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## 2 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. Our business, financial condition or results of operations could be materially and adversely affected if any of these risks occur. These are not the only risks argenx faces. Additional risks and uncertainties not presently known to argenx or that it currently considers immaterial or not specific may also impair its business, results of operation and financial condition. 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 as may be described in our subsequent SEC filings. See "[Forward-Looking Statements](#)".

### 2.1 Summary 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:

- 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.
- We will face significant challenges in successfully commercializing our products and additional product candidates after they are launched.
- Our products and product candidates for which we have obtained or intend to seek approval as biological products, including for new indications, may face biosimilar competition.
- Enacted and future legislation and regulations 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, which affect the prices we may charge the government for our products and the reimbursement our customers may obtain from the government. Changes in such laws, regulation, and enforcement may place downward pressure on the prices we can charge in the marketplace, and our failure to comply with these laws could harm our results, operations and/or financial conditions.
- We may not obtain or maintain adequate pricing and coverage or reimbursement status for our products and product candidates.
- If we fail to obtain orphan drug designation or we do not have valid and enforceable patents covering our products and their uses and product candidates and fail to obtain and/or maintain orphan drug exclusivity for our products or product candidates, our competitors may be able to sell products to treat the same conditions and our revenue may be reduced.
- Failure to successfully identify, select and develop our products in other indications, or additional products or product candidates could impair our ability to grow.
- Failure to successfully develop or obtain marketing approval for our products and product candidates could negatively impact our business.
- Certain of our clinical trials have not succeeded, and may in the future also not succeed, and even if they succeed, we may not obtain regulatory approval for our products or product candidates or regulatory approval may be delayed.
- If we decide to pursue accelerated approval for any of our product candidates, it may not lead to faster development or regulatory review or approval and we may still need to conduct additional clinical trials, which could increase the expense of obtaining, if at all, necessary marketing approvals.

- Our products and product candidates may have serious adverse, undesirable or unacceptable side effects, and we or others may identify undesirable or unacceptable side effects caused by any of our products or product candidates before and after they have received marketing approval.
- 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.
- We rely, and expect to continue to rely, on third parties to conduct some of our research activities, manufacturing 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 raw materials and 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.
- We are subject to healthcare laws, regulation and potential enforcement. The failure to comply with these laws could harm our results, operations and/or financial condition.
- Our performance tracked by our Environmental, Social and Governance metrics is subject to risks and the outcomes may not achieve the anticipated benefits or align with new regulations and stakeholders' expectations.
- We may not be able to be profitable or sustain net profitability in the future and may require additional financing to fund our operations.
- We may become exposed to costly and damaging liability claims.
- 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.
- Our business and operations could suffer in the event of system failures or unauthorized or inappropriate use of or access to our systems.
- We may be unable to adequately maintain, enforce or protect our intellectual property rights in products, product candidates and platform technologies which could adversely affect our ability to maximize the value for patients in our marketed products and product candidates.
- Intellectual property litigation could lead to substantial resource diversion or issued patents could be found invalid, not infringed, or unenforceable if challenged in the applicable patent office or court.
- Our future growth and ability to compete depends on maintaining our culture, 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.
- Holders of our ADSs have fewer rights than our ordinary shareholders.
- The price of our ADSs may be volatile and may fluctuate due to factors beyond our control. An active public trading market may not be sustained.
- Claims of U.S. civil liabilities may not be enforceable against us or the members of our Senior Management Team and our Board of Directors.
- As a foreign private issuer, we are exempt from various rules and regulations that a U.S. domestic public company would be required to follow, including those requirements under U.S. securities laws and Nasdaq listing standards.
- 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.
- If we were to be classified as a passive foreign investment company for U.S. federal income tax purposes, this could result in adverse U.S. tax consequences to certain U.S. holders.

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

**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 any 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 or sustain net profitability in the future. This will depend on a number of factors, many of which are beyond our control, including, but not limited to:

- consumer perceptions or publicity regarding our business or the efficacy, safety and quality of the products and product candidates in our profile, our clinical trials for new indications, or any similar products distributed by other companies, and the prevalence and severity of any adverse effects discovered before or after marketing approval has been received;
- 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;
- relative availability, cost, and convenience of alternative approved therapies;
- labeling may require significant use or distribution restrictions or safety warnings;
- acceptance by physicians, public health bodies, patients and healthcare payors of each product as safe, effective and cost-effective; and
- patients continued commitment required to receive periodic in-center infusions.

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, including by one of our competitors, 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 and product candidates 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, it 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. Many of these companies are highly sophisticated and often strategically collaborate with each other.

Competition in the autoimmune field is intense and involves multiple mAbs, other biologics and small molecules either already marketed or in development by many different companies including, but not limited to, large pharmaceutical companies such as AstraZeneca plc, AbbVie, Inc., Amgen, Inc., Biogen Inc., GlaxoSmithKline plc, F. Hoffman-La Roche AG, Johnson & Johnson Innovation, Inc. and Novartis AG.

In addition, these and other pharmaceutical companies have mAbs or other biologics in clinical development for the treatment of autoimmune diseases.

Currently, our commercial revenue is generated by VYVGART and VYVGART SC in gMG, CIDP and ITP (Japan only). We face and expect to continue to face intense competition from other biopharmaceutical companies, who have launched or are developing products for the treatment of gMG and/or CIDP 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 by competitors 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 certain biopharmaceutical companies selling products for the treatment of adult patients with gMG, and several biopharmaceutical companies are developing drugs that may have utility for the treatment of gMG and/or CIDP.

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 personnel in all areas of our business, 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.

Competition is also increasing from companies that are utilizing artificial intelligence and other computational approaches for the development of products. These competitors may incorporate artificial intelligence into their businesses more quickly or more successfully than us, which could impair our ability to compete effectively and adversely affect our results of operations. We anticipate that we will continue to face increasing competition in the future as new companies enter our market and scientific developments surrounding the pharmaceutical market continue to accelerate. We cannot predict the extent to which these developments will impact potential future sales of our products or our product candidates. 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.

Such competing products or technology platforms may gain faster or greater market acceptance than our products or technology platforms. If we, our products and product candidates or our technology platforms do not compete effectively, it is likely to have a material adverse effect on our business, financial condition and results of operation.

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

The commercialization of VYVGART in new indications or other product candidates if and when approved, or entrance of any of our products or product candidates into new 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 force in certain of the countries where VYVGART is approved 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 natural or man-made disasters, 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.

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

In the U.S., the Biologics Price Competition and Innovation Act (**BPCIA**) created an abbreviated approval pathway for biological products that are demonstrated to be “biosimilar” to or interchangeable with a U.S. FDA-licensed reference biological product. However, during the 12-year regulatory exclusivity period applicable to reference biological products, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor’s own preclinical data and data from adequate and well-controlled clinical trials of their product.

We believe that any of our product candidates approved as a biological product under a BLA in the U.S. should qualify for the Biologics Price Competition and Innovation Act 12-year period of exclusivity, as is the case with VYVGART. The base regulatory exclusivity period for VYVGART is expected to extend until December 2033 in the U.S. whereas regulatory protection in the EU is expected to expire in August 2032. However, in the U.S., 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. The same applies to the EU, as there is also a risk that this exclusivity could be shortened due to legislative actions.

We are aware that some of our competitors may be actively developing competing or biosimilar products for VYVGART. It is possible our competitors will be successful in developing biosimilar or interchangeable products for our products and product candidates, and the approval of such competing products may lead to substantial competition in the market, a decrease in sales, or force us to make VYVGART available at lower prices due to competitive pressures. Moreover, an interchangeable biosimilar product, once approved, may be substituted under existing state laws for any one of our reference products. In addition, the Further Consolidated Appropriations Act, 2020, which incorporated the framework from the Creating and Restoring Equal Access To Equivalent Samples (CREATES) legislation, allows biosimilar developers to obtain access to reference biological products, which may facilitate the development of biosimilars to our products. The FDA has also recently issued guidance eliminating the need for data from comparative clinical efficiency studies to demonstrate biosimilarity in many circumstances, which may accelerate biosimilar market entry. If competing or biosimilar products are approved, the market position of our products for existing and recently approved indications may be adversely affected.

