1 Presentation of the Group

1 Presentation of the Group

1.1 Company Profile

1.1.1 General

At argenx, we are defining the future of immunology with an entrepreneurial mindset, bringing together agility, focus, and a collaboration in all that we do. We are a global, commercial-stage, entrepreneurial science company. Our co-creative discovery engine, the Immunology Innovation Program, is powered by partnerships between leading disease biologists and our antibody engineers, enabling us to advance with urgency a robust pipeline of differentiated therapies for severe diseases. We are committed to accelerating innovation, breaking down barriers to access, and building lasting trust through transparency and evidence. Our dynamic pipeline and evidence-driven approach position argenx to deliver sustainable growth and long-term value for patients, healthcare providers, and investors alike.

We developed and commercialized the first approved FcRn blocker and we are evaluating efgartigimod in multiple serious autoimmune diseases. We are also advancing our second and third assets, empasiprubart, a complement 2 (***C2***) inhibitor and adimanebart, a muscle-specific kinase (***MuSK***) agonist, both of which are now in Phase 3 clinical trials.

Our legal and commercial name is argenx SE. We were incorporated under the laws of the Netherlands on April 25, 2008, as a private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*). From incorporation until August 28, 2009, our research and development activities were initially performed in the Netherlands, then Belgium, by argenx N.V. and its legal predecessors. Since August 28, 2009, all our research and development activities have been performed by our wholly-owned subsidiary, argenx BV, under a license provided by argenx N.V. Throughout this time, argenx BV assigned all resulting intellectual property to argenx N.V. On May 28, 2014, we converted to a Dutch public company with limited liability (*naamloze vennootschap*). On April 26, 2017, we converted to a Dutch European public company with limited liability (***Societas Europaea*** or ***SE***). On May 5, 2017, we transferred the legal ownership of all intellectual property rights of argenx SE to argenx BV, effective retroactively as of January 1, 2017. As a result, since January 1, 2017, (i) argenx BV holds all legal and economic ownership of our intellectual property rights, and (ii) the research and development agreement between argenx SE and argenx BV has been terminated.

Our official seat is in Amsterdam, the Netherlands, and our registered office is at Laarderhoogtweg 25, 1101 EB Amsterdam, the Netherlands. We are registered with the trade register of the Dutch Chamber of Commerce under number 24435214. Our European legal entity identifier number (***LEI***) is 7245009C5FZE6G9ODQ71. Our telephone number is +31 (0) 10 70 38 441. Our website address is www.argenx.com. This website is not incorporated by reference in this Annual Report. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at www.sec.gov. The registered agent for service of process in the U.S. is CT Corporation System, with an address at 111 8th Avenue, New York, NY 10011.

Our ordinary shares are listed on the regulated market of Euronext Brussels in Belgium under ISIN NL0010832176 under the symbol “ARGX” since 2014 and ADSs, each representing one ordinary share in argenx (or a right to receive such share), are listed on the Nasdaq Global Select Market (***Nasdaq***) under the symbol “ARGX” since 2017.

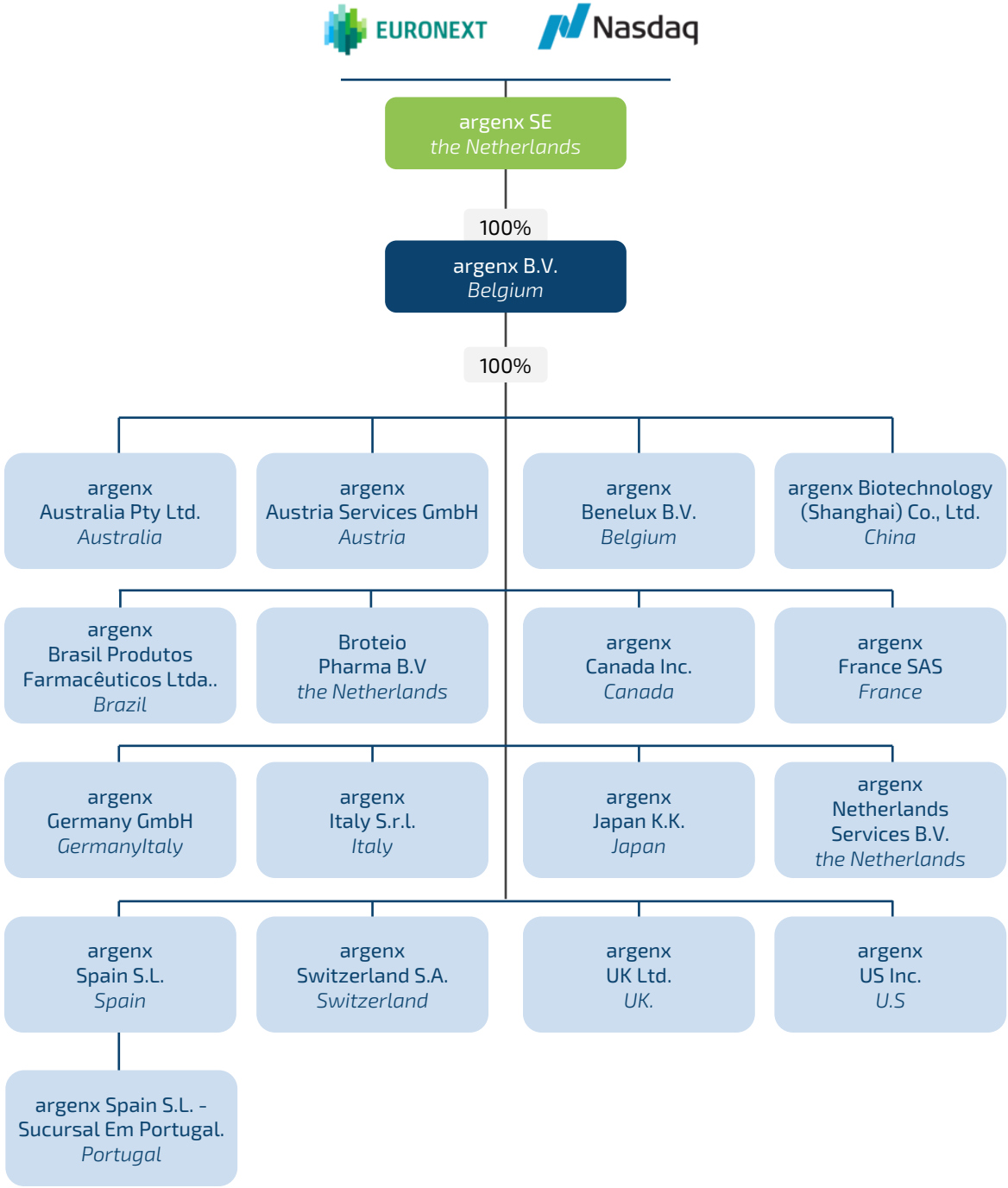
argenx SE is the parent entity of the Group and the sole shareholder of:

- **argenx B.V.**, a private company with limited liability (besloten vennootschap/société à responsabilité limitée) incorporated under the laws of Belgium, having its registered seat in Zwijnaarde, Belgium and its address at Industriepark-Zwijnaarde 7, 9052 Zwijnaarde, Belgium. argenx B.V. is the sole shareholder of:
  - **argenx Australia Pty. Ltd.**,incorporated under the laws of Australia, having its registered office and address at Level 14, 2 Riverside Quay, Melbourne VIC 3006, Australia;

- **argenx Austria Services GmbH**, incorporated under the laws of Austria, having its registered office and address at Graben 19, 4th & 5th floor Vienna A-1010 Austria;
- **argenx Benelux B.V.** (prior to October 31, 2022 known as argenx IIP BV), incorporated under the laws of Belgium, having its registered seat in Zwijnaarde, Belgium and its address at Industriepark-Zwijnaarde 7, 9052 Zwijnaarde, Belgium;
- **argenx Biotechnology (Shanghai) Co., Ltd.**, incorporated under the laws of China, having its registered office and address at Room 301-3, No. 481-479 Ping Xing Guan Road, Jingan District, Shanghai, China;
- **argenx Brasil Produtos Farmacêuticos Ltda**, incorporated under the laws of Brazil, having its registered office in Sao Paulo, Brazil and its address at Estrade da Lagoinha, 489 – Bloco 4, Bairro Lagoa CEP 06730-000, City of Vargem Grande Paulista, Sao Paulo, Brazil;
- **argenx Canada Inc.**, incorporated under the laws of Ontario, having its registered office in Ontario, Canada and its address at 9131 Keele Street Suite A4, Vaughan, Ontario, Canada, L4K 0G7;
- **argenx France SAS**, incorporated under the laws of France, having its registered office in Issy-les-Moulineaux, France and its address at 24 rue Gouverneur Général Félix Éboué, 92130 Issy-les-Moulineaux, France;
- **argenx Germany GmbH**, incorporated under the laws of Germany, having its registered office in Munich, Germany and its address at Konrad-Zuse-Platz 8, 81829 Munich, Germany;
- **argenx Italy S.r.l.**, incorporated under the laws of Italy, having its registered office in Milan, Italy and its address at Largo Francesco Richini 6 CAP, 20122 Milan, Italy;
- **argenx Japan KK.**, incorporated under the laws of Japan, having its registered office in Tokyo, Japan and its address at HULIC JP Akasaka Building 2-5-8, Akasaka, Minato-ku, Tokyo, 107-0052, Japan;
- **argenx Netherlands Services B.V.**, incorporated under the laws of the Netherlands having its registered office at Laarderhoogtweg 25, 1101 EB Amsterdam, the Netherlands;
- **argenx Spain S.L.**, incorporated under the laws of Spain, having its registered office in Madrid, Spain and its address at Paseo dela Castellana 200, Planta 8a, Oficina 819, 28046 Madrid, Spain, with the branch office: **argenx Spain S.L. - Sucursal em Portugal**, organized under the laws of Portugal, having its registered office and address at Palácio Sottomayor, Rua Sousa Martins, nº1, 1º esquerdo 1050 217, Lisboa, Portugal;
- **argenx Switzerland, S.A.**, incorporated under the laws of Switzerland, having its registered office in Geneva, Switzerland and its address at Rue du Pré-de-la-Bichette 1, 1202 Geneva, Switzerland;
- **argenx UK Ltd.**, incorporated under the laws of the UK, having its registered office in Gerrards Cross, UK and its address at Spaces Gerrards Cross Chalfont Park, Building 1 Gerrards Cross, SL9 0BG, UK;
- **argenx US, Inc.**, incorporated under the laws of the state of Delaware, U.S., having its registered office in Wilmington, Delaware and its address at 33 Arch Street, Boston, Massachusetts 02110and;
- **Broteio Pharma B.V.**, incorporated under the laws of the Netherlands, having its registered office at Laarderhoogtweg 25, 1101 EB Amsterdam, the Netherlands.

The following chart provides an overview of the Group as of the date of this Annual Report. Percentages refer to both the share of capital and voting rights.

argenx Corporate Legal Structure



1.1.2 Overview

Our Medicines

VYVGART and VYVGART HYTRULO is a first-and-only immunoglobulin G (***IgG***) Fc-antibody fragment that targets the FcRn. It is approved for the treatment in three indications, including gMG and CIDP globally and ITP in Japan (as VYVDURA).

Our Pipeline

- **efgartigimod** is an IgG1 antibody Fc fragment that has been engineered for increased affinity to FcRn compared to endogenous IgG. Efgartigimod selectively reduces IgG by blocking FcRn-mediated IgG recycling without impacting antibody production or affecting other parts of the immune system. It is approved in three indications, including gMG, CIDP and ITP, and is being evaluated in more than ten additional serious autoimmune indications.
- **empasiprubart (C2 inhibitor)** is a novel complement inhibitor targeting ***C2***, blocking the function of both the classical and lectin pathways while leaving the alternative pathway intact. We believe empasiprubart has the potential to be a pipeline-in-a-product candidate and is being evaluated in two indications currently in Phase 3 clinical trials.
- **adimanebart (MusK agonist)**: adimanebart is an agonist SIMPLE ANTIBODY™ to the ***MuSK*** receptor with potential in multiple neuromuscular indications. It is currently in clinical trials for CMS (Phase 3 clinical trial) and SMA (Phase 2).
- **Earlier Stage Programs:**
  - Two future FcRn molecules are progressing: ARGX-213, an FcRn-targeted antibody engineered for half-life extension and sustained IgG reduction, and ARGX-124, a first-in-class FcRn pipeline candidate.
  - ARGX-109 (targeting IL-6) and ARGX-121 (a first-in-class molecule targeting immunoglobulin A (***IgA***)) are also progressing.
  - Entered into a research collaboration with Tensegrity Pharma, including an option for future acquisition, to advance Tensegrity's lead program TSP-101 in autoimmune disease and other indications.
  - Three new molecules expected to enter Phase 1 clinical trials in 2026, including ARGX-118, a first-in-class molecule targeting Galectin-10, ARGX-125, a first-in-class bispecific antibody, and TSP-101, targeting Fn14.
- In addition to our wholly-owned pipeline, we have candidates that emerged from our IIP that we out-licensed to a partner for further development and for which we have milestone, royalty or profit-share agreements. These candidates include, amongst others: cusatuzumab (*anti-CD70 antibody – OncoVerity*), ARGX-112 (*LP-0145 – anti-IL-22R antibody – LEO Pharma*), ARGX-114 (*AGMB-101 – agonistic anti-MET antibody – Agomab*) and ARGX-115 (*ABBV-151 – anti-GARP antibody – AbbVie*).

