating in studies conducted in Ukraine or Russia. The U.S. Department of the Treasury’s Office of Foreign Assets Control has issued General License 6B, which authorizes “ongoing clinical trials and medical research activities”. Following a risk assessment relating to the conflict between Russia and Ukraine, we increased target enrollment, which delayed expected topline data of SC efgartigimod for PV and PF to the second half of 2023. Additionally, the conflict between Russia and Ukraine and the sanctions imposed upon Russia by the U.S., the UK, and the EU, among others could disrupt:

- the recruitment and enrollment of eligible patients who may not be able to travel safely to clinical trial sites or may be forced to withdraw for a number of reasons;
- the closure or destruction of clinical sites or treatment facilities;
- the ability to compensate patients or staff living in sanctioned countries;
- the manufacturing process for our products or supply chain, which could increase the costs of raw material and production costs;
- the ability to transport, deliver, supply and collect necessary materials, products or services to clinical trial sites or deliver them to third-party central laboratories’ for analysis;
- the ability to collect data from clinical trial sites and ensure the integrity of any data collected;
- the destruction or disruption of our data centers or our critical business or information technology systems; or

- the ability to submit data collected at Russian or Ukrainian sites due to the incompleteness or the fact that auditing by regulatory authorities was not fully possible.

To date, other than as described above and elsewhere in this Annual Report, we have no indication that the conflict between Russia and Ukraine and the corresponding sanctions imposed on Russia will significantly hinder our clinical development activities performed in the affected regions or regulatory activities relevant for our pending or expected approval requests. Moreover, we do not generate revenues in Russia, and we gather more regular feedback from and to stakeholders and team members in Russia and Ukraine. However, we also perform development activities in a number of countries neighboring Russia and Ukraine and if the conflict were to escalate further and impact neighboring countries, it could impact our development activities in those countries.

We face risks related to natural disasters and public health issues, such as the COVID-19 pandemic, that could negatively affect our business and financial condition.

Our business could be adversely impacted by the effects of catastrophic global events including natural disasters such as an earthquake, fire, hurricane, tornado, flood or significant power outage and pandemics, such as the COVID-19 pandemic.

For example, 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 cGMPs. 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.

Public health issues could also negatively affect our business and financial condition. We operate and conduct our clinical trials globally, including in areas impacted by COVID-19 in North America, Europe, the PRC and Japan. We cannot presently predict the scope and severity of any potential future business shutdowns or disruptions as a result of COVID-19. 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, were to experience shutdowns, quarantines, or other business disruptions to stop the spread of a pandemic, it may impair our or our third-party partners' ability to initiate clinical trials and recruit and retain patients, particularly if quarantine or travel restrictions impede healthcare provider or patient movement, impact the usability of the data due to treatment interruptions and require protocol amendments. 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. In addition, if we and/or one of our partners elect not to move forward with some or all of our 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.

The COVID-19 pandemic has also impacted third parties in a number of different ways. For example, we were 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. Moreover, as of the date of this Annual Report, the FDA is subject to ongoing travel restrictions that impact FDA 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. While the number of FDA inspection-related delays decreased in 2022, there is a risk that such delays may occur again. 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.

We may encounter difficulties efficiently managing our growth and our increasing development, regulatory and sales and marketing capabilities, which could disrupt our operations.

We have grown significantly in the number of employees and scope of operations over 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. In particular, we must efficiently leverage our own sales and marketing capabilities in order to launch or market our products candidates effectively.

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. Our limited financial, manufacturing and management resources, could cause us to forgo or delay the pursuit of opportunities with potential product candidates that later prove to have greater market potential, fail to capitalize on viable commercial products or profitable market opportunities or 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. 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.

We have benefited from certain research and development incentives in Belgium, which may be re-evaluated if our shareholder base changes significantly. The Belgian authorities may challenge our eligibility for or our calculation of such incentives.