In the EU, biosimilars are evaluated for marketing authorization pursuant to a set of general and product class-specific guidelines. Moreover, the EU’s legislative bodies are currently working toward finalizing a reform of the EU Pharmaceutical Legislation, likely shortening the baseline of market exclusivity periods for medicinal products. In addition, some EU Member States have adopted, or are considering the adoption of, biosimilar uptake measures or may impose automatic price reductions upon market entry of one or more biosimilar competitors. While the degree of competitive effects of biosimilar competition among EU Member States may vary, continuation of policies promoting biosimilar products in the EU and in EU Member States could erode market share or introduce competitive pricing pressures for our products and product candidates.

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

In the U.S. and the EU and other jurisdictions, there have been a number of legislative and regulatory changes to 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, including pharmaceutical pricing reforms under the IRA. The IRA authorizes Medicare drug price negotiation, imposes inflation-based rebate obligations and significantly redesigns the Medicare Part D benefit, including establishing manufacturer discount requirements and capping beneficiary out-of-pocket costs. Although the program remains subject to legal challenges, the IRA is being implemented and may materially reduce the prices we are able to charge for our products, increase our rebate and discount obligations, and affect coverage, formulary placement and demand for our products and product candidates. See Section 1.7.4 “Regulatory Framework – Coverage, Pricing, and Reimbursement” for additional details.

The HHS has and will continue to issue and update guidance and rulemaking as these IRA programs are implemented. We cannot predict how the HHS will interpret the IRA in the future, or whether the U.S. Congress will enact legislation that further amends the law. However, at this time, the Trump administration is continuing to implement the IRA. Manufacturers that fail to comply with the IRA may be subject to significant penalties, including civil monetary penalties and excise taxes. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA (as defined below) marketplaces through plan year 2025. To date, none of the legislative attempts to extend the subsidies has been enacted. While the full economic impact of IRA is unknown at this time, 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, the adoption of these lower prices by commercial payors, 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, price transparency reporting, and programs designed to encourage importation from other countries and bulk purchasing. States are also enacting laws modeled on federal policies, such as the IRA and the 340B drug discount program. 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.

The EU, on the other hand, is in the final stages of adopting new EU Pharmaceutical Legislation in 2026, reforming its legislative framework for medicinal products (see “Agreement on new EU Pharmaceutical Legislation”).

Depending on the final text, which has yet to be published and is still subject to formal approval, the impact could be positive with respect to certain regulatory processes. Other aspects may, however, have a negative impact on innovative pharma and biotech companies such as argenx. In particular, this may be the case for the envisaged shorter baseline market exclusivity periods. In any case, these legislative changes will only enter into effect after a (not yet specified) transitional period, which will most likely conclude in 2028 the earliest.

**We are subject to government pricing laws, regulation and enforcement, which affect the prices we may charge the government for our products and the reimbursement our customers may obtain from the government. Changes in such laws, regulation, and enforcement may place downward pressure on the prices we can charge in the marketplace, and our failure to comply with these laws could harm our results, operations and/or 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 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 by the specified deadline, as well as potential allegations under the False Claims Act and other laws and regulations.

Statutory or regulatory changes, including changes in CMS guidance, could affect the average sales price calculations and the resulting Medicare payment rate for VYVGART and our potential future products. Any such measures may increase our financial obligations to government payors, reduce net realized prices, and adversely affect the demand, coverage and overall sales of our products. In addition, 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. See Section 1.7.4 **“Coverage, Pricing and Reimbursement”** for additional details on the regulatory framework regarding the coverage, pricing and reimbursement of our products and product candidates.

In addition, the current U.S. Presidential administration has taken several steps to try to align U.S. drug prices with drug prices in other countries through an approach known as MFN pricing. On November 6, 2025, CMS announced the GENEROUS Model under its CMMI authority. The GENEROUS Model is a voluntary model that tests the impact of CMS-facilitated supplemental rebate agreements that align the Medicaid net price with a defined MFN price. In December 2025, CMS issued proposed rules for the GLOBE Model and the GUARD Model under its CMMI authority. The GLOBE and GUARD Models are mandatory models that, if finalized, would require manufacturers of certain drugs to pay additional rebates based on the difference between the Medicare price and the price in market basket countries. CMS proposes that the new rebate would apply to utilization by approximately 25% of Medicare Part B fee-for-service beneficiaries and 25% of Medicare Part D enrollees. In Congress, there also are pending legislative proposals that, if enacted, would require MFN pricing in certain healthcare programs.

It is also currently uncertain how these U.S. policy efforts to align US pharmaceutical pricing more closely to international benchmarks from countries with competing healthcare cost containment measures will affect our business.

Any expansion, finalization or implementation of these or similar MFN-based pricing initiatives could subject our products to additional rebate obligations, negatively impact our pricing strategies, product demand, or competitive positioning across global markets, and may result in reduced revenue in critical markets.

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

Sales of VYVGART 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. Patients generally rely on third-party payors to reimburse all or part of the associated healthcare costs, and 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.

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, often relying upon Medicare coverage policy and payment limitations. However, decisions regarding the extent of coverage, formulary tier placement, utilization management requirements (including step therapy), and the amount of reimbursement to be provided for any product candidate that we develop through approval will be made on a plan-by-plan basis. 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, and their coverage and reimbursement policies may vary, subject to certain statutory and regulatory requirements. Additionally, Medicaid programs vary from state to state in their coverage policies and reimbursement rates, subject to certain federal requirements. 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 and CIDP in the U.S., access to VYVGART for any other indication may be reduced or restricted by limited payor 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 sustaining net profitability in the future, which would adversely affect our business, financials and results of operations.

In many foreign countries, pricing, coverage, and level of reimbursement of prescription drugs are subject to governmental and/or third-party payor control, and we and our collaborators may be unable to obtain coverage, pricing, and/or reimbursement on terms that are favorable to us or necessary for us or our collaborators to successfully commercialize our marketed products in those countries. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country, and may take into account the clinical effectiveness, cost, and service impact of existing, new, and emerging drugs

and treatments. For example, in the EU, pricing and reimbursement of medicinal products, is almost exclusively a matter for national, rather than EU, provisions and regulations. EU Member States may restrict the range of medicinal products for which their national health insurance systems provide reimbursement and may control the prices of medicinal products for human use. An EU Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we or our collaborators are unable to market our products in foreign countries or if coverage and reimbursement for our marketed products in foreign countries is limited or delayed. Downward price pressures in the EU and other countries may, in turn, contribute to downward price pressure in the U.S. because of MFN initiatives.

**If we fail to obtain orphan drug designation or we do not have valid and enforceable patents covering our products and their uses and product candidates and fail to obtain and/or maintain orphan drug exclusivity for our products or product candidates, our competitors may be able to sell products to treat the same conditions and our revenue may be reduced.**

We have and may from time to time seek orphan drug designation in the U.S., Japan and, the EU for certain indications addressed by our products and product candidates. 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 exclusivity upon approval. In the U.S., orphan drug exclusivity applies only to the specific uses or indications for which a drug is approved within the designated rare disease or condition, and therefore may be narrower than the scope of the original orphan designation. 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 MHRA, the EMA, respectively the European Commission, the FDA, the MHLW (collectively, the **Relevant Regulatory Authorities**) or other comparable regulatory authorities 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.

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

### **Failure to successfully identify, select and develop our products in other indications, or 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 for new indications, empasiprubarb and adimanebart. This 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 inaccurate, improper or fraudulent scientific data, including data sourced from third parties. 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 VYVGART in new indications based upon our technological approach, we may not be able to obtain product or collaboration revenues in future periods.

Obtaining regulatory approval for our products and product candidates is inherently uncertain. 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 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.