Immunology Innovation Program (IIP)

Our IIP is the engine behind our robust and expansive pipeline. By fostering deep, ongoing collaboration between leading academic researchers and our in-house antibody engineers, we aim to translate breakthrough science into first-in-class therapies across multiple indications. This co-creation model has enabled every candidate in our wholly owned and partnered pipelines to emerge from IIP collaborations, underscoring our ability to identify and advance novel targets with speed and precision.

Our approach is designed for scale and sustainability: we run parallel development programs, optimize trial design for efficiency, and maintain a relentless focus on unmet patient needs. This strategy has delivered measurable results – accelerating our path to profitability, driving strong commercial growth, and positioning argenx as a leader in immunology innovation. By integrating the aspirations of patients and the insights of healthcare professionals into every stage of discovery and development, we are not only building a differentiated pipeline but also setting new standards for impact and value creation in the sector.

We bring to the collaboration our unique suite of antibody discovery and antibody engineering technologies and experience in clinical development to complement our partners' expertise in disease and target biology. Our suite of technologies includes amongst others our **SIMPLE ANTIBODY™** platform technology and **NHANCE™, ABDEG™, POTELLIGENT®,** and **DHS mutations** that focus on engineering the Fc region of antibodies in order to augment their intrinsic therapeutic properties.

Our Suite of Technologies

- **SIMPLE ANTIBODY™** platform technology: Our proprietary SIMPLE ANTIBODY™ platform technology, based on the powerful llama immune system, allows us to exploit novel and complex disease biology targets. The platform sources antibody variable regions (***V-regions***) from the immune system of outbred llamas, each of which has a different genetic background. The llama produces highly diverse panels of

antibodies with a high human homology, or similarity, in their V-regions when immunized with targets of human disease. Our SIMPLE ANTIBODY™ platform technology allows us to access and explore a broad target universe while potentially minimizing the long timelines associated with generating antibody candidates using traditional methods.

- **NHANCE™, ABDEG™, POTELLIGENT®**, and **DHS mutations** focus on engineering the Fc region of antibodies in order to augment their intrinsic therapeutic properties. In addition, we obtained a non-exclusive research license and option from Chugai Pharmaceutical Co., Ltd. for the **SMART-Ig®** ("Recycling Antibody" and part of "Sweeping Antibody") and **ACT-Ig®** (Antibody half-life extending) technologies. These technologies are designed to enable us to expand the therapeutic index of our product candidates, which is the ratio between toxic and therapeutic dose, by potentially modifying their half-life, tissue penetration, rate of disease target clearance and potency.

1.2 Strategy and Objectives

1.2.1 Company's Strategies

Our objective is to transform the lives of at least 50,000 patients and their communities before 2030 by providing them with life-changing medicines built on scientific breakthroughs in immunology. To reach this, we aim to deliver on a set of different goals:

- Transform the lives of 50,000 patients, by redefining treatment expectations in MG & CIDP and delivering at least eight additional labeled indications and a second self-administered FcRn medicine by 2030.
- Be the precision complement inhibitor that sets a new SOC and improves patient experience and outcomes across indications, with 3+ labeled indications and five total indications in development by 2030.
- Be the leader in neuromuscular junction (***NMJ***) therapeutics, redefining patient expectations and reigniting hope in one labeled indication and at least four total indications by 2030.
- Expand our pipeline of transformational innovation to enable consistent cadence of value creation for patients; >5 new molecules in late stage by 2030.
- Scale in The argenx Way to remain a unique, independent company.
- Solidify our place in the biotech ecosystem as the benchmark for entrepreneurial science delivering value for patients.

1.2.2 Competitive position

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

Competition in the autoimmune field is intense and involves multiple monoclonal antibodies (mAbs), other biologics and small molecules either already marketed or in development by many different companies, including large pharmaceutical companies. We compete with a wide range of biopharmaceutical companies that are developing products for the treatment of gMG, CIDP, ITP 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. We are aware of several FcRn inhibitors that are in clinical development or marketed.

In addition, we may face future competition from biosimilar versions of approved biologics in the autoimmune and immunology fields. The regulatory frameworks in the United States, Europe and other key markets could evolve in ways that may facilitate the entry of biosimilars once reference products lose market exclusivity. While FcRn inhibitors are a relatively new therapeutic class, the broader biologics market

has seen an increase in biosimilar development and commercial activity, supported by maturing regulatory pathways, expanding manufacturing capabilities and ongoing payer and health-system initiatives aimed at reducing the cost of care.

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 compete with us to recruit and retain qualified scientific and management personnel, establish clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, the development of our products. Please see the risk factor titled "**We face significant competition for our drug discovery and development efforts".**
We compete in this dynamic landscape by aiming to advancing differentiated, first-in-class and best-in-class therapies grounded in novel biology, enabled by our deep scientific expertise and our technology platforms. Our strategy is to innovate ahead of the field—identifying new pathways, engineering unique mechanisms of action, and continuously expanding our understanding of Fc-mediated biology and related immunology. We also actively protect and strengthen our intellectual property through a comprehensive global portfolio of patents, trade secrets and proprietary know-how covering our product candidates, platforms and manufacturing processes. This commitment to scientific innovation and robust IP protection is central to sustaining our competitive position and delivering long-term value.

1.3 Our Products and Product Candidates

The following table summarizes key information on our portfolio of lead products and product candidates as of the date of this Annual Report.

Program	Indication	Preclinical	Phase 1	Proof of Concept	Registrational	Commercial
VYVGART	gMG					
	ITP (Japan)					
VYVGART HYTRULO	gMG					
	CIDP					
efgartigimod	Seronegative gMG					
	Ocular MG					
	Primary ITP					
	Graves' Disease					
	Myositis					
	SjD					
	Systemic Sclerosis					
	AMR					
empasiprubart	MMN					
	DGF					
	CIDP					
adimanebart	CMS					
	SMA					
ARGX-213	Undisclosed					
ARGX-121	IgA Nephropathy					
ARGX-124	Undisclosed					
ARGX-109	Undisclosed					
TSP-101	Undisclosed					
ARGX-118	Undisclosed					
ARGX-125	Undisclosed					

NEUROLOGY | NEPHROLOGY AND HEMATOLOGY | ENDOCRINOLOGY | RHEUMATOLOGY | UNDISCLOSED

1.3.1 VYVGART

Approvals and Regulatory Plan

VYVGART is approved in more than 30 countries with three active indications (gMG, CIDP and ITP) and three presentations (IV, SC, PFS). More approvals and launches of VYVGART in multiple jurisdictions and countries are planned following pricing and reimbursement negotiations. The following table summarizes the status of regulatory approvals for VYVGART as of February 2026:

	Product	Indication	Geography	Regulatory Status
VYVGART IV	VYVGART	gMG	US	Approved
	VYVGART	gMG	Europe	Approved
	VYVGART	gMG	Canada	Approved
	VYVGART	gMG	Israel	Approved
	VYVGART	gMG	Japan	Approved
	VYVGART	gMG	The UK	Approved
	VYVGART	gMG	China	Approved
	VYVGART	gMG	Australia	Approved
	VYVGART	gMG	Kuwait	Approved
	VYVGART	gMG	Saudi Arabia	Approved
	VYVGART	gMG	Korea (the Republic of)	Approved
	VYVGART	gMG	United Arab Emirates	Approved
	VYVGART	gMG	Switzerland	Approved
	Pending	gMG	Brazil	Submitted
	VYVGART	gMG	Singapore	Approved
	VYVGART	ITP	Japan	Approved
VYVGART SC	VYVGART HYTRULO	gMG	US	Approved
	VYVGART HYTRULO	CIDP	US	Approved
	VYVGART	gMG	Australia	Approved
	VYVGART	CIDP	Australia	Submitted
	VYVGART	gMG	Europe	Approved
	VYVGART	CIDP	Europe	Approved
	VYVGART	gMG	Switzerland	Approved
	VYVGART	CIDP	Switzerland	Submitted
	VYVGART	gMG	The UK	Approved
	VYVGART	CIDP	The UK	Approved
	VYVGART SC	gMG	Israel	Approved
	VYVGART HYTRULO	gMG	China	Approved
	VYVGART HYTRULO	CIDP	China	Approved
	VYVDURA	gMG	Japan	Approved
	VYVDURA	CIDP	Japan	Approved
PFS	VYVDURA	gMG	Japan	Approved
	VYVDURA	CIDP	Japan	Approved
	VYVGART HYTRULO	gMG	U.S.	Approved
	VYVGART HYTRULO	CIDP	U.S.	Approved
	VYVGART	gMG	Europe	Approved
	VYVGART	CIDP	Europe	Approved
	VYVGART SC	gMG	Canada	Approved
	VYVGART SC	CIDP	Canada	Approved
	VYVGART	gMG	The UK	Approved
	VYVGART	CIDP	The UK	Approved
	VYVGART	gMG	Australia	Approved
	VYVGART	CIDP	Australia	Submitted
	VYVGART		Switzerland	Submitted
	VYVGART	gMG	Israel	Submitted
	VYVGART	CIDP	Israel	Submitted

Commercialization

We have established our own sales force in the U.S., Japan, Europe and Canada for VYVGART for the treatment of gMG and CIDP (where approved). We plan to expand our own sales and marketing capabilities and promote our products and product candidates in other regions if we decide there is a business case to do so after regulatory approval has been obtained.

Development and commercialization may also be done through collaborations with third parties. In January 2021, we entered into an exclusive out-license agreement with Zai Lab (***Zai Lab Agreement***), a commercial-stage biopharmaceutical company, for the development and commercialization of efgartigimod in Greater China, (which includes Mainland China, Hong Kong, Taiwan and Macau, ***Greater China***). Zai Lab announced approval of VYVGART in Mainland China in June 2023 for the treatment of adult gMG patients and in 2024 Zai Lab also announced the approval of VYVGART SC for gMG and CIDP. Under the Zai Lab Agreement, we received and continue to be eligible for certain sales-based milestone payments and royalties based on annual product net sales of efgartigimod in Greater China.

We intend to continue expanding into new markets and will evaluate the most appropriate commercialization approach for each territory, whether through our own commercial organization or through additional distribution partnerships.

In the U.S., argenx advertises certain products via digital and traditional media channels, including the internet and television.

For a discussion of total revenues by geographic market, please see "Note 16 Segment Reporting" in our consolidated financial statements which are included in our Annual Report for the period ended December 31, 2025.

Pre-Approval Access Program

We are committed to improving the lives of people suffering from rare diseases. We are driven to discover new treatment approaches fueled by the resilience of patients to urgently deliver them. We aim to do this in partnership; we listen to patients, supporters and advocacy communities, and we hear their stories. Their insights guide us as we develop our investigational therapies and motivate us to advance the understanding of rare diseases.

We have a Pre-Approval Access program (***PAA***) for patients with gMG which opened on February 21, 2021 for patients who are unable to participate in an ongoing clinical trial. In 2024, we approved access to this PAA for over 403 gMG patients in 14 countries. The PAA program remains open in countries where VYVGART is not yet launched or reimbursed.

1.3.2 efgartigimod (ARGX-113) Development

Mechanism of Action

As shown in Figure 1, efgartigimod is a human IgG1 Fc fragment equipped with our ABDEG™ mutations that is designed to target the FcRn and reduce IgG. FcRn is foundational to the immune system and functions to recycle IgG, extending its serum half-life over other IgGs that are not recycled by FcRn. IgGs that bind to FcRn are rescued from lysosomal degradation. By binding to FcRn, efgartigimod can reduce IgG recycling and increase IgG degradation.

Figure 1: efgartigimod's mechanism of action blocks the recycling of IgG antibodies and removes them from circulation. FcRn, neonatal Fc receptor; Ig, immunoglobulin; LDL, low-density lipoprotein.

1) Ulrichts P, et al. J Clin Invest. 2018;128:4372–86
6) Roopenian DC, Akilesh S. Nat Rev Immunol. 2007;7:715–25.
7) Ward ES, Ober RJ. Trends Pharmacol Sci. 2018;39:892–904.