As a company active in research and development in Belgium, we have benefited from certain research and development tax incentives, in particular a tax credit and a payroll withholding tax exemption. The tax credit is calculated as a percentage of qualifying investments in research and development; it can be offset against corporate income tax and is refunded to us in cash after five years to the extent it could not be offset. The payroll tax exemption results in a reduction of the payroll cost for highly qualified personnel engaged in research and development projects. We also expect to benefit from the Belgian innovation income deduction, which allows net profits attributable to revenue from among others patented products (or products for which the patent application is pending) to be taxed at a lower effective tax rate than other revenues. The relevant Belgian authorities may challenge our eligibility for, or our calculation of, such tax incentives and, should such a challenge be successful, we may be liable for additional taxes, and penalties and interest related thereto, which could have a significant impact on our results of operations and future cash flows. In case of a change of control of the Company, we could be exposed to the risk of losing the unused tax credit and innovation income deduction. Furthermore, if the Belgian legislator decides to eliminate, or change the conditions for claiming, such tax incentives, or reduce the scope or the rate of, such incentives, any of which it could decide to do at any time, our results of operations could be adversely affected.

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, fully available in future periods. We cannot guarantee that our interpretation of applicable tax laws or our 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 or change in law 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.

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 or the interpretation thereof by the relevant tax authorities in countries where we have material operations, including changes to the Belgian innovation income deduction, to the corporate income tax base, or to other tax incentives and the implementation of new tax incentives. A successful challenge to our qualifications for and application of these tax incentives by the tax authorities in Belgium or other country where we have material operations would have a significant impact on our effective tax rate and on our tax assets. An increase of the effective tax rates could have an adverse effect on our business, financial position, results of operations and cash flows.

On December 14, 2022, the Council of the EU adopted Directive (EU) 2022/2523 on ensuring a global minimum level of taxation for multinational enterprise groups and large-scale domestic groups in the Union (***Pillar Two Directive***). The Pillar Two Directive should be implemented in the EU Member States' national law by December 31, 2023. If the Pillar Two Directive is implemented under domestic laws in any of the jurisdictions in which the Group operates, or via international treaties entered into between such jurisdictions, the Pillar Two Directive may have an impact on the Group's effective tax rate as well as increase the Group's tax compliance costs incurred to track and collect such taxes. Based on current information, we expect that the Group could become subject to the Pillar Two Directive and implementing domestic laws as early as 2025. However, whether the Pillar Two Directive will have an impact on the Group's tax liabilities and operations cannot be determined accurately and remains uncertain.

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, we have considerable material tax assets in Belgium and some of these tax assets may be forfeited in whole, or in part, as a result of various transactions, including corporate reorganizations or transactions relating to our shareholding structure, or their utilization may be restricted by statutory law in the relevant jurisdiction.

Risks Related to the ADSs

The price of our 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 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. During 2022, the closing sales price of our ADSs representing our ordinary shares on Nasdaq fluctuated greatly, ranging from $254.45 to $402.31. 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, which may limit or prevent investors from readily selling their ADSs or ordinary shares and may otherwise negatively affect the liquidity of our ADSs and ordinary shares. 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 the market price of our securities or our ability to raise capital through the sale of additional equity securities.

In addition, an active public trading market for our ADSs or our ordinary shares may not be sustained. Further, fluctuations in exchange rates may also impact the price of our ADSs and ordinary shares which may result in heavy trading by investors seeking to exploit such differences, or impact the proceeds holders receive.

If we fail to maintain an effective system of disclosure controls and internal control over financial reporting, our ability to comply with applicable regulations could be impaired, and the trading price of our ADSs may be negatively impacted.

We are required to comply with various corporate governance and financial requirements under the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the Nasdaq listing requirements, and other applicable securities rules and regulations. Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, we are

required to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting and an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation. Moreover, any failure to maintain internal control over financial reporting or any material weaknesses or significant deficiency thereover, could result in a loss of investors' in the accuracy, completeness and reliability of our financial statements, subject us to sanctions or investigations, or negatively impact the trading price of our ADSs.

Holders of our ADSs are not treated as holders of our ordinary shares and 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, 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 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. Temporary delays in the cancellation of 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.

Holders of our ADSs do 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 their right to vote.

Except as described in this Annual Report or any deposit agreements, holders of ADSs are not treated as our shareholders unless they withdraw the ordinary shares underlying their ADSs. The depository, or its nominee, is the holder of the ordinary shares underlying the ADSs. Holders may vote them in person or by proxy in accordance with applicable laws and regulations and our Articles of Association. We cannot guarantee that holders of ADSs will receive the voting materials in time to ensure that they can instruct the depositary to vote the ordinary shares underlying their ADSs. Our shareholders are only entitled to participate in, and vote at, a general meeting of our shareholders (***General Meeting***), provided that their shares are recorded in their name sat midnight (Central European Time) at the end of the twenty-eighth day preceding the date of such General Meeting. In addition, the depositary's liability to holders of ADSs for failing to execute voting instructions or for the manner of executing voting instructions is limited by the deposit agreements. As a result, holders of our 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.