### **Failure to successfully develop or obtain marketing approval for our products and product candidates could negatively impact our business.**

The time required to obtain approval by the Relevant Regulatory Authorities and other comparable regulatory authorities is unpredictable but typically takes many years, if obtained at all, following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion or interpretation 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 have experienced delays in our prior clinical trials, and 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 clinical trials, including as described in Section 2.5 "Risk Factors Related to Other Government Regulations — 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."

Over the last several years, the U.S. government has shut down several times and average review times at the FDA have fluctuated in recent years as a result. If a prolonged government shutdown occurs it could significantly impact the ability of the FDA to timely review and process our regulatory submissions. Inadequate funding for the FDA and other government agencies, or other disruptions to these agencies' operations, could also prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.

In addition, ongoing efforts by the current U.S. Presidential administration to limit the size of the FDA and other agencies of HHS, including through reductions in staff, may further increase the unpredictability in approval timelines for our products and product candidates. In 2025, HHS announced and implemented a restructuring that included significant reductions in the FDA's workforce pursuant to an executive order directing federal workforce optimization. These staffing reductions together with resignations, resulting in leadership turnover and loss of institutional knowledge, may disrupt agency operations and adversely affect the timing, consistency or outcome of regulatory review. Ongoing initiatives by the current U.S. Presidential administration to deregulate and to review the scientific basis for, and otherwise attempt to influence, FDA decisions and policies create regulatory uncertainty for pharmaceutical companies.

Additionally, uncertainty remains as to how the FDA's agency-wide implementation of ELSA, a generative artificial intelligence tool, including for review of drug product applications, as well as its deployment of agentic artificial intelligence capabilities, will impact the outcomes and timeliness of FDA reviews and other activities. In addition, the future of the currently applicable Prescription Drug User Fee Act construct to ensure timely FDA review of applications may be impacted due to expressed concerns about the effect on industry-FDA relations, and staffing shortages.

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

### **Certain of our clinical trials have not succeeded, and may in the future also not succeed, and even if they succeed, we may not obtain regulatory approval for our products or product candidates or regulatory approval may be delayed.**

Certain of our clinical trials have not succeeded, and may in the future also not succeed. We could experience operational challenges as we undertake an increasing number of clinical trials, including those conducted in countries outside the EU, UK 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, non-UK and non-U.S. contract research organizations (**CROs**). Such trials may also expose us to risks associated with clinical investigators and institutions who apply different standards of diagnosis, screening and medical care or are otherwise unfamiliar with standards and requirements imposed by the Relevant Regulatory Authorities.

If we experience delays in the completion of, or termination of, any clinical trial of our products or product candidates, 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.

Even if clinical trials are initiated, our development efforts may not be successful. Even if we obtain positive results from preclinical trials or initial clinical trials, we may not achieve the same success in future clinical trials, which may negatively impact the price of our ordinary shares or ADSs.

Regulatory approval of our products or product candidates may be delayed or refused for many reasons, including for reasons outside our control. Some of the reasons for regulatory delay or refusal include:

- the Relevant Regulatory Authorities or other comparable regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate, to the satisfaction of the Relevant Regulatory Authorities or other comparable regulatory authorities, that our product candidates are safe, pure, potent and effective for any of their proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the Relevant Regulatory Authorities or other comparable regulatory authorities for approval;
- the chemistry, manufacturing and controls information submitted in an 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.

**If we decide to pursue accelerated approval for any of our product candidates, it may not lead to faster development or regulatory review or approval and we may still need to conduct additional clinical trials, which could increase the expense of obtaining, if at all, necessary marketing approvals.**

The accelerated approval pathway has come under scrutiny by various stakeholders, and the Food and Drug Omnibus Reform Act of 2022 (*FDORA*) revised the requirements for this pathway. Although this legislation did not change the standard for accelerated approval, it authorized the FDA to require a post-approval clinical trial to be underway prior to approval or within a specified time period following approval, and must specify conditions of any required post-approval clinical trial. FDORA also requires sponsors to submit progress reports for required post-approval studies. Failure to conduct due diligence for required post-approval studies is deemed a prohibited act under the FDCA. FDORA also details procedures the FDA must follow to withdraw an accelerated approval on an expedited basis, including where the required post-approval studies are not conducted with due diligence or fail to verify clinical benefit, other evidence demonstrates that the product is not shown to be safe or effective under the conditions of use, or the sponsor disseminates false or misleading promotional materials with respect to the product. FDA has been exercising these authorities and has issued guidance documents regarding the accelerated approval pathway. If we decide to pursue accelerated approval for any of our product candidates, the failure to obtain accelerated approval (or the withdrawal of any accelerated approval) 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. For example, if standard of care were to evolve or if any of our competitors were to receive approval for a drug or biological product for a disease or condition for which we are seeking accelerated approval before we receive accelerated approval, we may not be able to demonstrate that our product candidate provides a meaningful advantage over other available therapies and accelerated approval may not occur.

**Our products and product candidates may have adverse, undesirable or unacceptable side effects, and we or others may identify undesirable or unacceptable side effects caused by any of our products or product candidates before and 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 or other comparable regulatory authorities. We have observed adverse events and treatment emergent adverse events in our clinical trials, and we may see additional adverse events and treatment emergent adverse events 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 caused by any of our products or product candidates that we or others identify could, among other things, 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.

Any undesirable drug-related side effects can also cause the Relevant Regulatory Authorities or other comparable regulatory authorities to withdraw approvals or revoke licenses of such products and require us to take such products off the market, require the addition of labeling statements, specific warnings, or a contraindication or other modification of the product labeling, request the issuance of safety alerts, require a REMS to ensure that the benefits of the product outweigh its risks, and/or require us to change the way the product is administered, conduct additional clinical trials or change the labeling of the product.

**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 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 trial, 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 Section 2.1 "Risk Factors Related to Commercialization of argenx's Products and Product Candidates, Including for New Indications—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.

## 2.4 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, manufacturing 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 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, 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 in place with several distribution partners for VYVGART. We 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, our collaborators, CROs, CMOs, distributors, and other third-party service providers are subject to extensive healthcare, regulatory, data privacy, manufacturing, anti-corruption and other laws and regulations. Although we seek to structure our relationships in compliance with applicable laws and regulations and monitor the activities of these third parties, we do not control their day-to-day operations and cannot guarantee that they will comply with all applicable legal and regulatory requirements. Any failure by our third-party partners to comply with such requirements could result in regulatory enforcement actions, monetary penalties, exclusion from government healthcare programs, reputational harm, delays in development or commercialization, or other adverse consequences. In particular, regulatory authorities enforce GCP requirements through periodic inspections of clinical trial sponsors, principal investigators and clinical 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. In addition, our collaborative partners may not adhere to, or may 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.

### **Disruptions caused by our reliance on third parties for our raw materials and 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 products 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 prices increased, or 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 increased demand 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 exacerbated by pressure on the supply chain, for example due to power shortages, natural disasters, extreme weather conditions, public health crises, changed laws or regulations, military conflicts, executive orders, or geopolitical events, including trade disputes, embargoes or economic or financial sanctions enacted as a result of international conflict. The cost of our raw materials may also increase based on actual or threatened trade restrictions or increased tariffs on foreign exports. As we continue to grow our business we may need to establish additional sources of supply for our products. The lead time needed to establish a relationship with a new supplier can be lengthy and require us to devote substantial time and resources, which could result in additional costs, or delays and adversely affect our business.

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. Regulatory authorities may require additional studies if we adopt a new supplier. 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, embargoes or economic or financial sanctions imposed, administered or enforced by the UN Security Council, the U.S., the UK, the EU, or the respective governmental institutions of any of the foregoing including, without limitation, the Office of Foreign Assets Control of the US Department of the Treasury, the US Department of Commerce, the US Department of State and any other agency of the US government.

### 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 and supply of our products and product candidates.

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), although 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, 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.

Most notably, we contract with Lonza for their manufacturing sites in Slough, UK, Portsmouth, U.S., Singapore and Visp, Switzerland as well as with Fujifilm, based in Denmark, for activities relating to the development of cell banks, development of our manufacturing processes and the manufacturing of drug substance. We 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. While we work with our CMOs and partners on optimization, strengthening and upscaling our manufacturing, 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 supply shortages or disruptions of raw materials, fires, pandemics, natural hazards or acts of 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, reputational damage or affect our ability to obtain, and the terms of, any future financing, which may harm our business.