Formulations

Overview

We are developing two formulations of efgartigimod to address the needs of patients, physicians, and payers across indications and geographies, including efgartigimod IV (VYVGART) and efgartigimod SC (VYVGART SC).

1.3.3 efgartigimod Indications

Clinical trial overview

Clinical Trial	Stage	Indication	Patients	Primary Endpoint	Status
ADAPT	Registrational	gMG		The proportion of responders based on the Myasthenia Gravis Activities of Daily Living (MG-ADL) score	Marketed
ADAPT-SC	Registrational	gMG		The proportion of responders based on the Myasthenia Gravis Activities of Daily Living (MG-ADL) score	Marketed
ADAPT-SERON	Registrational	Seronegative gMG	119	MG-ADL total score change from baseline to day 29 (w4)	Positive clinical trial results reported in 2025 with expected PDUFA date of May 10, 2026
ADAPT-OCULUS	Registrational	Ocular MG	141	Change in MGII PRO ocular score from baseline to day 29 (w4)	Positive clinical trial results reported in February 2026
ADHERE	Registrational	CIDP	322	The hazard ratio for the time to first adjusted INCAT deterioration	Marketed
ADVANCE-IV	Registrational	ITP		The proportion of patients that achieved sustained platelet response	Marketed
ADVANCE-NXT	Registrational	ITP	63	Extent of disease control (cumulative number of weeks over the planned 24-week treatment period with platelet counts of ≥ 50×109/L	Ongoing clinical trial results expected in 4Q 2026
ALKIVIA	Registrational	Myositis	Target 240	The total improvement score (TIS) at the end of treatment period	Ongoing clinical trial results expected in 3Q 2026
UNITY	Registrational	SjD	Target 580	The change from baseline on the ClinESSDAI score (w48)	Ongoing clinical trial results expected in 2H 2027
In partnership with Zai Lab	PoC	LN	Target 60	The change in urine protein creatinine ratio from baseline to end of the treatment period	Clinical trial discontinued in 2025
uplighTED	Registrational	TED	Target 108/trial	Percentage of participants who were proptosis responders at week 24	Clinical trial discontinued in 2025
shAMRock	PoC	AMR	Target 30	Safety and tolerability. Efficacy measures such as estimated glomerular filtration rate, histology and urine protein creatinine ratio are captured in the secondary endpoints	Ongoing clinical trial
ADAPT-JUNIOR IV	Phase 2/3	gMG	Target over 12	To confirm an age-adjusted optimum dose of efgartigimod IV and provide (model-predicted) evidence for a treatment response	Ongoing clinical trial
ADAPT-JUNIOR SC	Phase 2/3	gMG	Target over 12	To confirm an appropriate dose of efgartigimod PH20 SC in pediatric participants with gMG	Ongoing clinical trial
Other clinical trials	PoC	AIE	To be confirmed		Ongoing clinical trial
	PoC	AIM	To be confirmed	To be confirmed	Ongoing clinical trial

gMG

Overview

gMG is a rare, chronic autoimmune disease in which pathogenic IgG autoantibodies disrupt neuromuscular signaling, leading to fluctuating and sometimes life-threatening muscle weakness. Autoantibodies block or remove acetylcholine receptors and activate complement, damaging the neuromuscular junction. MG often begins with ocular symptoms such as ptosis and diplopia, and approximately 85% of patients progress to generalized MG (gMG), which can impair bulbar, limb, and respiratory function. Respiratory crises occur in 15–20% of patients. MG prevalence in the U.S. is estimated at approximately 20 per 100,000, and roughly 85% of gMG patients have detectable AChR antibodies.

efgartigimod has demonstrated consistent and robust clinical benefit across MG populations. Pivotal ADAPT data formed the basis for global approvals of VYVGART IV, and positive ADAPT-SC results supported approval of the subcutaneous formulation. In 2025, we reported positive topline results from ADAPT-SERON, our Phase 3 clinical trial in anti-AChR antibody-negative gMG, demonstrating a clear treatment effect and reinforcing the broad applicability of FcRn across MG subtypes. These data support our supplemental regulatory submission to expand VYVGART into the seronegative population, which was accpeted for priority review with an expected PDUFA target action date of May 10, 2026. We also reported positive data from our ADAPT OCULUS clinical trial, which met its primary endpoint, showing that patients living with oMG and treated with VYVGART demonstrated statistically significant improvement from baseline in Myasthenia Impairment Index (MGII) Patient Reported Outcome (PRO) ocular scores at Week 4 compared to placebo. The results support our supplemental regulatory submissions to expand VYVGART into the ocular MG population. We also have ongoing clinical trials in pediatric gMG patients (ADAPT-JUNIOR) with efgartigimod IV and efgartigimod SC.

CIDP

Overview

CIDP is a chronic autoimmune disorder of peripheral nerves and nerve roots caused by an autoimmune-mediated destruction of the myelin sheath, or myelin producing cells, insulating the axon of the nerves and enabling speed of signal transduction. The cause of CIDP is unknown, but abnormalities in both cellular and humoral immunity have been shown. CIDP is a chronic and progressive disease: onset and progression occur over at least eight weeks in contrast with the more acute Guillain-Barré-syndrome. Demyelination and axonal damage in CIDP lead to loss of sensory and/or motor neuron function, which can lead to weakness, sensory loss, imbalance and/or pain. The U.S. prevalence is estimated at approximately 42,000 patients, of whom roughly 24,000 receive treatment. Most patients rely on IVIg as first-line therapy, while glucocorticoids, plasma exchange, and other immunosuppressants are used less frequently given safety, tolerability, and access limitations.

In July 2023, the pivotal ADHERE clinical trial demonstrated that VYVGART SC significantly reduced the risk of relapse compared to placebo and provided evidence that pathogenic IgG autoantibodies play an important role in CIDP biology. Sixty-seven percent of patients entering the open-label Stage A improved clinically, and efgartigimod SC was well tolerated with a safety profile consistent with prior clinical trials. Nearly all eligible patients (99%) continued into the ADHERE-Plus OLE. Based on these data, VYVGART SC received regulatory approvals in the U.S. in June 2024, in China in November 2024, and in Japan in December 2024, with regulatory review ongoing in additional jurisdictions, including the EU.

Primary ITP

Overview

Primary ITP is an acquired autoimmune bleeding disorder, characterized by a low platelet count (<100×109/L) in the absence of other causes associated with thrombocytopenia. In most patients, IgG autoantibodies directed against platelet receptors can be detected. They accelerate platelet clearance and destruction, inhibit platelet production, and impair platelet function, resulting in increased risk of bleeding and impaired quality of life. Primary ITP is differentiated from secondary ITP, which is associated with other illnesses, such as infections or autoimmune diseases, or which occurs after transfusion or taking other drugs, such as cancer drugs. Platelet deficiency, or thrombocytopenia, can cause bleeding in tissues, bruising and slow blood clotting after injury. Patients may suffer from depression and fatigue as well as side effects of existing therapies, impairing their quality of life. Current therapeutic approaches include non-

specific immunosuppression (e.g., steroids and rituximab), inhibition of platelet clearance (e.g., splenectomy, IVIg, anti-D globulin, and spleen tyrosine kinase inhibitor fostamatinib13) or stimulation of platelet production (e.g., thrombopoietin receptor agonist TPO-RA). Splenectomy remains the only treatment that provides sustained remission off therapy for one year or longer for a high proportion of patients. ITP affects approximately 72,000 patients in the U.S.

In 2022, the Phase 3 ADVANCE (IV) clinical trial met its primary endpoint, demonstrating that a higher proportion of chronic ITP patients receiving efgartigimod achieved a sustained platelet count response compared to placebo. These results supported approval of efgartigimod for ITP in Japan. In 2023, the accompanying subcutaneous clinical trial, ADVANCE-SC, did not meet its primary endpoint. To fulfill the requirement for two well-controlled trials needed for global registration, argenx is now conducting ADVANCE-NEXT, a Phase 3, randomized, double-blinded, placebo-controlled trial evaluating efgartigimod IV in adults with primary ITP. ADVANCE-NEXT remains ongoing, with topline Phase 3 results expected in the fourth quarter of 2026.

AIM

Overview

AIM are a rare and heterogeneous group of autoimmune diseases that can affect muscle alone or multiple organ systems, including the skin, joints, lungs, gastrointestinal tract, and heart. These conditions are severe, disabling, and materially impact quality of life. Advances in understanding disease biology and the discovery of characteristic autoantibodies have led to clearer differentiation of AIM into clinically meaningful subtypes, including immune-mediated necrotizing myopathy (***IMNM***), antisynthetase syndrome (***ASyS***), and dermatomyositis (***DM***). Each subtype presents with distinct autoantibody profiles and manifestations, though proximal muscle weakness remains a defining feature across AIM. Today, there are no FDA-approved therapies for IMNM or ASyS, and treatment is largely dependent on steroids or broad immunosuppressants; IVIg was approved for DM in 2021.

argenx is advancing the registrational ALKIVIA clinical trial of efgartigimod SC for the treatment of AIM. ALKIVIA is a seamless Phase 2/3 clinical trial enrolling approximately 240 patients across IMNM, ASyS, and DM, with Total Improvement Score (TIS) as the primary endpoint and a broad set of functional and quality-of-life secondary measures. In November 2024, following achievement of statistical significance on the primary endpoint in the Phase 2 portion and consistent improvement across all six core components of the TIS, argenx announced a 'GO' decision to proceed with the Phase 3 portion in all three AIM subtypes. Safety and tolerability were consistent with the known profile of efgartigimod. ALKIVIA remains ongoing, with topline Phase 3 results expected in the third quarter of 2026.

SjD

Overview

SjD is a chronic, progressive autoimmune disease, characterized by lymphocytic infiltration and progressive destruction of exocrine glands. B-cells play a pivotal role in the development of the disease and this results amongst others in production of IgG autoantibodies, especially those which target SSA/Ro, SSB/La ribonuclear complexes. In addition to symptoms of dry eyes, dry mouth, chronic pain and fatigue, a substantial subset of patients suffer from extraglandular systemic disease. There are no FDA-approved treatments currently registered for the treatment of SjD.

argenx is advancing the registrational UNITY clinical trial of efgartigimod SC for the treatment of SjD. UNITY is a Phase 3, randomized, placebo-controlled, double-blind clinical trial assessing the safety and efficacy of efgartigimod SC in 480 patients with at least moderate systemic disease (ClinESSDAI ≥6) who are on stable background therapy and positive for anti-SSA/Ro. After the 48-week treatment period, eligible participants may roll over into an OLE. The primary endpoint is change from baseline in clinESSDAI, with key secondary endpoints focused on patient-reported outcomes, ESSDAI, and STAR. UNITY remains ongoing, with topline Phase 3 results expected in the second half of 2027.

1.3.4 empasiprubart (ARGX-117) Development

Mechanism of Action

empasiprubart is a differentiated therapeutic mAb targeting C2 equipped with our proprietary NHANCE™ mutations. By addressing a novel target at the intersection of the complement and lectin pathways of the complement cascade, we believe empasiprubart represents a broad pipeline opportunity across several severe autoimmune indications. Activation of the classical and lectin pathway of complement may contribute to tissue damage and organ dysfunction in a number of autoimmune inflammatory diseases and ischemia-reperfusion conditions. Targeting C2 also leaves the alternative pathway of the complement system intact, which is an important component of the innate defense system.

empasiprubart exhibits both pH- and calcium dependent binding. These unique characteristics enable empasiprubart to capture free C2 in circulation and release it in the endosome to be sorted for degradation in the lysosome. empasiprubart is equipped with NHANCE™ mutations increasing its affinity for FcRn and allowing it to recycle back into circulation to capture more C2.

In addition to an IV formulation, we have exclusive access to Halozyme's ENHANZE® SC drug delivery technology for the C2 target.