If securities or industry analysts cease coverage of us, or publish inaccurate or unfavorable research about our business, the price of our 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 of our ADSs and ordinary shares would likely be negatively affected. If one or more of the analysts who cover us downgrade our ADSs or ordinary shares or publish inaccurate or unfavorable research about our business, the price of our ADSs or ordinary shares would likely decline.

Risks Related to being a Foreign Private Issuer or a Dutch Company

The risks in this subsection that relate to our status as a foreign private issuer will change if we lose our status as a foreign private issuer.

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. 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.

As a result of these differences between Dutch corporate law and our Articles of Association, on the one hand, and the U.S. federal and state laws, on the other hand, in certain instances, our shareholders and holders of our ADSs could receive less protection than they would as shareholders or ADS holders of a listed U.S. company.

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 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.

Holders of our ordinary shares outside the Netherlands, and holders of ADSs 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 a General Meeting, or by a resolution of the Board of Directors (if the Board of Directors has been designated by the shareholders at a 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 U.S. 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. 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 holders of ADSs, which we are not required to do.

We are not obligated to, and do not comply with, all the best practice provisions of the DCGC, which may affect shareholders' rights.

As a Dutch public company with limited liability, we are subject to the DCGC. 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 filed in the Netherlands.

Claims of U.S. civil liabilities may not be enforceable against us or the members of our management and our Board of Directors.

Substantially all of our assets are located outside the U.S. The majority of the members of our senior management team and our directors are not U.S. residents and we do not have significant assets in the U.S. As a result, it may not be possible, or may be very difficult, for investors to effect service of process within the U.S. 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. There are no treaties between the U.S. 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 U.S. based on civil liability, whether or not predicated solely upon U.S. securities laws, would not automatically be recognized or enforceable in the Netherlands or in Belgium unless the underlying claim was re-litigated before a Dutch or Belgian court of competent jurisdiction. This will depend on the applicable Dutch or Belgian national rules. In light of the above, U.S. investors may not be able to enforce any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities laws, against us, members of our management or our Board of Directors or certain experts named herein who are residents of the Netherlands, Belgium or countries other than the U.S.. In addition, there is doubt as to whether a Dutch or Belgian court would impose civil liability on us or the members of our management or of our Board of Directors in an original action predicated solely upon the U.S. federal securities laws brought in a court of competent jurisdiction against us, our management or directors.

As a foreign private issuer, we are exempt from certain rules under U.S. securities laws and are permitted to file less information with the SEC than a U.S. company.

As a "foreign private issuer" defined in the SEC's rules and regulations, we are exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies.

We are subject to Dutch laws and regulations with regard to such matters. While we furnish quarterly unaudited financial information to the SEC on Form 6-K, the information we furnish to the SEC is less extensive and less timely compared to that required to be filed with the SEC by U.S. domestic issuers.

As a foreign private issuer, we are permitted to adopt certain home country governance practices rather than the corporate governance requirements of Nasdaq. These practices may afford less protection to shareholders than they would enjoy if we complied fully with corporate governance listing standards.

As a foreign private issuer listed on Nasdaq, we are subject to corporate governance listing standards. However, we are permitted to rely on home country governance requirements and certain exemptions thereunder. Certain of our corporate governance practices may differ significantly from other corporate governance listing standards, as set forth in Item 16.G. *"Corporate Governance."*

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.

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 U.S. 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 U.S. and (iii) our business must be administered principally outside the U.S. As of February 1, 2023, 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 U.S.).

The regulatory and compliance costs to us as a U.S. domestic issuer may be significantly higher than those we incur as a foreign private issuer. 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 were to be classified as a PFIC for U.S. federal income tax purposes, this could result in adverse U.S. tax consequences to certain U.S. holders.

If our Company is classified as PFIC for any taxable year, U.S. investors may be subject to adverse U.S. federal income tax consequences described under Item 10.E. *"Taxation–Certain Material U.S. Federal Income Tax Considerations for U.S. Holders–Passive Foreign Investment Company Considerations."* Our Company will be a PFIC