## 2.5 Risk Factors Related to Other Government Regulations

**We are subject to healthcare laws, regulation and enforcement. The failure to comply with these laws could harm our results, operations and/or financial condition.**

Our current and future operations are and may become directly, or indirectly through our customers and third-party payors, subject to various U.S. federal and state, EU and EU Member State, Japanese, Chinese, UK, Canadian and Israeli healthcare laws, and healthcare laws of other jurisdictions in which we conduct our business. This includes, but is not limited to, the U.S. FDCA, the U.S. False Claims Act and EU Directive 2001/83/EC.

In particular, our sales, marketing and business arrangements are subject to healthcare fraud and abuse, anti-kickback and similar laws designed to prevent fraud, misconduct, improper inducements and other abusive practices. For example, EU Directive 2001/83/EC restricts the provision of gifts, pecuniary advantages or other benefits to persons qualified to prescribe or supply medicinal products, subject to limited exceptions. Compliance with these complex and evolving requirements requires significant resources and may constrain our commercial activities.

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 these 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. As we continue to grow our headcount to

support our business, we face increased compliance risk as we need to train and supervise additional personnel to comply with relevant healthcare laws and regulations. This involves substantial costs and, notwithstanding our investment, 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 applicable 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, 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. Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations also involve substantial costs, and because we do not fully control the operations or compliance practices of these third parties, we cannot assure you that they will comply with all applicable healthcare laws and regulatory requirements.

The scope, interpretation and enforcement of healthcare laws remain uncertain and subject to change, particularly in the current environment of healthcare reform. Federal and state authorities in the U.S. have increased scrutiny of interactions between healthcare companies and healthcare providers, as well as promotional practices, including direct-to-consumer prescription drug advertising and manufacturer-sponsored platforms that facilitate patient access to products. The FDA has also heightened its review of the data supporting advertising and promotional claims. Compliance with these evolving requirements, and responding to investigations or enforcement actions, may require significant time and resources and could divert management attention, result in penalties or otherwise adversely affect our business.

**All aspects of our business, including preclinical research, clinical trials, marketing and commercialization, are highly regulated, and any delay by relevant regulatory authorities could jeopardize our development and approval process and/or result in suspensions of marketing authorizations, refusals to approve our products, or withdrawal of existing approvals.**

Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing to support our IND or planned IND applications in the U.S. or Japan, or our clinical trial applications (CTAs) in the EU, or comparable applications in other jurisdictions. We cannot be sure that we will be able to submit INDs or CTAs or comparable applications for our development 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 Relevant Regulatory Authorities or other regulatory authorities allowing clinical trials to begin.

Clinical trials must be conducted in accordance with applicable laws and regulations, Relevant Regulatory Authorities' and other comparable regulatory authorities' legal requirements and regulations and are subject to oversight by Relevant Regulatory Authorities and other comparable regulatory authorities as well as IRBs and ethics committees. In particular, clinical trials must be conducted in compliance with GCPs and clinical supplies of our products and product candidates must be produced under cGMPs and other regulations. We could encounter delays if a clinical trial is suspended or terminated, by us, by the IRB or ethics committee, by the data review committee or data safety monitoring board for such clinical trial, or 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 comparable regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, including those relating to the class to which our products and product candidates belong, failure to demonstrate a benefit from using 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 of our clinical programs may increase, the commercial prospects of our products and product candidates may be harmed, and our ability to generate product revenues from any of these products and product candidates may be delayed. 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. We can provide no assurances that such approval will be obtained on the timeline that we expect or at all. In addition, we anticipate submitting applications for approval of VYVGART in new indications, but can provide no assurances that such applications 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 countries where VYVGART is approved, 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 for any indication.

Even if approval is obtained, the Relevant Regulatory Authorities or other comparable regulatory authorities may approve the product for fewer or more limited indications or patient sub-segments than requested and/or with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product. Further, the Relevant Regulatory Authorities or other comparable regulatory authorities may impose extensive and ongoing unique regulatory requirements, such as granting 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.

The costs of compliance with all Relevant Regulatory Authorities' and other 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 and/or our collaborative partners' costs or delay or prevent 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, cybersecurity and AI laws, regulation and potential enforcement. The failure to comply with these laws could harm our results, operations and/or financial conditions.**

Privacy laws, regulations and related enforcement are particularly relevant to our business as we collect, store and process personal data and in particular data of vulnerable groups such as patients, and sensitive information including health data as well as human biological samples. We also collaborate 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 GDPR imposes strict requirements, including access controls, impact assessment and safeguards on cross-border transfers of personal data and imposes substantial penalties in the event of non-compliance. 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. Any investigation by a data protection authority could result in fines and other penalties.

The data privacy landscape is complex and fragmented. In the EU, national laws may impose stricter obligations than the GDPR, particularly for sensitive genetic, ethnic origin or race data, while regulations like the Directive 2002/58/EC of the European Parliament and of the Council of July 12, 2002 (as amended, the **e-Privacy Directive**) add further compliance risks.

This trend expands globally, with evolving laws in countries such as the U.S., Japan, Canada and China. For example, China has passed a number of laws concerning data protection and the collection, use and transfer of personal data (including data considered to be relevant as Chinese human genetic resources), and restricting the transfer of this data outside of China. These evolving laws and regulations impose increasing restrictions on the processing of personal data, which may require us to modify our data collection or processing practices and to incur significant expenses associated with our compliance efforts.

Moreover, in the current digital and regulatory landscape, privacy obligations are increasingly interconnected with broader cybersecurity laws and requirements, reflecting the close link between the protection of personal data and the security of information systems. Failure to comply with applicable cybersecurity frameworks and directives, including Directive (EU) 2022/2555 on Network and Information Security (**NIS2**), could result in significant legal, regulatory, and operational risks. In addition, inadequate cybersecurity and non-compliance with data protection laws and regulations increases the risk of personal data breaches, potentially resulting in regulatory sanctions, civil claims, reputational damage and loss of trust.

Furthermore, our integration of AI solutions into certain of aspects our business, introduce a new layer of regulatory risk. Most significantly, Regulation (EU) 2024/1689 (**AI Act**) establishes the world's first comprehensive legal framework for AI, impacting how we develop and deploy AI systems in the future. In particular, high-risk AI systems must comply with strict regulatory requirements to ensure safety, transparency, and fundamental rights protection. Non-compliance with the AI Act may result in significant penalties. As most provisions will take effect from August 2, 2026, we must continuously assess and adapt our compliance strategy to mitigate risks from this evolving legal landscape.

If we violate existing laws and regulations or fail to comply with changing laws and regulations, we might be subject to fines, penalties and other adverse consequences, which could have a material adverse effect on our reputation, business, results of operations, cash flows or financial condition.

**Failure to comply with anti-corruption laws and regulations, anti-money laundering laws and regulations, economic or financial sanctions, trade embargoes and/or export control regulations and other laws governing our operations could have an adverse impact on our business, financial conditions and operations.**

We are or may become subject to various laws and regulations regarding anti-corruption, anti-money laundering, economic or financial sanctions, trade embargoes, investment restrictions, anti-fraud, other comprehensive prohibitions against transaction activity pursuant to anti-terrorism laws or export control laws and regulations issued by multiple jurisdictions. These include the UK Bribery Act 2010 and the U.S. Foreign Corrupt Practices Act of 1977, in each case, as amended, as well as comparable laws and regulations in other countries in which we do business, including in the European Union and China, which prohibit, among other things, payments, offers, or promises made for the purpose of improperly influencing any act or decision of a foreign government official. In the UK, since September 1, 2025, it is an offense under the Economic Crime and Corporate Transparency Act 2023 for a large organization to fail to prevent certain fraudulent activities by an associated person (such as an employee, agent, or subsidiary), unless it can demonstrate that it had reasonable prevention procedures in place to prevent the fraudulent activity. The nature of our business means that we engage in significant interactions with foreign officials. Compliance with these laws and regulations in the U.S. and in foreign jurisdictions is complex, and may increase our cost of doing business internationally.