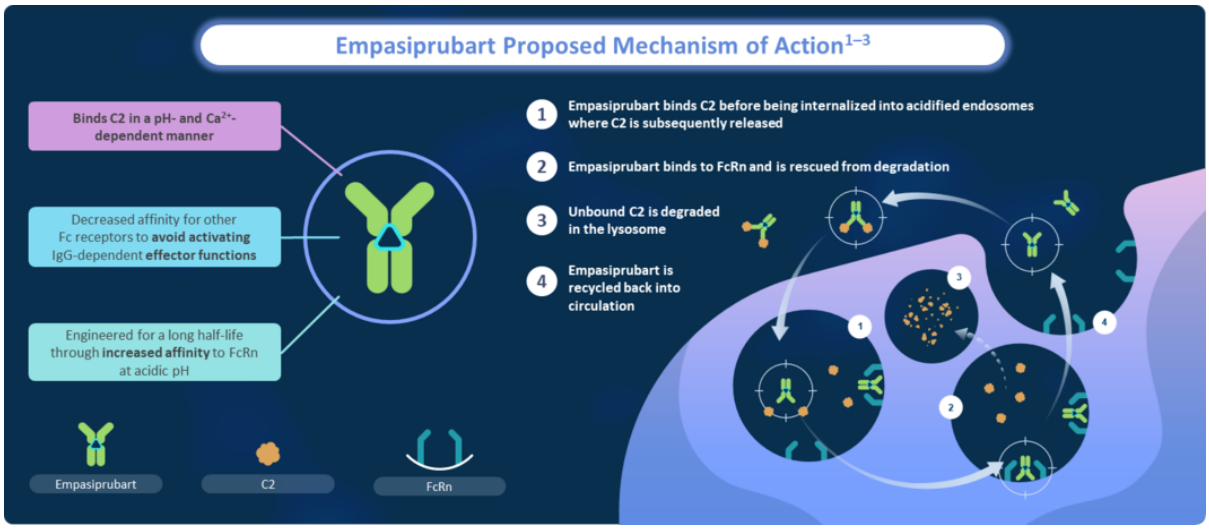


Figure 2: empasiprubart mechanism of action. C2, complement component 2; FcRn, neonatal Fc receptor; IgG, immunoglobulin G.

1) Van de Walle I, et al. J Allergy Clin Immunol. 2021;147:1420–9.
2) Vaccaro C, et al. Proc Natl Acad Sci. 2006;103:18709–14.
3) Brinkhaus M, et al. Nat Commun. 2022;13:6073.

empasiprubart Indications

MMN

Overview

MMN is a debilitating neuromuscular autoimmune disorder that is characterized by slowly progressive muscle weakness due to motor neuron degeneration. It mainly affects hands and forearms, mainly in males, and the median age of diagnosis is around 40 years. Diagnosis takes about a year and a half and is often misdiagnosed as ALS. There are estimated to be around 12,000 patients across key markets.

Specific pathophysiologic characteristics of MMN include the presence of IgM autoantibodies against the ganglioside GM1 and conduction block, i.e., impaired propagation of action potentials along the axon. GM1 is widely expressed in the nervous system by neurons, particularly around the nodes of Ranvier, and Schwann cells.

IVIg is the only approved treatment for MMN and needs to be dosed frequently to address the disease's progressive nature.

Phase 2 POC ARDA Clinical Trial

The Phase 2 POC ARDA clinical trial was a randomized, double-blinded, placebo-controlled multicenter clinical trial evaluating the safety and tolerability, efficacy, PK, PD, and immunogenicity of two dose regimens of empasiprubart in adults with MMN. Safety and tolerability were the primary endpoint and additional endpoints included time to IVIg retreatment, biomarker analyses of C2 levels, and changes in key functional scores (modified medical research council-10 sum score, grip strength, MMN-RODS) as well as several patient-reported quality-of-life measures (fatigue severity score (FSS), chronic acquired polyneuropathy patient-reported index (CAP-PRI), and patient global impression change scale). In 2024, argenx announced positive data from the first cohort (n=16), which were confirmed with the second cohort (n=16) in July 2024, establishing POC in MMN, with empasiprubart demonstrating a 91% reduction in the need for IVIg rescue compared to placebo [HR (95% CI)=0.09 (0.02; 0.44)] in cohort 1 and an 84% reduction in IVIg rescue compared to placebo [HR (95% CI)=0.16 (0.02; 1.54)] in cohort 2.

Based on these results argenx initiated the EMPASSION Phase 3 clinical trial evaluating empasiprubart in MMN head to head with IVIg at the end of 2024.

Phase 3 EMPASSION Clinical Trial Design

A Phase 3, randomized, double-blinded, double-dummy clinical trial evaluating the efficacy and safety of empasiprubart versus intravenous immunoglobulin in adults with multifocal motor neuropathy. The clinical trial comprises a screening period of up to 15 weeks, including a minimum of 2 IVIg cycles; a 24-week (6-month), randomized, double-blinded, double-dummy treatment period (part A) evaluating the efficacy and safety of empasiprubart vs IVIg continuation; a 24-month OLE period (part B); and a 15-month safety follow-up period starting after the last dose of IMP. The primary objective is to demonstrate the efficacy of empasiprubart compared to IVIg in improving functional ability. This will be measured by change from baseline in the 25-item MMN-RODS centile score at week 24. Additional key secondary endpoints include changes in measurements on key functional scores (modified medical research council -14 sum score, grip strength) as well as patient-reported quality of life outcome measures (polyneuropathy patient-reported index, and values of the patient global impression change scale and evaluation of manual dexterity using 9HPT.

DGF

Delayed graft function (***DGF***), defined as the need for dialysis in the first week after kidney transplant, affects up to 40% of deceased-donor recipients and is associated with poorer long-term outcomes. Decision for Phase 2 VARVARA clinical trial is now expected mid-year 2026 to complete 52-week efficacy analysis

CIDP

Overview

Please refer to Section "1.3.3 efgartigimod Indications" (CIDP) for more information on CIDP.

Phase 3 EMVIGORATE and EMNERGIZE Clinical Trials

argenx is advancing two Phase 3 clinical trials of empasiprubart in CIDP: EMVIGORATE and EMNERGIZE. EMVIGORATE is a head-to-head clinical trial comparing empasiprubart to IVIg in adults with CIDP. EMNERGIZE is a randomized, placebo-controlled clinical trial evaluating the efficacy and safety of empasiprubart. Topline results from both EMVIGORATE and EMNERGIZE are expected in the second half of 2027.

1.3.5 adimanebart (ARGX-119) Development

adimanebart is a humanized agonist monoclonal antibody that specifically targets and activates MuSK to promote maturation and stabilization of the NMJ, with planned development across severe neuromuscular diseases including CMS, ALS, and SMA. It is the first highly specific agonist mAb targeting human MuSK and was developed using the SIMPLE ANTIBODY™ platform in collaboration with leading experts, with preclinical proof-of-concept demonstrated in a DOK7-CMS model.

A Phase 3 clinical trial in CMS is expected to initiate in the third quarter of 2026, following positive results from the Phase 1b clinical trial.

A proof-of-concept clinical trial is also ongoing in SMA.

1.4 Collaborations and licenses

At argenx, our approach to collaboration and licensing is rooted in the conviction that progress accelerates when boundaries are challenged and expertise is shared. We follow a disciplined strategy to maximize the value of our pipeline. We retain full development and commercialization rights for programs where we believe our platform and capabilities can deliver the greatest impact, ensuring we capture the full value of our innovation. At the same time, we actively seek out partnerships with organizations that share our drive to redefine what's possible, leveraging complementary strengths to unlock new opportunities for patients.

Our licensing strategy is dynamic and pragmatic: we license out select intellectual property to expand the reach of our science, while we also in-license or acquire technologies and assets that can amplify our pipeline or accelerate development. We have partnered, and plan to continue to partner, to develop products and product candidates that we believe have promising utility in disease areas or have patient populations that may benefit from resources of other biopharmaceutical companies. We believe every agreement is shaped by a clear-eyed focus on execution, mutual benefit, and the potential to create lasting change. We aim to be disciplined in our diligence and financial commitments, but not at the expense of agility or ambition. By building alliances that transcend traditional hierarchies and by staying relentlessly focused on unmet needs, we are not just advancing our own portfolio, we are helping to reshape the landscape of immunology for the long term.

We also have several license agreements in place, under which we license patents, patent applications and other intellectual property to third parties. We have also entered into several license agreements under which we license patents, patent applications and other intellectual property from third parties. License agreements can relate to research and development and/or commercialization of the relevant product candidates (and technologies) or products. The licensed intellectual property covers some of our product candidates and some of the antibody engineering technologies that we use. Some of these licenses impose various diligence and financial payment obligations on us. We expect to continue to enter into these types of license agreements in the future.

We have entered into multiple collaboration agreements with pharmaceutical partners and license agreements, some of which are described below.

1.4.1 Our Strategic Partnership with Zai Lab for efgartigimod

Pursuant to the Zai Lab Agreement, Zai Lab obtained the exclusive right to develop and commercialize efgartigimod in Greater China. Zai Lab will also contribute patients to our global Phase 3 clinical trials of efgartigimod. Our Zai Lab strategic collaboration allows us to accelerate development of efgartigimod into new autoimmune indications with Zai Lab taking operational leadership of selected Phase 2 POC Clinical trials.

We are eligible to receive a one-time sales based milestone and tiered royalties based on annual net sales of efgartigimod in Greater China thereafter.

1.4.2 Our Exclusive License with Halozyme for ENHANZE®

In February 2019, we entered into an in-license agreement with Halozyme for the use of certain patents, materials and know-how owned by Halozyme and relating to its ENHANZE®, for application in the field of prevention and treatment of human diseases (the ENHANZE® License Agreement). Pursuant to the ENHANZE® License Agreement, we were granted exclusive rights to apply ENHANZE® to biologic products against pre-specified targets, in order to research, develop and commercialize SC formulations of our therapeutic antibody-based product candidates.

Our first therapeutic target for which we received an exclusive license from Halozyme was FcRn, which allows us to apply ENHANZE® to efgartigimod and any other product candidates selective and specific for FcRn. Moreover, the breadth of our exclusive license to FcRn precludes either Halozyme itself or any of its current or future partners from utilizing ENHANZE® in the context of an FcRn-targeted product. Our second therapeutic target for which we received an exclusive license from Halozyme was human C2 associated with the product candidate empasiprubart, which is being developed to treat severe autoimmune diseases. Pursuant to the ENHANZE® License Agreement, we also have the right to nominate future targets for an exclusive ENHANZE® license if the target in question has not already been licensed by Halozyme or is not already being pursued by Halozyme.

We have expanded our collaboration with Halozyme for ENHANZE® drug delivery technology to additional targets for a total of six, including FcRn and C2.

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

1.4.3 Our Exclusive License with the University of Texas for NHANCE™ and ABDEG™

In February 2012, we entered into an exclusive in-license with the Board of Regents of the University of Texas System (***UT BoR***) for the use of certain patent rights relating to the NHANCE™ platform for any use worldwide (the ***UT Agreement***). The UT Agreement was amended on December 23, 2014 to also include certain additional patent rights relating to the ABDEG™ platform. Upon commercialization of any of our products that use the in-licensed patent rights, we will be obligated to pay UT BoR a percentage of net sales as a royalty until the expiration of any patents covering the product. This royalty varies with net sales volume and is subject to an adjustment for royalties we receive from a sublicensee of our rights under the UT Agreement, but in any event does not exceed 1%. In addition, we must make annual license maintenance payments to UT BoR until termination of the UT Agreement and we have assumed certain development and commercial milestone payment and reimbursement obligations. We also have diligence requirements with respect to development and commercialization of products which use the in-licensed patent rights.

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

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

1.4.4 OncoVerity for cusatuzumab

In 2022, we, the University of Colorado Anschutz Medical Campus and the University of Colorado Health (***UCHealth***) created an asset-centric spin-off, OncoVerity, Inc (***OncoVerity)***, focused on optimizing and advancing the development of cusatuzumab, a novel anti-CD70 antibody, in acute myeloid leukemia (***AML***). OncoVerity is an entity of co-creation, combining the extensive translational biology insights from Dr. Clayton Smith, M.D. from the University of Colorado with our experience on the CD70/CD27 pathway.

In 2023, we granted an exclusive license for cusatuzumab to OncoVerity and provided, together with a joint venture of University of Colorado Health and University License Equity Holdings, Inc. on the University of Colorado Anschutz Medical Campus, and funding for ongoing clinical development of cusatuzumab.

In 2024 and 2025, we participated in a further funding round to support the continued, ongoing, clinical development of cusatuzumab by OncoVerity.

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

In 2016, we entered into a collaboration agreement with AbbVie for ARGX-115 (ABBV-151), targeting GARP in oncology (the AbbVie Collaboration Agreement). After completing IND-enabling work, AbbVie exercised its option and assumed full responsibility for global development and commercialization. We are eligible for up to $625 million in potential development, regulatory and commercial milestones, plus tiered royalties from the mid-single digits to lower teens. We also retain co-promotion rights in the EEA and Switzerland. The agreement continues on a product-by-product basis until AbbVie's payment obligations expire, and AbbVie may terminate the AbbVie Collaboration Agreement with prior notice.

