








Annual Report 2022

argenx

Disclaimer PDF print – this document is only a “printed version” and is not the original annual financial reporting including the audited financial statements pursuant to Article 361 of Book 2 of the Dutch Civil Code. These original annual financial reporting included in the audited financial statements and the auditor’s report thereto, are included in the single report package which can be found at **https://www.argenx.com/investors/financial-reports**.

2022 Annual Report including the Annual Financial Statements for the Year ended December 31, 2022

argenx SE (herein ***argenx*** or the ***Company*** and, together with its subsidiaries, the ***Group, we*** or ***us***) is a European public company (*Societas Europaea*) incorporated under the laws of the Netherlands with its statutory seat in Rotterdam, the Netherlands, which is publicly listed in Belgium and the United States of America (***U.S.***). The applicable regulations with respect to public information and protection of investors, as well as the commitments we make by argenx to securities and market authorities, are described in this annual report (***Annual Report***).

Forward-looking Statements

This Annual Report contains certain forward-looking statements. A forward-looking statement is any statement that does not relate to historical facts or events or to facts or events as of the date of this Annual Report or that are derived from our management's beliefs and assumptions based on information currently available to our management. Forward-looking statements are generally identified by the use of forward-looking words, such as "anticipate", "believe", "can", "could", "estimate", "expect", "intend", "is designed to", "may", "might", "objective", "plan", "potential", "project", "predict", "target", "will", "should", or other variations or the negative of such terms, or by discussion of strategy, although not all forward-looking statements contain these identifying words. These statements relate to our future results of operations and financial positions, prospects, developments, business strategies, plans and our objectives for future operations, results of clinical trials and regulatory approvals, and are based on analyses or forecasts of future developments and estimates of amounts not yet determinable. These forward-looking statements represent the view of management only as of the date of this Annual Report, and we disclaim any obligation to update forward-looking statements, except as may be otherwise required by law. The forward-looking statements in this Annual Report involve known and unknown risks, uncertainties and other factors that could cause our actual future results, performance and achievements to differ materially from those forecasted or suggested herein. These include changes in general economic and business conditions, as well as the factors described in section 2 "**Risk Factors**" of this Annual Report.

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To our Shareholders

Shareholder Letter

Dear Shareowners,


Tim Van Hauwermeiren


Peter Verhaeghe

Commitment is the word that comes to mind when I look back at 2022 and all that we accomplished as a team. For the first time in our history, we were able to honor our commitment and deliver a transformative therapy to patients with the potential to change how generalized myasthenia gravis (***gMG***) is treated. It was also our first opportunity to show our ability to execute commercially in the same way we have in developing breakthrough pipeline candidates. We had an ambitious task before us to launch VYVGART globally and bring our first-in-class immunology innovation to people living with *gMG*. We are proud to say we accomplished what we set out to do, thanks to the unwavering commitment demonstrated by our team of Argonauts.

It was a year of pivotal growth for us as an organization as we broadened our core capabilities to launch VYVGART in the U.S., Japan and Europe. We expanded our teams and our global reach, while maintaining a strong connection among our employees through our unified commitment to our patients and their supporters. This commitment helped drive our strong commercial performance in the first year of launch – generating over $400 million in net sales globally. Our strategies to engage and activate our key stakeholders were the right ones to empower patients to demand better, and to provide what we believe is best-in-class patient support, drive rapid physician adoption of VYVGART and enable broad and appropriate access to this important therapy.

The stories we hear from patients continue to inspire our everyday work and fuel us on our mission to reach argenx 2025. We heard from a woman living with gMG, who loved to garden before her diagnosis but had to give it up because of her symptoms. We talked to another patient who had not been able to travel to see her family because she was not able to physically sit on a plane. There are gMG patients who can no longer walk or hold a job, or who had lost their love of food because of difficulty swallowing. In the first year of our VYVGART launch, we were motivated by the significant unmet needs of all of these patients and were humbled to be able to bring another treatment option to the gMG community.

We will be prepared in the year ahead to bring another first-in-class treatment option to the gMG community with the expected launch of our subcutaneous formulation of efgartigimod, anticipated in June 2023. We know gMG presents itself differently for each person and want to offer multiple ways in which patients can individualize their treatment to their unique experience.