We are also subject to economic and financial sanctions, trade embargoes, other comprehensive prohibitions against transaction activity pursuant to anti-terrorism laws and export control rules and regulations, including those imposed, administered or enforced by the UN Security Council, the U.S., the UK, and the EU. Any change in export or import regulations, economic or financial sanctions regulations, trade embargo 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 conduct our planned research and development activities and to manufacture, import, export or sell our products internationally, which could require us to expend additional resources to achieve our goals and adversely affect our business, financial conditions and operations.

We have mechanisms in place to promote compliance with such 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. In the event of non-compliance, we could be subject to substantial civil or criminal penalties, including sanctions against us, incarceration for responsible employees and managers, the possible loss of export or import privileges, debarment from participation in government contracting, reputational harm, and resulting loss of revenue and profits, which could have a material adverse impact on our business, financial conditions and operations.

### **Our performance tracked by our Environmental, Social and Governance metrics is subject to risks and the outcomes may not achieve the anticipated benefits or align with new regulations and stakeholders' expectations.**

There has been an increasing focus from stakeholders and regulators relating to environmental, social and governance (**ESG**) matters across all industries in recent years. The standards and stakeholder expectations continue to evolve, sometimes with contradictory expectations, and criteria to evaluate ESG practices may change rapidly. We are subject to evolving rules, including the European Union's Corporate Sustainability Reporting Directive (**CSRD**) and ancillary European Union legislation. The SEC adopted rules in 2024 requiring enhanced climate-related disclosures, but after legal challenges, subsequently announced that it would end its defense of such climate disclosure rule. As a result, various U.S. states have enacted or proposed climate- and sustainability-related disclosure laws that may apply to companies doing business in those jurisdictions, such as California's climate and carbon market disclosure laws, which would require in-scope companies to report on greenhouse gas emissions, climate-related financial risks, and the use of carbon offsets and emissions reduction claims relating to their operations or products. The future of the California climate disclosure laws is uncertain, as these laws are subject to ongoing litigation.

In response to new ESG initiatives and regulations we may voluntarily elect, or be required, to adopt strategies, policies, or procedures related to ESG matters. Such efforts could divert management's attention from central operational matters and cause us to expend significant capital and human resources. Moreover, increasingly, different stakeholder groups and regulators have divergent views, particularly in the U.S., on ESG matters, which increases the risk that any action or lack thereof with respect to sustainability or ESG matters will be perceived negatively by at least some stakeholders and regulators and adversely impact our business and reputation. The current sociopolitical landscape has led to rapid and unpredictable shifts in public sentiment, which has resulted in dynamics that increase the risk of reputational damage, boycotts and shifts in consumer behavior that could adversely affect our business and reputation. Reports could also lead to the disclosure of information that may have a negative impact on our operations and reputation which may lead to additional exposure. In addition, any required disclosures and measurements of ESG metrics are highly dependent on third-parties, such as our suppliers and CROs, that we do not control. Failure to accurately comply with any sustainability reporting obligations may result in enforcement actions, sanctions, fines and penalties, reputational harm or private litigation.

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

Our operations, including our research, development and testing, and our third-party manufacturers' and suppliers' operations, are subject to numerous environmental, health and safety laws and regulations and for which we may become liable. 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 one of our CMOs or third-party distributors, manufacturers, suppliers, licensees or co-marketers fail to comply with such laws and regulations, such failure could result in substantial liability, fines, penalties or other sanctions and incur substantial expenses, and could also face significant reputational loss.

We face a risk of environmental liability inherent in our current and historical activities, including liability relating to releases of our exposure to hazardous or biological materials. Furthermore, environmental, health and safety laws and regulations are becoming more stringent. Both us and our third-party manufacturers and suppliers 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.

## 2.6 Risk Factors Related to argenx's Financial Position

### **We may not be able to be profitable or sustain net profitability in the future and may require additional financing to fund our operations.**

To be profitable or sustain net profitability in the future, we must continue to succeed in commercializing products that generate significant product net sales. Our future results of operations and profitability may fluctuate from period to period, and we will need to generate significant revenues to be profitable or sustain net profitability in the future. We may not be able to generate these revenues, and we may never achieve profitability on a sustained basis in the future. If we do not succeed in sustaining profitability or in funding our operations, we would not be able to use deferred tax assets against taxable profits which would result in a de-recognition of our deferred tax asset balance.

In addition, 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. As a result, we anticipate that our operating expenses will increase as we execute on our strategic objectives and could increase more significantly if we experience delays or encounter issues relating thereto, including failed clinical trials, ambiguous clinical trial results, safety issues or other regulatory challenges.

To finance our operations, particularly if we are unable to generate sufficient product net sales or otherwise control expenses, 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 cannot raise additional capital when needed on acceptable terms, we may be required to delay, reduce or terminate research and development programs; defer or forego commercialization of our products and product candidates (including for new indications); and limit expansion or otherwise fail to capitalize on business opportunities, any of which could have a material adverse effect 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.**

We invest our cash in accordance with an established internal investment policy. Currently, substantially all of our available cash and cash equivalents and current financial assets are invested in either current accounts, savings accounts, term accounts or highly liquid money market funds. 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 investment policy. These investments may be subject to general credit, liquidity, market, inflation, foreign currency and interest rate risks and we may realize losses in the fair value of these investments or a complete loss of these investments. The

aforementioned 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 the euro and Japanese Yen, versus the U.S. dollar. 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. 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 on expenses. 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 on expenses. Continued volatility in foreign exchange rates is likely to impact our operating results and financial condition.

## 2.7 Risk Factors Related to argenx's Business and Industry

### 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.

Product liability risk in the EU will increase in the future once plaintiff-friendly reforms, such as Directive (EU) 2024/2853 (the **new Product Liability Directive**), take effect. The new Product Liability Directive introduces claimant-friendly changes. This includes, for instance, the expansion of the definition of "damage" (e.g. by including medically recognized psychological harm), creating rebuttable presumptions as to defect and causation to help claimants prove their case (e.g. if the claimant faces excessive difficulties to prove this due to scientific complexity) and abolishing minimum or maximum financial thresholds for claims. The new Product Liability Directive, like its predecessor, provides that claims shall expire if the injured person does not initiate proceedings within ten years after the defective product was placed on the market. However, it extends this long stop period (a statute of limitations) to 25 years if this is due to the latency of the underlying personal injury. Member States must transpose the Product Liability Directive into national law by December 2026.

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 our 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.

In the ordinary course of business we may also face substantial, complex or extended litigation that could cause us to incur significant costs and distract our management. This is especially relevant for biopharmaceutical companies. Such litigation or proceedings could substantially increase our operating expenses and could adversely affect our business.

### **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. We may be unable to complete a proposed transaction if we or our shareholders are unable to obtain required regulatory approvals in the various jurisdictions in which we or a potential acquisition target or acquirer operate. 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 and our third-party partners' 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 data 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.

In addition to these threats, we are subject to stringent cybersecurity laws, most notably NIS2 with respect to our activities in the European Union. As a company involved in the development and manufacturing of pharmaceutical and medicinal products, our operations could be brought within the scope of NIS2. This would require us to implement robust measures to secure our network and information systems. We are also subject to cybersecurity laws in other international jurisdictions in which we conduct our operations, such as the Cybersecurity Review Measures in China. Failure to comply with these cybersecurity standards could result in significant penalties. See Section 2.5 “Risk Factors Related to Other Government Regulations—We are subject to privacy, cybersecurity and AI laws, regulation and potential enforcement. The failure to comply with these laws could harm our results, operations and/or financial conditions.”