1.5 Manufacturing and Supply

At argenx, our manufacturing and supply strategy is built for scale, resilience, and speed, reflecting our commitment to move science forward and deliver for patients worldwide. We utilize third-party contract manufacturers who act in accordance with the FDA's current good manufacturing practices (***cGMPs***) for the manufacture of drug substances and drug products. We partner with a global network of contract manufacturers who share our standards for quality and innovation, with the goal that every step, from cell bank development to large-scale drug substance production, meets the highest industry benchmarks. Our global supply chain and distribution strategy is to serve patients in region for that region. We work with Lonza teams based in Slough, UK, Portsmouth, U.S., Singapore and Visp, Switzerland for activities relating to the development of cell banks, development of our manufacturing processes and the manufacturing of drug substance, thereby using validated and scalable systems broadly accepted in our industry. In 2022, we started our collaboration with FUJIFILM Diosynth Biotechnologies Denmark ApS (***Fujifilm***) based in Hillerød, Denmark, for activities relating to the large-scale manufacturing of efgartigimod drug substance. In 2025, we expanded our partnership with Fujifilm to include new manufacturing site in North Carolina, U.S., strengthening our global supply chain and supporting anticipated growth in efgartigimod and pipeline assets.

We use additional contract manufacturers to fill, label, package, store and distribute (investigational) drug products.

1.6 Intellectual Property

1.6.1 Introduction

We strive to protect and maintain exclusivity for the proprietary technologies that we believe are important to our patients, business, and shareholders. We continue to pursue and maintain patent protection intended to cover core platform technologies incorporated into, or used to produce, our product candidates and commercial products. We will seek protection for our patient innovations in key global jurisdictions. We continue to focus our exclusivity strategies on all aspects of our assets, including our compositions of matter, methods of use for our approved products, and other inventions that are important to our business (e.g., the patient innovations described in our product labels/product inserts and our core manufacturing technologies).

Our intellectual property portfolio continues to grow and keep pace with the innovations arising from our discovery, development, and commercial efforts. We expect the total volume of patent positions under our management to increase each year as our pipeline evolves. We currently oversee more than 500 pending applications and granted patents. More importantly, as we continue to innovate for patients, we will work to protect our patient innovations with new intellectual property filings to enable future reinvestment for patients.

In addition to patent protection, we rely on trademarks and trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection, including certain aspects of our llama immunization and antibody affinity maturation approaches.

Our commercial success depends in part upon our ability to obtain and maintain exclusivity, including regulatory exclusivities, patent, trade secret, and other proprietary protection for commercially important technologies, inventions and know-how related to our business. We will defend and enforce our intellectual property rights, particularly our patent rights, and preserve the confidentiality of our trade secrets while operating without infringing valid and enforceable intellectual property rights of others. Specifically, we are materially dependent on elements of our regulatory, patent and other proprietary protection, including certain of those related to our core platform technologies, described in Section 1.6.2 "**Platform Technologies**" below and our product candidates, as described in Section 1.6.3 "**Our Internal Programs**" below and Section 1.6.4 "**Our Partnered Programs**" below.

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

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

In the U.S., the term of a patent covering an FDA-approved drug may be eligible for a limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (***Hatch-Waxman Act***) as compensation for the loss of patent term during the FDA regulatory review process as described in Section 1.7.1 "**Licensure and Regulation of Biologics in the U.S**" below. Similar provisions are available in the EU and in other jurisdictions to extend the term of a patent that covers an approved drug and/or its use. It is possible that issued U.S. patents covering each of our products/product candidates may be entitled to patent term extensions. If our product candidates receive FDA approval, we intend to apply for patent term extensions, if available, to extend the term of patents that cover the approved product candidates and/or their uses. We also intend to seek patent term extensions in any jurisdictions where available. There is no guarantee that the applicable authorities, including the FDA, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions.

1.6.2 Platform Technologies

With regard to our platform technologies, we own or control intellectual property rights directed to our SIMPLE ANTIBODY™ discovery platform, the ABDEG™ and NHANCE™ technologies.

With regard to our SIMPLE ANTIBODY™ discovery platform, we have a broad patent portfolio providing exclusivity on the SIMPLE ANTIBODY™ platform. We expect to enjoy exclusivity under this patent portfolio until between 2029 and 2033.

With regard to the ABDEG™ platform, we co-own the technology with the University of Texas Southwestern Medical Center and enjoy certain exclusive license rights. We have a broad patent portfolio covering the composition of matter and uses of certain FcRn antagonists to achieve certain biological effects. A composition of matter patent expires in 2036 in the U.S., whereas in many other countries the base expiry date is 2034.

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

1.6.3 Our Internal Programs

efgartigimod

efgartigimod incorporates the ABDEG™ platform technology, for which we co-own the technology with the University of Texas Southwestern Medical Center and enjoy certain exclusive license rights. We have a broad patent portfolio with multiple patent families covering the composition of matter and uses of certain FcRn antagonists to achieve disease-modifying effects. A composition of matter and other relevant patents arising from the same patent family in the U.S. expire in 2036 and 2037 in Europe whereas in many other countries the base expiry date is 2034. We anticipate several more patient innovations to evolve during development and commercialization for which we will seek additional patent protection with later expiration dates.

Our ARGX-109 Product Candidate

With regard to our wholly-owned ARGX-109 product candidate, we have one patent family with composition of matter claims directed to ARGX-109. The patent family has a base expiry date in 2033. We anticipate several more patient innovations to evolve during development for which we will seek additional patent protection. Furthermore, ARGX-109 incorporates or employs the SIMPLE ANTIBODY™ platform technology and the NHANCE™ platform technology.

empasiprubart Product Candidate

With regard to the empasiprubart product candidate, we own or have rights to multiple patent families (with several granted patents and pending patent applications in multiple jurisdictions in North America, South America, the EU and Asia, directed to composition of matter claims and method of treatment claims. The patent families have base expiry dates in 2034, 2039 and 2040. We anticipate several more patient innovations to evolve during development for which we will seek additional patent protection. empasiprubart product candidate incorporates or employs the NHANCE™ platform technology.

adimanebart Product Candidate

With regard to the adimanebart product candidate, we in-licensed patent families from/with New York University Langone Health, a U.S. medical center based in New York, and additional patent families from/with the Leiden University Medical Centre, with a U.S. granted patent and several pending applications in multiple jurisdictions . We anticipate several more patient innovations to evolve during development for which we will seek additional patent protection.

Our ARGX-118 Product Candidate

With regard to the ARGX-118 product candidate, we co-own a patent portfolio with VIB, an inflammation research center in Ghent, Brussels, and Ghent University, with one U.S. granted patent and pending patent applications in multiple jurisdictions in North America, South America, the EU and Asia. The patent family has a base expiry date in 2039.

1.6.4 Our Partnered Programs

Our cusatuzumab (ARGX-110) Product Candidate

With regard to the cusatuzumab product candidate, we have a broad patent portfolio that include claims to the composition of matter, uses of the molecule, and other important inventions. The issued U.S. patents expire in 2032 and 2033, without taking a potential patent term extension into account. cusatuzumab incorporates or employs the SIMPLE ANTIBODY™ and POTELLIGENT® platform technologies.

Our ARGX-115 (ABBV-151) Product Candidate

With regard to the ARGX-115 (ABBV-151) product candidate that we co-own with, and exclusively license from, the Ludwig Institute for Cancer Research and UCL, we have a patent portfolio that includes a U.S. patent with a base expiry date in 2034, without taking a potential patent term extension into account. There is a second family with meaningful patent coverage to the composition of matter and epitope claims that are expected to expire in 2036 and 2038. Furthermore, ARGX-115 (ABBV-151) incorporates or employs the SIMPLE ANTIBODY™ platform technology.

Our ARGX-112 (LP-0145) Product Candidate

With regard to the ARGX-112 (LP-0145) product candidate, we have one patent family with composition of matter claims directed to an antibody that binds human IL-22R. The patent family has a base expiry date in 2037. Furthermore, ARGX-112 (LP-0145) incorporates the SIMPLE ANTIBODY™ platform technology.

1.6.5 Trade Secret Protection

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

1.7 Regulation

Government authorities in the U.S., at the federal, state and local level, and in the EU and its Member States and other countries and jurisdictions, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products, including biological products. In addition, many countries and jurisdictions regulate the pricing of pharmaceutical products. The processes for obtaining marketing approvals in the U.S. and in other countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial personnel and financial resources, and breach of which can result in enforcement activity under civil, administrative and/or criminal law.

1.7.1 Licensure and Regulation of Biologics in the U.S.

In the U.S., biological products used for the prevention, treatment, or cure of a disease or condition in a human being are subject to regulation under the U.S. Federal Food, Drug, and Cosmetic Act (***FDCA***) and its implementing regulations. Biologics are approved for marketing under provisions of the Public Health Service Act (***PHSA***) via biologics license applications (***BLAs***).

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

- preclinical laboratory tests, animal studies and formulation studies all performed in accordance with applicable requirements, including the GLPs;
- submission to the FDA of an IND application for human clinical testing, which contains results of the preclinical tests, together with manufacturing information and analytical data and must become effective before human clinical trials may begin;
- approval by an institutional review board (***IRB***) representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials to establish the safety, potency and purity of the product candidate for each proposed indication, in accordance with good clinical practices (***GCPs***);
- preparation and submission to the FDA of a BLA for a biological product requesting marketing for one or more proposed indications, including submission of detailed information on the manufacture and composition of the product in clinical development and proposed labeling;
- one or more FDA inspections of the manufacturing facility or facilities, including those of third parties, at which the product, or components thereof, are produced to assess compliance with cGMP requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, potency, quality and purity;
- FDA inspections of the clinical trial sites and/or sponsor to assure compliance with GCPs, and the integrity of clinical data in support of the BLA;
- payment of user fees and securing FDA approval of the BLA and licensure of the new biological product; and
- compliance with any post-approval requirements, including the potential requirement to implement a risk evaluation and mitigation strategy (***REMS***) and any post-approval studies required by the FDA.

Human Clinical Trials in Support of a BLA

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

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

A sponsor who wishes to conduct a clinical trial outside the U.S. may, but is not required to, obtain FDA clearance to conduct the clinical trial under an effective IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of the BLA so long as the clinical trial is well-designed and well-conducted in accordance with GCPs, including review and approval by an independent ethics committee, and the FDA is able to validate the clinical trial data through an onsite inspection, if necessary. In some cases, the FDA may approve a BLA for a product candidate but require the sponsor, or the sponsor may otherwise choose, to conduct additional clinical trials to further assess, amongst other things, the product candidate's safety and effectiveness after approval. Such post-approval clinical trials are typically referred to as Phase 4 clinical trials. Failure to exhibit due diligence with regard to conducting required Phase 4 clinical trials could result in FDA enforcement, including withdrawal of approval for products.

Review and Approval of a BLA

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

The FDA has 60 days after submission of the application to conduct an initial review to determine whether the BLA is sufficient to file based on the agency's threshold determination that it is sufficiently complete to permit substantive review. If the FDA determines the BLA is not sufficiently complete, it will refuse to file the BLA. Once the submission has been filed, the FDA begins an in-depth review of the application. Under the goals agreed to by the FDA under the PDUFA, the FDA has 10 months from the filing date in which to complete its initial review of a standard application and respond to the applicant, and six months from the filing date for an application granted priority review. The FDA does not always meet its PDUFA goal dates and they may be extended in certain circumstances.

After the FDA's evaluation of the application and accompanying information, including the results of any necessary inspections, the FDA will issue an approval letter, or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. Under the PHSA, the FDA may approve a BLA if it determines that the product is safe, pure and potent and the facility where the product will be manufactured meets standards designed to ensure that it continues to be safe, pure and potent. If the application is not approved, the FDA will issue a complete response letter, which will identify the deficiencies in the application. Sponsors that receive a complete response letter may resubmit to the FDA information addressing the issues identified by the FDA, withdraw the application, or request a hearing. Even if a BLA is resubmitted with data and information addressing the deficiencies, the FDA may decide that the BLA does not satisfy the criteria for approval.

The FDA may also refer the application to an advisory committee, consisting of independent experts, for review, evaluation and recommendation as to whether the application should be approved, particularly when applications present difficult or novel questions of safety or efficacy. The FDA is not bound by the

recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

If the FDA approves a new product, it may require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, to help ensure that the benefits of the product outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and/or elements to assure safe use. This can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patent registries. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs.

After approval, many types of changes to the approved product, such as adding new indications, certain manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Expedited Development and Review Programs

The FDA is authorized to designate products meeting certain criteria for expedited development and review programs. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification, or the time period for FDA review or approval may not be shortened.

The FDA may designate a product for fast track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and demonstrates the potential to address unmet medical needs for such a disease or condition. For fast track products, sponsors may have more frequent interactions with the FDA and the FDA may initiate review of sections of a fast track product's application before the application is complete (rolling review). The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's PDUFA clock for a rolling review application does not begin until the last section of the application is submitted.