Although we are making significant efforts to maintain the security and integrity of our information systems and the information systems of our third-party partners 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 third-party partners, contractors and consultants are vulnerable to damage or interruption from computer viruses, unauthorized or inappropriate access or use, natural disasters, pandemics, terrorism, war (including the ongoing conflict in Ukraine and conflict in the Middle East), and telecommunication and electrical failures. 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, personal or proprietary 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 data, and the development and potential commercialization of our product candidates could be delayed. Disruptions in the our and our third-party partners' information technology systems could adversely affect our business operations and harm our competitive position.

Not all of our contracts contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices.

## 2.8 Risk Factors Related to argenx's Intellectual Property

**We may be unable to adequately maintain, enforce or protect our intellectual property rights in products, product candidates and platform technologies which could adversely affect our ability to maximize the value for patients in our marketed 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 obtain, maintain, enforce, protect, or extend adequate patent and other intellectual property rights, which can be challenging and costly, could adversely affect our ability to develop and market our products and product candidates and reduce 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 and we may not be the first to file patent applications related to our product candidates and products. The scope of patent protection that the European Patent Office and the USPTO will grant with respect to products in our product pipeline is uncertain and may vary. It is possible that the European Patent Office and USPTO will not allow broad claims that cover molecules closely related to our products and product candidates as well as the specific molecule, and competitors may be free to market substantially similar molecules if granted approval, thereby reducing our market potential. We and our current or future licensors, licensees or collaboration partners may not be able to prepare, file, prosecute and maintain all necessary or desirable patent applications at a reasonable cost or in a timely manner. Our current and future licensors', licensees' or collaboration partners' ability to ensure the issuance, scope, validity, enforceability and commercial value of technology licenses is uncertain and we may need to rely on them to obtain costly additional IP licenses. Additionally, such parties may not fully comply with applicable patent rules or laws, which could result in loss of patent rights, or such parties may disagree with us as to the strategy for prosecution, maintenance or enforcement of any such patent rights.

Filing, prosecuting, and defending patents on product candidates in all jurisdictions throughout the world would be prohibitively expensive and the laws of certain jurisdictions may not protect our rights to the same extent as the laws of the U.S., UK or EU. We may face difficulties in enforcing patent rights in the future, including in certain jurisdictions where we have not yet filed patent applications.

Competitors may use our and our licensors' or collaboration partners' technologies in jurisdictions where we have not obtained patent protection, or where broad research exemptions are available, to develop their own products. Third parties may export otherwise infringing products to territories where we, our licensors or collaboration partners have patent protection, but where enforcement is not as strong as that in the U.S., UK and the EU. In such cases, we would have little effective recourse to prevent such products from competing with ours.

In addition, 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.

### **Intellectual property litigation could lead to substantial resource diversion or issued patents could be found invalid, not infringed, or unenforceable if challenged in the applicable patent office or court.**

Our patents may remain open to invalidity challenges after allowance or grant, whereby third parties can challenge the scope or validity of such granted patent. In the course of such proceedings, we may be compelled to limit the scope of patent claims thus challenged or may lose the claims altogether.

We may elect to initiate adversarial proceedings 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 to protect our competitive position. We may need to divert substantial time and resources to the enforcement and protection of our or our collaboration partners' intellectual property rights. In addition, the outcomes of any proceedings could be uncertain and any remedies or damages awarded may not be meaningful. An adverse ruling of non-infringement, limiting claim scope, or invalidating one or more of our issued patents could allow third parties to commercialize our products after the expiration of our market exclusivity or use our platform technologies to compete directly with us, without payment to us.

In many jurisdictions (including the Unified Patent Court), an action to enforce a patent may not be brought until immediately before, or even after, the infringing product of a competitor has been launched in the market. In these jurisdictions, infringement rulings and injunctions (even in preliminary injunction proceedings) are often issued only after the competing product has already been launched and potentially impaired the competitive advantage on the market.

### **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 in the senior management team (consisting of our CEO and senior personnel reporting directly to the CEO) (**Senior Management Team**), were previously employed at other competing or potentially competing biotechnology or pharmaceutical companies and some have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we take measures to ensure third parties, consultants and employees do not use such proprietary information in their work for us, we may be subject to claims that we or these consultants and employees have improperly used or disclosed confidential information or intellectual property of their former employer.

Additionally, many of our collaborators do not commit to assigning all intellectual property arising out of our collaborations 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 may be required to make additional payments to secure valuable intellectual property rights under our existing collaborations or become subject to inventorship disputes.

In addition, although we take steps to ensure that our collaborators do not use our intellectual property rights other than for the purposes of our collaboration, there may be instances where former or current collaborators or other third parties nevertheless apply for or obtain patent protection for inventions to which we believe we have rights, in whole or in part. In such cases, we may elect to assert our ownership of such intellectual property. There is no guarantee that we will be successful in asserting such claims.

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 ensuring effective assignment of intellectual property under such agreements. Our assignment agreements may not be self-executing, or may be breached, and we may be forced to bring or defend against claims to assert ownership of such intellectual property. There is no guarantee we will be successful in pursuing such claims, which could result in us paying monetary damages or losing valuable personnel or intellectual property rights.

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

Our revenue generated may suffer if valid and enforceable third-party intellectual property rights cover our products, product candidates, manufacturing processes, or those of our partners. In such cases, our freedom to develop or commercialize products or product candidates may require obtaining a license, designing around third party intellectual property rights with significant time and materials costs, or invalidating the third party rights.

If our products are found to infringe a valid and enforceable patent claim, we and our partners could be prevented from continuing to develop or commercialize the affected product without an appropriate license, which may be costly or unavailable on commercially reasonable terms, if at all. Similarly, other companies may have filed patent applications or have patents directed toward molecules and/or uses of those molecules that modulate similar targets modulated by our products and we may not be aware of unpublished pending patent applications or patent applications that are amended to cover our products or platform technologies.

Even if we or our partners can obtain the appropriate license, it may be non-exclusive, thereby providing third parties with the opportunity to access the same licensed technology. If the breadth and scope of protection provided by our or our partners' patents, licensed patents, or patent applications is threatened or limited, it could dissuade companies from future collaborations with us to license, develop, or commercialize products and product candidates which would have an adverse effect on our business position.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, some of our confidential information could be disclosed in any such proceedings.

### **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 necessary or useful for development or commercialization of our product, product candidates or technology. We sometimes collaborate with U.S. and non-U.S. academic institutions and typically receive an option to negotiate a license to the institution's proprietary interest in any collaboration technology. However, we may be unable to successfully negotiate such license and the institution may offer such intellectual property rights to third parties thereby devaluing our exclusive rights to pursue the applicable program.

In addition, our competitor companies may be unwilling to license desirable or necessary intellectual property rights to us, or we may be otherwise unable to license or acquire other third party intellectual property rights on commercially reasonable terms which could negatively impact current development or hinder our ability to pursue development of new programs.

Under our existing licenses, failure to comply with our obligations thereunder could result in termination of such licenses, thereby limiting our ability to develop and commercialize products covered by such licensed technology. Moreover, despite our efforts to comply with our contractual obligations, our licensors could conclude we have materially breached any such agreement and we could incur significant costs and disruption to our business defending against any breach alleged by the licensor.

Moreover, several of our existing license agreements are sub-licenses from third parties. We have little control if our licensors fail to comply with their obligations under their upstream license agreements, whereby the original third-party licensor may have the right to terminate the original license and possibly our sub-license. In such cases, we may not be able to procure a direct license covering such intellectual property possibly materially affecting our ability to develop and commercialize certain products and product candidates.

**If our brand protection strategies, including the filing, prosecution and enforcement of trademarks and trade names, are not adequately executed, we may not be able to build name recognition for approved products in our markets of interest in line with our strategic priorities.**

Third parties may seek to oppose, attempt to cancel our trademark applications, or challenge, infringe or circumvent our registered and unregistered trademarks, including through counterfeiting of our products. In the event that our trademarks are successfully challenged, we may not be able to use these trademarks to continue to effectively market our branded products and could be forced to rebrand them, which could result in loss of their brand recognition or require us to devote resources to develop new brand profiles. Such efforts could also hinder our efforts to commit to and deliver on strategic internal initiatives.