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

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

The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality (***IMM***) and that is reasonably likely to predict an effect on IMM or other clinical benefit (intermediate clinical endpoint), taking into account the severity, rarity, or prevalence of the

condition and the availability or lack of alternative treatments. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

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

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

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, a post-approval confirmatory clinical trial or studies to verify and describe the product's clinical benefit. These confirmatory clinical trials must be completed with due diligence, and the FDA may require that the confirmatory clinical trial be designed, initiated, and/or fully enrolled prior to, or within a certain period following, approval. The FDA must also specify the conditions of any required post-approval clinical trial. Sponsors are required to submit progress reports for required post-approval studies, and the failure to conduct with due diligence a required post-approval clinical trial, including a failure to meet any required conditions specified by the FDA, or to submit timely reports, are prohibited acts under the FDCA. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the product from the market on an expedited basis. Unless otherwise informed by the FDA, all promotional materials for product candidates approved under accelerated approval are subject to prior review by the agency.

Orphan Drug Designation and Exclusivity

Orphan drug designation in the U.S. is designed to encourage sponsors to develop products intended for rare diseases or conditions. In the U.S., a rare disease or condition is statutorily defined as a condition that affects fewer than 200,000 individuals in the U.S. or that affects more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making available the product for the disease or condition will be recovered from sales of the product in the U.S. An application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. If the FDA grants orphan drug designation, the generic identity of the product and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation qualifies a company for tax credits. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other application to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety or providing a major contribution to patient care, or if the holder of the orphan exclusivity is unable to supply the market. Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication, which could be used off-label in the orphan indication. Orphan drug exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval before we do for the same product, as defined by the FDA, for the same indication we are seeking approval, or if our product is determined to be contained within the scope of the approval of the competitor's product for the same indication or disease.

Post-Approval Regulation

If regulatory approval for marketing of a product or new indication for an existing product is obtained, the sponsor will be required to comply with all post-approval regulatory requirements, including those that the FDA has imposed as part of the approval process. The sponsor will be required to report certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling. Manufacturers and other parties involved in the drug supply chain for prescription drug and biological products must also comply with product tracking and tracing requirements and must notify the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the U.S. Manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMPs. Accordingly, the sponsor and its third-party manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMPs and other regulatory requirements.

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

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

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

Pediatric Studies and Exclusivity

Under the Pediatric Research Equity Act of 2003, as amended (***PREA***), certain BLAs or supplements thereto must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric sub-populations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Sponsors must also submit an initial Pediatric Study Plan (***PSP***), within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 clinical trial. The initial PSPs must contain an outline of the proposed pediatric clinical trial or studies the applicant plans to conduct, including clinical trial objectives and design, any deferral or waiver requests and other information required by regulation. The applicant and the FDA must agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time.

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

Pediatric exclusivity is another type of non-patent regulatory exclusivity in the U.S. and, if granted for a biologic, provides for the attachment of an additional six months of protection to the term of any existing regulatory exclusivity (i.e., reference product exclusivity and orphan drug exclusivity) that has at least 9 months left to expiration. This six-month exclusivity may be granted if a BLA sponsor submits reports of pediatric studies that fairly respond to a written request from the FDA for such studies, were conducted in accordance with commonly accepted scientific principles and protocols, and have been reported in accordance with filing requirements.

Biosimilars and Exclusivity

The Biologics Price Competition and Innovation Act (***BPCIA***) established a regulatory scheme authorizing the FDA to approve biosimilars and interchangeable biosimilars.

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

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date of approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. We note that patent positions may be available to preclude the introduction into commerce of such competing product independent of any FDA exclusivities. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. Products deemed interchangeable by the FDA may be substituted by pharmacies as dictated by individual state law.

U.S. Patent Term Restoration

Depending upon the timing, duration, and specifics of FDA review and approval of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act that permits restoration of the patent term of up to five years as compensation for patent term lost during the FDA regulatory review process. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date, and only those claims covering such approved product, a method for using it or a method for manufacturing it may be extended. The patent-term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved biologic is eligible for the extension and the application for the extension must be submitted within 60 days of approval from FDA and prior to the expiration of the patent. The U.S. Patent and Trademark Office (***USPTO***), in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond

the current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

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

Similar to the U.S., the EU comprehensively regulates, among other things, the development, manufacturing, placing on the market, advertising, distribution, import and export of medicinal products. Particularly, the placing on the market of a medicinal product for human use in the EU requires a marketing authorization (***MA***). Main provisions governing medicinal products in the EU are Directive 2001/83/EC and Regulation (EC) No 726/2004 (each as amended). Regulation (EC) No 141/2000 and Regulation (EC) No. 847/2000 (each as amended) are also of particular relevance for orphan medicinal products. While directives need to be transposed into national law by member states of the EU (***EU Member States***) before they are applicable, regulations directly apply in the EU Member States once these have been enacted.

The process governing approval of MA applications (MAA) for the placing on the market of medicinal products in the EU generally follows the same lines as in the U.S. It entails satisfactory completion of pharmaceutical development, pre-clinical trials and adequate and well-controlled clinical trials to establish the safety and efficacy of the medicinal product for each proposed indication. The EU also requires an application for authorization of clinical trials to relevant competent authorities and the submission of an MAA to the European Medicines Agency (EMA) or to competent authorities in EU member states and granting of such MA by the European Commission or relevant national authorities before the medicinal product can be marketed and sold in the EU or the relevant EU Member States. The below mentioned principles and rules generally apply within the EEA, i.e., the EU including Iceland, Liechtenstein and Norway.

Clinical Trial Approval

Both non-clinical and clinical data are generally required to support an MAA for a medicinal product in the EU. Non-clinical investigations are performed to demonstrate the health or environmental safety of new biological substances. Non-clinical (pharmaco-toxicological) investigations must generally be conducted in compliance with the principles of good laboratory practice (GLP) as set forth in EU Directive 2004/10/EC (as amended).

Clinical trials are comprehensively regulated in the EU under the Clinical Trials Regulation (EU) No 536/2014 (***CTR***), which entered into application on January 31, 2022, and gradually replaced the Clinical Trials Directive 2001/20/EC (***CTD***).

As before, many of the CTR's legal obligations are on the so-called sponsor, which is defined as the individual, company, institution, or organization that takes responsibility for the initiation, for the management and for setting up the financing of a clinical trial. The sponsor must obtain an authorization from the competent authority in the EU Member State(s) in which the clinical trial will be conducted as well as an approval from the competent national ethics committee in accordance with relevant national legislation in each of the relevant member states, before the commencement of such clinical trial.

The CTR also imposes requirements, among others, regarding the conduct of a clinical trial (which must be conducted in accordance with the protocol and good clinical practice to generate acceptable data for MA submission), safety reporting of adverse events and reactions, changes to clinical trials, protection and informed consent of clinical trial subjects. Clinical trials conducted outside the EEA must follow the principles set forth in EU legislation if their results are to be submitted in an MAA in the EU.

Orphan Designation and Exclusivity

Regulations (EC) No. 141/2000 and No. 847/2000 (each as amended) provide that a product can be designated as an orphan medicinal product by the European Commission if its sponsor can establish: (i) that the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition, (ii) either (a) the prevalence of the condition is not more than five in ten thousand persons in the EU when the application is made, or (b) without incentives it is unlikely that the marketing of the product in the EU would generate sufficient return to justify the necessary investment in its

development and (iii) there exists no satisfactory method of diagnosis, prevention, or treatment of the condition in question that has been authorized in the EU or, if such method exists, the product has to be of a significant benefit compared to products available for the condition.

An orphan designation provides a number of benefits, including fee reductions and, regulatory assistance. If an MA is granted for an orphan medicinal product, this generally results in a ten-year period of market exclusivity for the approved orphan indication. It is, however, not possible to combine non-orphan and orphan indications within the same MA. Thus, for non-orphan indications treated with the same active pharmaceutical ingredient, a separate MA has to be sought. Alternatively, the orphan designation may be waived to allow for the addition of non-orphan indications to an existing MA. As a result, the approved medicinal product would no longer profit from the orphan designation's benefits.

During an orphan medicinal product's market exclusivity period, neither the EMA, the European Commission nor the EU Member States can accept an application or grant an MA for a "similar medicinal product." A "similar medicinal product", i.e., a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The market exclusivity period for the authorized therapeutic indication may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation. For orphan medicinal products intended for pediatric use, the market exclusivity period may be prolonged by additional two years if they are authorized with a pediatric indication based on the results from studies conducted under an EMA-approved pediatric investigation plan or if they are authorized without a pediatric indication but the results of the studies conducted under the EMA-approved pediatric investigation plan are reflected in the summary of product characteristic and, if appropriate, in the package leaflet. Market exclusivity may also be revoked in very select cases, such as if (i) it is established that a similar medicinal product is safer, more effective or otherwise clinically superior; (ii) the MA holder (***MAH***) for the authorized orphan medicinal product consents to the second orphan application; or (iii) the MAH for the authorized orphan medicinal product cannot supply sufficient quantities. Orphan designation must be requested before submitting an MAA and is reconfirmed during the MAA process. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and MA approval process.

Marketing Authorization

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

The centralized procedure provides for the grant of a single MA by the European Commission that is valid for all EEA Member States. Pursuant to Regulation (EC) No. 726/2004 (as amended), the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products (gene therapy, somatic cell therapy or tissue engineered products) and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of cancer and auto-immune diseases and other immune dysfunctions and neurodegenerative disorders. The centralized procedure is optional for certain other medicinal products.

Under the centralized procedure, the EMA's Committee for Medicinal Products for Human Use (***CHMP***) is responsible for conducting the assessment of a product to define its risk/benefit profile. The CHMP recommendation is then sent to the European Commission, which adopts a decision binding in all EEA Member States. Under the centralized procedure, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions asked by the CHMP, which can considerably extend the 210 days. Accelerated evaluation (150 days excluding clock stops) may be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation.

MAs have an initial validity for five years, in principle, and they may be renewed after five years on the basis of a reevaluation of the risk benefit balance by the EMA, or by the competent authority of the EU Member State. Once renewed, the MA is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any MA that is not followed by the placement of the medicinal product on the EU market or on the market of the authorizing EU Member State(s) within three years after authorization, or if the drug is removed from the market for three consecutive years, ceases to be valid.

European Data and Market Exclusivity

In the EU, innovative medicinal products, approved on the basis of a complete independent data package, qualify for eight years of data exclusivity upon MA and an additional two years of market exclusivity (for the more comprehensive protections applying to orphan medicinal products, please refer to Section 1.7.2 "**Orphan Designation and Exclusivity**" above). The data exclusivity, if granted, prevents generic or biosimilar applicants from referencing the innovator's preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar MA in the EU, for a period of eight years from the date on which the reference product was first authorized in the EU. During the additional two-year period of market exclusivity, a generic or biosimilar MAA can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be marketed in the EU until the expiration of the market exclusivity period. The overall ten-year period will be extended to a maximum of 11 years if, during the first eight years of those 10 years, the MAH obtains an MA for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are determined to bring a significant clinical benefit in comparison with currently approved therapies. There is no guarantee that a product will be considered by the EMA to be an innovative medicinal product, and products may not qualify for data exclusivity. Even if a product is considered to be an innovative medicinal product so that the innovator gains the prescribed period of data exclusivity, another company nevertheless could also market another version of the product if such company obtained an MA based on an MAA with a complete independent data package of pharmaceutical tests, preclinical tests and clinical trials.

Regulatory Requirements after Marketing Authorization

Following MA approval, the MAH is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of the medicinal product. These include compliance with the EU's stringent pharmacovigilance or safety reporting rules under Directive 2001/83/EC and Regulation (EU) 726/2004 (each as amended) and the associated guideline on good pharmacovigilance practices (as amended), pursuant to which post-authorization studies and additional monitoring obligations can be imposed. In addition, the manufacturing of authorized medicinal products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the principles of good manufacturing practice (***GMP***) set forth in Commission Directive 2017/1572 GMP and comparable requirements of other regulatory bodies in the EU, which mandate the methods, facilities and controls used in manufacturing, processing and packing of products to assure their safety and identity. Further, the wholesale distribution of authorized medicinal products requires a separate distribution license and must be conducted in strict compliance with good distribution practice standards. Finally, the marketing and promotion of authorized medicinal products is strictly regulated under Directive 2001/83/EC, (as amended) and as transposed into national laws.

Potential consequences for a failure to maintain regulatory compliance mainly depend on the relevant regulations in the EU Member States, but are, for example, in Germany, similar to those in the U.S. Please refer to Section 1.7.1. "**Post-Approval Regulations**" above.

Agreement on new EU Pharmaceutical Legislation

On December 11, 2025, the EU legislative bodies agreed to overhaul, modernize, and streamline the existing general pharmaceutical legislation, including e.g., Directive 2001/83/EC, as well as Regulations (EC) No. 726/2004, No. 141/2000, or No. 1901/2006 (***EU Pharmaceutical Legislation***). This agreement is still subject to formal approval by the European Parliament and the Council of the EU, before being formally adopted. It is expected that the EU Pharmaceutical Legislation will become applicable in 2028. Although the final text has not yet been published, agreed key elements appear to include, among others, certain changes to the baseline marketing exclusivity periods, the streamlining of regulatory procedures as well as a broadening of the so-called "Bolar exemption", which allows developers to undertake testing and to prepare for regulatory submissions before patent expiry.

1.7.3 Regulation and Procedures Governing Approval of Medicinal Products in Japan

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

Business License

Under the Pharmaceutical and Medical Devices Act, a company or individual must obtain a Marketing Authorization Holder (***MAH***) license from the MHLW to engage in the marketing or provision of medical products. This requirement applies to medical products that are either manufactured by the company itself outsourced to a third party for manufacturing or imported.

To manufacture medical products for the Japanese market, a company must obtain a manufacturing license from the MHLW for each production facility. This license is separate from the marketing authorization and is required for both domestic and foreign manufacturing sites.

Marketing Approval

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

Clinical Trial

Under the Pharmaceutical and Medical Devices Act, it is required to file notification of clinical trials with the PMDA. The data of clinical trials and other pertinent data, which must be attached to an application for marketing approval, must be obtained in compliance with the standards established by the MHLW, such as GLPs and GCPs stipulated by the ministerial ordinances of the MHLW.

Regulatory Requirements after Marketing Approval

A MAH that has obtained marketing approval for a new pharmaceutical is subject to re-examination by the PMDA for a specified period after receiving marketing approval. Such re-examination period for VYVGART is stated to be 10 years after the marketing approval in January 2022. The purpose of this re-examination process is to ensure the safety and efficacy of a newly approved pharmaceutical by imposing on the MAH the obligation to gather clinical data for a certain period after the marketing approval was granted to enable the PMDA to re-examine the product. Results of use and other pertinent data must be attached to

an application for a re-examination. An MAH that has obtained a marketing approval is also required to investigate, among other things, the results of use and to periodically report to the PMDA pursuant to the Pharmaceutical and Medical Devices Act.

Price Regulation

Japan's public medical insurance systems cover virtually the entire Japanese population. The public medical insurance system, however, does not cover any medical product which is not listed on the National Health Insurance (***NHI***) price list published by the Minister of the MHLW. Accordingly, an MAH of medical products must first have a new medical product listed on the NHI price list to obtain coverage under the public medical insurance system. VYVGART was listed on the NHI price list in April 2022 and the price was adjusted in February 2024. VYVDURA was listed in April 2024.

The NHI price of a medical product is determined either by price comparison of comparable medical products with necessary adjustments for innovation, usefulness or size of the market; or, in the absence of comparable medical products, by the cost calculation method, determined after considering of the opinion of the manufacturer. Prices on the NHI price list are subject to revision, generally once every year, based on the actual prices at which the medical products are purchased by medical institutions.

1.7.4 Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may obtain regulatory approval. Even if our product candidates are approved for marketing, sales of such product candidates will depend, in part, on the extent to which third-party payors, including government health programs in the U.S. (such as Medicare and Medicaid), commercial health insurers, and managed care organizations, provide coverage and establish adequate reimbursement levels for such product candidates. Moreover, increasing efforts by governmental and third-party payors in the EU, the U.S. and other markets to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes.

The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

In the U.S. and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Patients are unlikely to use any product candidates we may develop unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of such product candidates.

Factors payors consider in determining reimbursement are based on whether the product is (i) a covered benefit under its health plan; (ii) safe, effective and medically necessary; (iii) appropriate for the specific patient; (iv) cost-effective; and (v) neither experimental nor investigational.

The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates. No uniform policy for coverage and reimbursement for drug products exists among third-party payors in the U.S. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor including formulary tier placement and utilization management requirements (if any). As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first

instance. The position of a product on a formulary generally determines the co-payment that a patient will need to make to obtain the product and can strongly influence the adoption of a product by patients and physicians. Third-party payors may limit coverage to specific products on a formulary, which might not include all of the approved products for a particular indication. Additionally, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved or that cost-sharing will be acceptable for patients. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more of our products for which we or our collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services and imposing controls to manage costs, especially drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidate and other therapies (in some cases even off-label treatments) as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidate, pricing of existing drugs may limit the amount we will be able to charge for our product candidate. These payors may deny or revoke the reimbursement status of a given drug product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates and may not be able to obtain a satisfactory financial return on products that we may develop.

In Mainland China, VYVGART IV has been included in the National Reimbursement Drug List (***NRDL***) for the treatment of adults with gMG who are AChR-AB+ after going through price negotiations with the National Healthcare Security Administration (NHSA) since January 2024, which means that the price of this drug can be (partly) reimbursed by the social security program of Mainland China for the treatment of this indication in accordance with relevant rules within certain period. According to the current regulations of Mainland China, if we want our products in addition to VYVGART IV to be included in the NRDL or want VYVGART to be included in the NRDL for the treatment of other indications, we will need to go through price negotiations with the NHSA, for which purpose we will likely need to significantly reduce their prices. Although the inclusion of our products in the NRDL may increase the demand for the relevant products, our potential revenue from the sales of these products may still decrease as a result of lower prices.

Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely. Outside the U.S., we will face challenges in ensuring obtaining adequate coverage and payment for any product candidates we may develop. Pricing of prescription pharmaceuticals is subject to governmental control in many countries. In order to secure coverage and reimbursement for any product that might be approved for sale, we have needed and may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, and the cost of these studies would be in addition to the costs required to obtain FDA or other comparable marketing approvals. Conducting such studies could be expensive, involve additional risk and result in delays in our commercialization efforts. Even after pharmacogenomic studies are conducted, product candidates may not be considered medically necessary or cost-effective. A decision by a third-party payor not to cover any product candidates we may develop could reduce physician utilization of such product candidates once approved and have a material adverse effect on our sales, results of operations and financial condition. Third-party reimbursement and coverage may not be adequate to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. The insurance coverage and reimbursement status of newly approved products for orphan diseases is particularly uncertain, and failure to obtain or maintain adequate coverage and reimbursement for any such product candidates could limit our ability to generate revenue. As noted above, in the U.S., we plan to have various programs to help patients afford our products, including patient assistance programs and co-pay coupon programs for eligible patients. More specifically, patients can enroll into MY VYVGART PATH™, a patient support program that provides personalized support from a nurse case manager and committed support team. In addition to providing support on questions on the treatment and on navigating the insurance process, the program provides a VYVGART Co-pay Program to eligible patients, aids in referring patients to charitable foundations that may be able to help with out-of-pocket costs and informs patients of financial assistance programs that may be available.

The containment of healthcare costs also has become a priority of U.S. federal, state and international governments and the prices of pharmaceuticals have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any future product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our potential revenue from the sale of any products for which we may obtain approval.

The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicinal products, is almost exclusively governed by national laws, rather than EU legislation. National governments and health service providers have different priorities and approaches to the delivery of healthcare and the pricing and reimbursement of products in that context. Therefore, in the EU, pricing and reimbursement schemes vary widely from EU Member State to another. Some EU Member States provide that products may be marketed only after a reimbursement price has been agreed. Some EU Member States may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies (so called health technology assessments) in order to obtain reimbursement or pricing approval. EU Member States may approve a specific price for a product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Other EU Member States allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions.

Recently, many EU Member States have increased the amount of discounts required on medicinal products and these efforts could continue as Member States attempt to further manage healthcare expenditures. For example, Germany introduced a specific discount on certain combination products with new active ingredients.

The downward pressure on healthcare costs in general, particularly medicinal prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU Member States and parallel trade (arbitrage between low-priced and high-priced Member States) can further reduce prices. Special pricing and reimbursement rules may apply to orphan medicinal products. Inclusion of orphan drugs in reimbursement systems tend to focus on the medical usefulness, need, quality and economic benefits to patients and the healthcare system as for any drug. Acceptance of any medicinal product for reimbursement may come with cost, use and often volume restrictions, which again can vary by country. In addition, results-based rules of reimbursement may apply. There can be no assurance that any EU Member State that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products, if approved in those countries. Historically, products launched in the EU do not follow price structures of the U.S. and generally prices tend to be significantly lower.

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

reduced compared with the U.S. and may be insufficient to generate commercially reasonable revenue and profits.

1.7.5 Government Pricing and Reimbursement Programs for Marketed Drugs in the U.S.

Medicaid, the 340B Drug Pricing Program, and Medicare

Federal law requires that a pharmaceutical manufacturer, as a condition of having its drug and biological products receive federal reimbursement under Medicaid and Medicare Part B, must pay rebates to state Medicaid programs for all units of its covered outpatient drugs dispensed to Medicaid beneficiaries and paid for by a state Medicaid program under either a fee-for-service arrangement or through a managed care organization. This federal requirement is effectuated through a Medicaid drug rebate agreement between the manufacturer and the Secretary of U.S. Department of Health and Human Services (***HHS***). The Centers for Medicare & Medicaid Services (***CMS***) administers the Medicaid drug rebate agreements, which provide, among other things, that the drug manufacturer will pay rebates to each state Medicaid agency on a quarterly basis and report certain price information on a monthly and quarterly basis. The rebates are based on prices reported to CMS by manufacturers for their covered outpatient drugs, including average manufacturer price (***AMP***) and best price. Effective January 1, 2024, the Medicaid total rebate amount is no longer capped at 100% of a covered outpatient drug's AMP, which means that a manufacturer could pay a total rebate amount on a unit of the drug that is greater than the average price the manufacturer receives for the drug.

The terms of participation in the Medicaid drug rebate program impose an obligation to correct the prices reported in previous quarters, as may be necessary. Any such corrections could result in additional or lesser rebate liability, depending on the direction of the correction. In addition to retroactive rebates, if a manufacturer were found to have knowingly submitted false information to the government, federal law provides for civil monetary penalties for failing to provide required information, late submission of required information, and false information.

A manufacturer must also participate in a federal program known as the 340B drug pricing program in order for federal funds to be available to pay for the manufacturer's drug and biological products under Medicaid and Medicare Part B. Under this program, the participating manufacturer agrees to charge certain safety net healthcare providers no more than an established discounted price for its covered outpatient drugs. The formula for determining the discounted price is defined by statute and is based on the AMP and the unit rebate amount as calculated under the Medicaid drug rebate program, discussed above. Manufacturers are required to report pricing information to the Health Resources and Services Administration on a quarterly basis. The Health Resources and Services Administration has also issued regulations relating to the calculation of the ceiling price as well as imposition of civil monetary penalties for each instance of knowingly and intentionally overcharging a 340B covered entity.

Federal law also requires that manufacturers report data on a quarterly basis to CMS regarding the pricing of drugs that are separately reimbursable under Medicare Part B. These are generally drugs and biologics, such as injectable products, that are administered incident to a physician service and are not generally self-administered. The pricing information submitted by manufacturers is the basis for reimbursement to physicians and suppliers for drugs covered under Medicare Part B. Under the Inflation Reduction Act (***IRA***), manufacturers are also required to provide quarterly rebates for certain single-source drugs and biologics (including biosimilars) covered under Medicare Part B with prices that increase faster than the rate of inflation. This requirement started on January 1, 2023 for drugs approved on or before December 1, 2020 and begins six quarters after a drug is first marketed for all other drugs. As with the Medicaid drug rebate program, federal law provides for civil monetary penalties for failing to provide required information, late submission of required information, and false information.

Additionally, the Infrastructure Investment and Jobs Act added a requirement, effective January 1, 2023, for manufacturers of certain single-source drugs (including biologics and biosimilars) separately paid for under Medicare Part B for at least 18 months and marketed in single-dose containers or packages (known as refundable single-dose containers or single-use package drugs) to provide annual refunds for any portions of the dispensed drug that are unused and discarded if those unused or discarded portions exceed an

applicable percentage defined by statute or regulation. Manufacturers will be subject to periodic audits and those that fail to pay refunds for their refundable single-dose containers or single-use package drugs shall be subject to civil monetary penalties.

Medicare Part D provides prescription drug benefits for seniors and people with disabilities. Beginning in 2025, the IRA eliminates the coverage gap phase and associated manufacturer discounts under Medicare Part D, significantly lowers the enrollee maximum out-of-pocket cost and establishes a new manufacturer discount program, which requires 10% discounts in the initial phase, and 20% discounts in the catastrophic phase. Although these discounts represent a lower percentage of enrollees' costs than coverage gap discounts, the new manufacturer contribution during the catastrophic phase could be considerable for certain high-cost drugs and the total contributions by manufacturers to a Part D enrollee's drug expenses may exceed those currently provided. The IRA also requires manufacturers to provide annual Medicare Part D rebates for single-source drugs and biological products with prices that increase faster than the rate of inflation.