If we attempt to enforce our trademarks or assert trademark infringement claims, a court may determine that our trademarks are invalid or unenforceable or that the party against whom we have asserted trademark infringement has superior rights with respect to such marks. If we are unable to establish name recognition and adequately protect and enforce our trademark portfolio, we may not be able to compete effectively in the market or build brand recognition for new products globally.

**We may not be able to obtain protection under the U.S. 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.**

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. However, the patent term extension under the Hatch Waxman Act 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.

If we are unable to obtain patent term extension, the term of any such extension is less than we request, or the statutes governing patent term extension are amended to reduce the term of such extensions, our patent exclusivity 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 across jurisdictions, or changes in any relevant government's enforcement procedure may weaken our ability to obtain new patents or to enforce rights in our owned and licensed patents. 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. Relatedly, the U.S. Congress is considering multiple draft bills that, if passed, may have a significant impact on U.S. patent laws. Any such changes by the U.S. Congress or U.S. courts and the relevant law-making bodies in other countries may materially affect our patents or patent applications and we cannot predict the effects of future changes in patent law.

**We may be unable to protect the confidentiality of our trade secrets and their disclosure to competitors, harming our market position.**

In addition to patent protection, we rely on trade secret protection to preserve the value of our proprietary information supporting our business model. We take balanced measures to preserve the commercial value of our trade secrets and prevent their misappropriation. However, despite these measures, which include segregation of key files, requiring our licensors, collaborators, suppliers, consultants and advisors to execute confidentiality agreements, we cannot fully protect against willful or inadvertent unauthorized disclosure of our trade secrets. Trade secret enforcement proceedings can be unpredictable and vary across geographies and we may not be able to secure adequate legal or equitable remedies to prevent lost value in our misappropriated trade secrets. Any misappropriation and use, whether willful or inadvertent, could result in lost value to the company and enable our competitors to duplicate or build upon our technology.

## 2.9 Risk Factors Related to argenx's Organization and Operations

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

We believe that our corporate culture has been, and will continue to be a key contributor to our success. However, as we implement more complex organizational structures, and increase our headcount to support the growth in our business, our ability to foster our key values - innovation, co-creation, empowerment, excellence and humility that we believe are important to support our growth - may be impacted. We may find it increasingly difficult to maintain the beneficial aspects of our corporate culture, which could similarly negatively impact our ability to attract, retain and motivate qualified employees and our future success.

As a global organization in a highly competitive and specialized industry, our success also 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 the 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. In addition, future leadership transitions and management changes may cause uncertainty in, or a disruption to, our business, and may increase the likelihood of senior management or other employee turnover. We are currently undergoing a leadership transition, as in early January 2026, we announced that Karen Massey, our current COO, will transition to the role of CEO and Executive Director and Tim Van Hauwermeiren, our current CEO, will transition to the role of Non-Executive Director and Chairperson of the Board of Directors. Both transitions are subject to shareholder approval at the 2026 General Meeting. Any failure to ensure an effective transition or any future management changes could adversely affect our business, and we cannot predict the likelihood, timing or effect of future transitions among our executive leadership.

As a Dutch company listed on Euronext Brussels and 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 with differing remuneration practices and policies compared to our competitors. For example, the Dutch Corporate Governance Code 2025 (**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.

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, inflationary pressures and a tight labor market for skilled workers may increase compensation expectations, requiring us to raise operating costs in order to attract and retain employees. Therefore, we might not be able to attract or retain these key persons or other employees 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 and 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. Such geo- and socio-political threats could also result in volatility in stock markets in general, causing our stock to have extreme price and volume fluctuations unrelated to our business and financial performance.

Such geo- and socio-political threats and uncertainties include:

- general economic and market conditions, including government shutdowns, including the U.S. government shutdown, instability resulting from inflationary pressures, and increasing interest rates;
- geopolitical events, including natural disasters, public health emergencies, acts of war, and terrorism;
- economic and financial sanctions, trade embargoes, import and export regulations, tariffs, customs, and inbound and outbound investment restrictions;
- restrictions, changes in trade agreements, trade barriers or other restrictions on foreign trade, and changes in trade regulations and restrictions, including between the U.S. and other countries;
- global or regional economic conditions that impact companies and customers with which we do business;
- political or social unrest, economic instability, repression, or human rights issues;
- disruptions in supply chains;
- risks related to other government regulation or required compliance with local laws;
- consumer and commercial credit availability, unemployment, and consumer debt levels; and
- local licensing and reporting obligations.

Due to our international operations and the fact that we run clinical trials across multiple jurisdictions, geopolitical conflicts and related sanctions may, in certain circumstances, impact our ability to conduct or complete clinical trials in the affected regions. For example, General License 6D issued by the U.S. Department of the Treasury's Office of Foreign Assets Control currently authorizes certain clinical trial and medical research activities that would otherwise be restricted by U.S. sanctions targeting Russia, the scope, availability, or duration of such authorizations may change.

We also perform development activities in a number of countries exposed to geopolitical risk and if conflicts in those countries were to escalate further and impact neighboring countries, it could impact our development activities in those countries.

Changes in U.S.-Mainland China relations, including tariffs, export controls, economic and financial sanctions, and other regulations may adversely impact our collaboration with Zai Lab in Mainland China, Hong Kong, Taiwan and Macau (together, Greater China). The U.S. government has taken steps and continues to take steps with regard to U.S.-Mainland China relations that will impact companies with connections to the U.S. or Mainland China, including by imposing tariffs affecting certain products manufactured in Mainland China, imposing economic and financial sanctions on certain individuals and entities in the Mainland China, and issuing statements indicating enhanced review of companies with significant Mainland China-based operations. The U.S. government has also passed laws, including the BIOSECURE Act, which was signed into law on December 18, 2025, that could limit or restrict our ability to purchase products or services from, or otherwise collaborate with, certain Chinese biotechnology companies without losing our ability to contract with or receive funding from the U.S. government. Such restrictions could have an adverse impact on our operations.

Several countries are considering or have implemented tariffs, trade barriers or restrictions, as well as other measures impacting cross-border commerce, which could negatively affect our business, financial conditions and results of operations, including by disrupting our research and development activities, affecting our suppliers and negatively impacting our supply chain, impacting our ability to sell our products outside of the United States and negatively impacting our revenues from product sales or our cost of goods sold. The U.S. federal government has implemented tariffs on certain foreign goods and may implement additional or revised tariffs in the future. Such actions could give rise to retaliatory tariffs imposed by foreign governments and an escalation of trade measures by the U.S. and impacted countries. Developments with regard to the timing and manner in which tariffs will be implemented; the amount, scope, and nature of tariffs; the countries subject to new or additional tariffs imposed by the U.S.; tariffs imposed by other countries on goods imported from the U.S.; and other wide-ranging retaliatory measures are rapidly evolving and may change unexpectedly at any time. For example, the U.S. President has repeatedly announced plans to impose 100% tariffs on imported branded or patented pharmaceuticals, unless the importing company is building U.S. manufacturing capacity. It is not yet clear whether these tariffs would apply to the importation of active pharmaceutical ingredients and possibly bulk drug products

that are intended for use in clinical trials and not for commercial sale, which could increase the costs of materials for our clinical trials. Any direct tariffs, if imposed on pharmaceutical products, may result in increased costs for raw materials and contract manufacturing services, reduced ability to source critical CMOs, and a delay in our development timelines. Although on February 20, 2026, the U.S. Supreme Court struck down certain tariffs imposed by the Trump Administration pursuant to the International Emergency Economic Powers Act, the Trump Administration responded by announcing new tariffs pursuant to another statute. Other countries may, in turn, retaliate with new tariffs against US exports. These events increase the uncertainty and the risks we face resulting from tariffs described above.

Any new legislation, executive orders, tariffs, export controls, economic and financial sanctions, trade embargoes and/or other regulations that may be implemented, any unfavorable government policies on international trade, including tariffs and export controls, the renegotiation of existing trade agreements, any increased scrutiny on companies with significant Mainland China-based operations, and any retaliatory actions taken by the U.S., EU, Chinese or other governments due to trade tensions could have an adverse effect on our business, including the development and commercialization of products containing argenx-licensed material. Further, general political uncertainty may have an adverse impact on our business, financial condition and results of operations.