The IRA also allows HHS to directly negotiate the selling price of a statutorily specified number of drugs and biologics each year that CMS reimburses under Medicare Part B and Part D. Only high-expenditure single-source biologics that have been approved for at least 11 years (7 years for single-source drugs) can qualify for negotiation, with the negotiated price taking effect two years after the selection year. In July 2025, Congress expanded the IRA's orphan drug exclusion to protect from selection drugs that are indicated only for orphan indications, as well as to extend the time before an orphan drug may be selected if it is later approved for a non-orphan indication. Negotiations for Medicare Part D products began in 2023 with the negotiated price taking effect in 2026, and negotiations for Medicare Part B products will begin in 2026 with the negotiated price taking effect in 2028.

U.S. Federal Contracting and Pricing Requirements

Manufacturers are also required to make their covered drugs, which are generally drugs approved under NDAs or BLAs, available to authorized users of the Federal Supply Schedule (***FSS***) of the General Services Administration. The law also requires manufacturers to offer deeply discounted FSS contract pricing for purchases of their covered drugs by the Department of Veterans Affairs, the Department of Defense, the Coast Guard, and the Public Health Service (including the Indian Health Service) in order for federal funding to be available for reimbursement or purchase of the manufacturer's drugs under certain federal programs. FSS pricing to those four federal agencies for covered drugs must be no more than the Federal Ceiling Price (***FCP***), which is at least 24% below the Non-Federal Average Manufacturer Price (***Non-FAMP***) for the prior year. The Non-FAMP is the average price for covered drugs sold to wholesalers or other middlemen, net of any price reductions.

The accuracy of a manufacturer's reported Non-FAMPs, FCPs, or FSS contract prices may be audited by the government. Among the remedies available to the government for inaccuracies is recoupment of any overcharges to the four specified federal agencies based on those inaccuracies. If a manufacturer were found to have knowingly reported false prices, in addition to other penalties available to the government, the law provides for significant civil monetary penalties per incorrect item. Finally, manufacturers are required to disclose in FSS contract proposals all commercial pricing that is equal to or less than the proposed FSS pricing, and subsequent to award of an FSS contract, manufacturers are required to monitor certain commercial price reductions and extend commensurate price reductions to the government, under the terms of the FSS contract Price Reductions Clause. Among the remedies available to the government for any failure to properly disclose commercial pricing and/or to extend FSS contract price reductions is recoupment of any FSS overcharges that may result from such omissions.

1.7.6 Healthcare Law and Regulation

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

- the U.S. federal Anti-Kickback Statute (***AKS***) prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good facility, item, or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers formulary managers and other persons and entities on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain activities from prosecution, the exceptions and safe harbors are drawn narrowly, and arrangements may be subject to scrutiny or penalty if they do not fully satisfy all elements of an available exception or safe harbor. A person or entity can be found guilty of violating the AKS without actual knowledge of the statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil money penalties statute. Violations of the AKS carry potentially significant civil and criminal penalties, including imprisonment, fines, administrative civil monetary penalties, and exclusion from participation in federal healthcare programs.
- the U.S. federal false claims and civil monetary penalties laws, including the civil False Claims Act and federal civil monetary penalty laws, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim or obligation to pay or transmit money to the federal government, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the False Claims Act. Manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The False Claims Act also permits a private individual acting as a "whistleblower" to bring qui tam actions on behalf of the federal government alleging violations of the False Claims Act and to share in any monetary recovery. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996 (***HIPAA***) which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or obtaining by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the pay (e.g., public or private) or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; similar to the AKS, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (***HITECH***) and its implementing regulations, and as amended again by the Omnibus Rule in 2013, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the Final HIPAA Omnibus Rule, i.e., certain covered health plans, healthcare clearinghouses and healthcare providers, as well as their business associates, those

independent contractors or agents of covered entities that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ***ACA***), which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to CMS information related to payments and other transfers of value made by that entity to physicians (currently defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician providers such as physician assistants and nurse practitioners and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in civil monetary penalties for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission;
- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- analogous state and local laws and regulations, including: state anti-kickback and false claims laws; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and local laws that require the licensure of sales representatives; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect; and state laws related to insurance fraud in the case of claims involving private insurers; and
- EU, UK and other foreign law equivalents, including reporting requirements detailing interactions with and payments to healthcare providers and data privacy and security laws and regulations that may be more stringent than those in the U.S.

State and foreign laws, including for example the EU General Data Protection Regulation (***GDPR***), also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement, we could be subject to penalties.

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

Other laws that may affect our ability to operate include:

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

In the U.S., to help patients afford our approved product, we may utilize programs to assist them, including patient assistance programs and co-pay coupon programs for eligible patients. Government enforcement agencies have shown increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. In addition, at least one insurer has directed its network pharmacies to no longer accept co-pay coupons for certain specialty drugs the insurer identified. Our co-pay coupon programs could become the target of similar insurer actions. In addition, in November 2013, the CMS issued guidance to the issuers of qualified health plans sold through the ACA's marketplaces encouraging such plans to reject patient cost-sharing support from third parties and indicating that the CMS intends to monitor the provision of such support and may take regulatory action to limit it in the future. The CMS subsequently issued a rule requiring individual market qualified health plans to accept third-party premium and cost-sharing payments from certain government-related entities. In September 2014, the Office of the Inspector General of the HHS issued a Special Advisory Bulletin warning manufacturers that they may be subject to sanctions under the AKS and/or civil monetary penalty laws if they do not take appropriate steps to exclude Part D beneficiaries from using co-pay coupons. Accordingly, companies exclude these Part D beneficiaries from using co-pay coupons. Additionally, certain third-party payors are modifying benefit designs based on the availability of manufacturer cost-sharing assistance (e.g., copay accumulator or maximizer programs). Following a federal district court decision vacating the provisions of the 2021 Notice of Benefit and Payment Parameter final rule that provided health plans with discretion whether to include manufacturer assistance toward the cost-sharing limit, CMS stated its intent to address this issue in future rulemaking. It is possible that changes in insurer policies regarding co-pay coupons and/or the introduction and enactment of new legislation or regulatory action could restrict or otherwise negatively affect these patient support programs, which could result in fewer patients using affected products, and therefore could have a material adverse effect on our sales, business, and financial condition.

Third-party patient assistance programs that receive financial support from companies have become the subject of enhanced government and regulatory scrutiny. The Office of the Inspector General of the HHS has established guidelines that suggest that it is lawful for pharmaceutical manufacturers to make donations to charitable organizations who provide co-pay assistance to Medicare patients, provided that such organizations, among other things, are bona fide charities, are entirely independent of and not controlled by the manufacturer, provide aid to applicants on a first-come basis according to consistent financial criteria and do not link aid to use of a donor's product. However, donations to patient assistance programs have received some negative publicity and have been the subject of multiple government enforcement actions, related to allegations regarding their use to promote branded pharmaceutical products over other less costly alternatives. Specifically, in recent years, there have been multiple settlements resulting out of government claims challenging the legality of their patient assistance programs under a variety of federal and state laws. It is possible that we may make grants to independent charitable foundations that help financially needy patients with their premium, co-pay, and co-insurance obligations. If we choose to do so, and if we or our vendors or donation recipients are deemed to fail to comply with relevant laws, regulations or evolving government guidance in the operation of these programs, we could be subject to damages, fines, penalties, or other criminal, civil, or administrative sanctions or enforcement actions.

We cannot ensure that our compliance controls, policies, and procedures will be sufficient to protect against acts of our employees, business partners, or vendors that may violate the laws or regulations of the jurisdictions in which we operate. Regardless of whether we have complied with the law, a government investigation could impact our business practices, harm our reputation, divert the attention of management, increase our expenses, and reduce the availability of foundation support for our patients who need assistance.

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

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance 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 the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment, reputational harm, and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, defending against any such actions can be costly and time-consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected.

1.7.7 Healthcare Reform

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

Healthcare reforms that have been adopted, and that may be adopted in the future, could result in further reductions in coverage and levels of reimbursement for pharmaceutical products, increases in rebates payable under U.S. government rebate programs and additional downward pressure on pharmaceutical product prices. As discussed above, in August 2022, the IRA was enacted codifying, among other things: a Medicare drug price negotiation program, under which HHS directly negotiates the selling price of statutorily specified number of Part B and Part D drugs and biologics each year; inflation rebates which penalizes drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation; and a redesign of the Part D benefit. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. To date, none of the legislative attempts to extend the subsidies has been enacted. These IRA provisions began taking effect progressively starting in 2023, although certain policies have been subject to legal challenges. For example, the provisions related to the negotiation of selling prices of high-expenditure single-source drugs and biologics have been challenged in multiple lawsuits. Additionally, we cannot predict whether the U.S. Congress will further amend the IRA or if the government will adopt new or different interpretations of the law in future guidance or rulemaking. However, at this time, the Trump administration is continuing to implement the IRA and to defend the law in litigation. While it is unclear how the IRA will be implemented in the future and the outcome of the litigation, it will likely have a significant impact on the pharmaceutical industry.

In addition, the Trump administration has taken several steps to try to align U.S. drug prices with drug prices in other countries through an approach known as most favored nation (***MFN***) pricing. For example, on May 12, 2025, the current Presidential administration published an executive order which, among other actions, instructed HHS to communicate MFN price targets. The executive order also directed certain steps if "significant progress towards [MFN] pricing . . . is not delivered." On July 31, 2025, the U.S. President issued letters to 17 pharmaceutical companies (not including argenx), calling on those manufacturers and

"every manufacturer" to take the following steps within 60 days: extend MFN pricing to Medicaid for all of their existing drugs; guarantee Medicare, Medicaid, and commercial payors receive MFN pricing for newly-launched drugs; return increased revenues abroad to American patients and taxpayers; and participate in direct-to-consumer or direct-to-business distribution models to provide "high-volume, high rebate" drugs at MFN pricing. Certain manufacturers have entered into direct agreements with the government.

On November 6, 2025, CMS announced the GENErating cost Reductions fOr U.S. Medicaid (***GENEROUS***) Model under its Center for Medicare and Medicaid Innovation authority (***CMMI***). 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 the Global Benchmark for Efficient Drug Pricing (***GLOBE***) Model and Guarding U.S. Medicare Against Rising Drug Costs (***GUARD***) Model proposed rules under its Center for Medicare and Medicaid Innovation authority. The GLOBE and GUARD models would require manufacturers to pay additional rebates for certain drugs based on the difference between the Medicare price and the price in market basket countries. CMS proposes that the agency would apply the new rebate requirement to utilization by approximately 25% of Medicare Part B fee-for-service enrollees (under GLOBE) and 25% of Medicare Part D enrollees (under GUARD). It is uncertain if these proposed rules will be finalized and if they are, how they will impact our business.

Additionally, in Congress, there are pending legislative proposals that, if enacted, would require MFN pricing in certain healthcare programs. We cannot predict if any of these legislative proposals will be enacted, how they would be implemented, and how they could impact our business.

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

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

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

In international markets, reimbursement and healthcare payment systems vary significantly by country (including across the EU's individual member states), and many countries have instituted price ceilings on specific products and therapies. Future political, economic, and regulatory developments may further affect the ability of pharmaceutical companies to profitably commercialize current and future products.

1.7.8 Environmental Aspects which may Influence the Use of our Material Fixed Assets

Our primary research and development activities take place in our facilities in Zwijnaarde, Belgium. For these activities we require, and have obtained, the necessary environmental and biohazard permits from the responsible governments, required by us for the manner in which we use said facilities.

1.8 Documents on display

We are subject to the information reporting requirements of the U.S. Securities Exchange Act of 1934, as amended (***Exchange Act***) applicable to foreign private issuers. Accordingly, we are required to file reports and other information with the SEC. Those reports may be inspected without charge at the locations described below. As a foreign private issuer, we are exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. Nevertheless, we will file with the SEC an Annual Report containing financial statements that have been examined and reported on, with an opinion expressed by an independent registered public accounting firm.

We maintain a corporate website at www.argenx.com. We make available on our website, free of charge, our Annual Report and the text of our reports on Form 6-K, including any amendments to these reports, as well as certain other SEC filings, as soon as reasonably practicable after they are electronically filed with or furnished to the SEC. Information contained on, or that can be accessed through, our website does not constitute a part of this Annual Report. We have included our website address in this Annual Report solely as an inactive textual reference.

The SEC maintains a website (www.sec.gov) that contains reports and other information regarding registrants, such as argenx SE, that file electronically with the SEC.

With respect to references made in this Annual Report to any contract or other document of argenx SE, such references are not necessarily complete and you should refer to the exhibits attached or included elsewhere to this Annual Report for copies of the actual contract or document.