### **We face risks related to natural disasters and public health issues, 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 earthquakes, fires, hurricanes, tornados, floods or significant power outages and public health crises.

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. We cannot presently predict the scope and severity of any potential future business shutdowns or disruptions as a result of public health issues. 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 due to natural disasters or global public health issues, 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. In addition, regulatory authorities may restrict their operations or be delayed in their operations during a pandemic, the outbreak of new variants or other public health issues, including further to travel restrictions which 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 are exposed globally to unanticipated changes in tax laws and regulations, adjustments to our tax provisions, exposure to additional tax liabilities, or adjustments of our tax assets.**

As a company active in research and development, we have benefited from certain research and development tax incentives including tax credits and a payroll withholding tax exemption. We also expect to benefit from the Belgian innovation income deduction.

The determination of our provision for income taxes and other tax liabilities requires 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 (including with respect to our eligibility for, or our calculation of, tax incentives such as the Belgian R&D tax credit, the Belgian payroll withholding tax exemption for R&D personnel, the Belgian innovation income deduction and similar tax incentives in other jurisdictions in which we have material operations or sales), our transfer pricing policies or our organizational and operational 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, will not be subject to change. Our effective tax rates could be adversely affected, now or in the future, by changes in tax laws, treaties and regulations or the interpretation thereof by the relevant tax authorities in countries where we have material operations. A successful challenge to tax positions in Belgium or other country where we have material operations may lead to adjustments in the amounts recorded in our financial statements and could have a significant impact on our effective tax rate and on our deferred 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.

In case of a change of control, we could be exposed to the risk of losing any unused tax credit and innovation income deduction. Furthermore, if any 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 including through the de-recognition of deferred tax assets.

### **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, and expect to continue to grow globally, significantly in the number of employees and scope of operations over recent years, particularly in the areas of drug research, drug development, regulatory affairs, and sales and marketing. To manage our anticipated future growth and support our expanding global footprint, we must continue to enhance our managerial, operational and financial systems, expand our facilities and recruit and train additional qualified personnel and build the internal infrastructure necessary. Any inability to manage growth effectively could delay the execution of our strategic objectives or disrupt our operations, which in turn could materially harm our business and prospects.

In particular, our planned international expansion subjects us to a number of risks, including risks following complexities in monitoring and coordinating research and development, marketing, supply chain and other operations in a large number of jurisdictions, risks related to laws, regulations and policies, including those implemented following changes in political leadership and trade, risks related to varying standards and practices in the legal, regulatory and business cultures in which we operate, risks related to capital and exchange controls, cross-border taxes and tariffs, cross-border data transfer restrictions, and complex sanctions regimes in various countries such as the U.S., the EU and other jurisdictions, violations of which could lead to fines or other penalties, risks related to geopolitical and local political instability and uncertain business environments and risks related to complexities associated with managing local personnel and preventing misconduct by local third-party partners.

The application of laws and regulations impacting global business operations is often unclear and may at times conflict. Compliance with these laws and regulations may involve significant costs or require changes in our business practices that result in reduced revenue and profitability. Non-compliance could also result in fines, damages, criminal sanctions, prohibited business conduct, and damage to our reputation.

## **2.10 Risk Factors Related to the ADSs**

### **Holders of our ADSs have fewer rights than our ordinary shareholders.**

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 in accordance with the deposit agreement and applicable laws and regulations. The depository, or its nominee, is the holder of the ordinary shares underlying the ADSs. ADSs are transferable on the books of the depository. The depository may refuse to deliver, transfer or register transfers of ADSs. Temporary delays in the cancellation of ADSs and withdrawal of the underlying ordinary shares may arise. 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 ADSs may vote them in person or by proxy in accordance with applicable laws and regulations and our articles of association (**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. 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.

### **The price of our ADSs 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. The trading price of our ADSs depends on a number of factors, including those described elsewhere 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. We provide guidance regarding our cash and expenses, which are inherently uncertain. Any guidance that we provide may not always be accurate or may vary. If we fail to meet our guidance, or if we have to revise such guidance, the price of our ADSs or ordinary shares could decline. Sales of a substantial number of ADSs or our ordinary shares in the public market, or the perception that these sales might occur, could depress the market price of ADSs or our 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 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 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. We do not have control over these analysts. 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.

### **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 listing rules of the Nasdaq Global Market (the **Nasdaq Listing Rules**) and requirements, and other applicable securities rules and regulations. 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 or ordinary shares.

## 2.11 Risk Factors 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 under U.S. law.

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

We are a Dutch European public company with limited liability (*Societas Europaea*). 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.

For example, 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 U.S. Securities Act of 1933, as amended (**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 depository to extend that offering to holders of ADSs, which we are not required to do.

### **Claims of U.S. civil liabilities may not be enforceable against us or the members of our Senior Management Team and our Board of Directors.**

A significant amount 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 more difficult, for investors 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 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 various rules and regulations that a U.S. domestic public company would be required to follow, including those requirements under U.S. securities laws and Nasdaq listing standards.**

As a “foreign private issuer” defined in the SEC’s rules and regulations, we are not subject to all of the disclosure and corporate governance requirements applicable to companies organized within the United States. For example, we are exempt from certain provisions of the U.S. Securities Exchange Act of 1934, as amended (**Exchange Act**), that are applicable to U.S. domestic public companies. In addition, our executive officers, directors and principal shareholders are exempt from the short-swing profit and recovery provisions contained in Section 16(b) of the Exchange Act. 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 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 the Nasdaq corporate governance listing standards. These practices may afford less protection to shareholders than they would enjoy if we complied fully with corporate governance listing standards.

As a Dutch public company with limited liability, we are not obligated to, and do not comply with, all the best practice provisions of the DCGC, which may affect shareholders’ rights. 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, we must list the reasons for any deviation from the DCGC in our annual report filed in the Netherlands.

**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) none of the following conditions may be true: (i) a majority of our executive officers or directors are U.S. citizens or residents, (ii) more than 50% of our assets are located in the U.S. and (iii) our business is administered principally in the U.S. As of February 19, 2025, 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.).

In June 2025, the SEC issued a concept release soliciting public comment on potential changes to the definition of a foreign private issuer. This release is the first review of the foreign private issuer framework since 2008, and the SEC is considering revisions that could significantly impact which foreign companies qualify for the more accommodative U.S. reporting, corporate governance requirements afforded to foreign private issuers, as well as the lack of Section 16(b) liability for certain FPI officers, directors and shareholders. The SEC may revise the requirements to qualify as a foreign private issuer in a way that changes our status as a foreign private issuer and results in us qualifying as a U.S. domestic issuer. This could cause us to have to comply with regulations applicable to U.S. domestic issuers in a very compressed timeframe. 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 passive foreign investment company for U.S. federal income tax purposes, this could result in adverse U.S. tax consequences to certain U.S. holders.**

If the Company is classified as a passive foreign investment company (**PFIC**) for any taxable year, U.S. investors may be subject to adverse U.S. federal income tax consequences described below under Section 5.15.1 "Taxation – U.S. Federal Income Tax Considerations – Passive Foreign Investment Company Considerations". The Company will be classified as a PFIC for U.S. federal income tax purposes for any taxable year in which, taking into account a pro rata portion of the income and assets of 25% or more owned subsidiaries, either (i) at least 75% of its gross income consists of "passive income" or (ii) at least 50% of the average quarterly value of its assets is attributable to assets that produce, or are held for the production of, passive income.

Based on our historic and anticipated operations, the composition of our income and the projected composition and estimated fair market values of our assets, we do not believe that we were a PFIC for our most recent taxable year and do not expect to be classified as a PFIC for the current taxable year or for the foreseeable future. However, our status as a PFIC is a factual determination made on an annual basis, and we cannot provide any assurances regarding our PFIC status for the current or future taxable years.