2022 was also the first year where our innovation mission and commitment to patients truly intersected, bringing our vision of redefining the treatment of autoimmunity to life. This was clearly demonstrated by the progress we made across our pipeline, advancing our clinical trials one step further. We reported positive pivotal data from our second autoimmune indication, immune thrombocytopenia (***ITP***), in May and presented these data during a plenary session at the American Society of Hematology annual meeting. We initiated several clinical trials and are evaluating efgartigimod in ten autoimmune indications with three more to start this year. We are set up for a busy 2023 and are expecting five clinical data readouts from efgartigimod and ARGX-117.

Through our commitment to both science and the patient, we are always striving to better understand and learn about the clinical findings we observe, which is perhaps best demonstrated by our 'bedside to bench' approach. In 2022, we produced and published on new breakthrough translational biology that emerged from our Phase 2 clinical trial in pemphigus and may show a potential disease-modifying mechanism for efgartigimod. These data were presented at the Society for Investigative Dermatology in May 2022.

We are excited to continue to demonstrate our commitment to innovation in 2023 and beyond as we progress closer to 'argenx 2025'. This is our core mission – simply put. We want to seek out breakthroughs in immunology and bring them to patients. We see real innovation, real impact as the only way to revolutionize the way autoimmunity is treated. We believe that when you follow scientific breakthroughs to meet the needs of patients – the opportunity is limitless.

Thank you first to the patients and their families who inspire us, to our shareholders for your continued support and belief in our mission, and to our employees for your commitment and passion every day. We are very proud of the progress we continue to make and are confident that we can achieve even more in the year to come.

Sincerely,
Tim Van Hauwermeiren & Peter Verhaeghe

2022 In Brief

Operational Highlights

In 2022, we executed on our global launch of VYVGART® (efgartigimod alfa) (***VYVGART***) our first-in-class neonatal Fc receptor (***FcRn***) blocker, which is now approved in the U.S., Japan and Europe. There are now over 3,000 people globally living with gMG who are on VYVGART.

gMG is just the beginning and efgartigimod is now being evaluated in ten autoimmune indications with three more to start in 2023. We announced positive Phase 3 data from ADAPT-SC evaluating subcutaneous (***SC***) efgartigimod in gMG and also from ADVANCE evaluating VYGART (intravenous (***IV***)) in ITP. We are well on our way to achieve our 'argenx 2025' vision of efgartigimod either being commercially available or in clinical development in fifteen indications by 2025.

Operational Highlights

We are advancing a pipeline of differentiated immunology assets across four commercial franchises including neurology, hematology/rheumatology, dermatology and nephrology. Our wholly-owned pipeline currently consists of efgartigimod, ARGX-117 targeting component 2 (***C2***) and ARGX-119 targeting muscle-specific kinase (***MuSK***). Our core mission is innovation, and we continue to invest in our immunology innovation program (***IIP***) from which we drive pipeline expansion by collaborating with leading disease biologists who are researching first-in-class disease targets or pathways. We believe that our IIP has a track record of success and eight programs have demonstrated human proof-of-concept since our inception.

Global Efgartigimod Launch

- Generated global net product VYVGART revenue of $400.7 million in 2022.
- VYVGART was approved for the treatment of gMG in the U.S., Japan and Europe:
    - On December 17, 2021, the U.S. Food and Drug Administration (***FDA***) approved VYVGART for the treatment of gMG in adult patients who are anti-acetylcholine receptor antibody positive (***AChR.AB+***). The U.S. commercial launch was initiated in January 2022.
    - On January 20, 2022, Japan's Ministry of Health, Labour and Welfare (***MHLW***) approved VYVGART (efgartigimod alfa) for the treatment of adult patients with gMG who do not have sufficient response to steroids or non-steroidal immunosuppressive therapies (***ISTs***). The Japan commercial launch was initiated in May 2022.
    - On August 11, 2022, the EU Commission granted marketing authorization for VYVGART (efgartigimod alfa-fcab) as an add-on to standard therapy for the treatment of adult patients with gMG who are AChR-AB+. The approval is applicable in all 27 European Union (***EU***) Member States, Iceland, Norway and Liechtenstein. The commercial launch in Germany was initiated in September 2022.

- In addition, in 2022, we made the following progress towards our global launch of VYVGART:
    - argenx Canada was established in February 2022 in preparation for a potential Health Canada approval, expected in the third quarter of 2023, and, if granted, commercial launch in Canada.
    - argenx UK Ltd. was established in August 2022 in preparation for launch in the United Kingdom (***UK***).
    - argenx Netherlands Services B.V. was established in September 2022 in preparation for launch in the Netherlands.
    - 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, 20122 Milan, Italy.
    - Zai Lab Ltd (***Zai Lab***) filed for approval of efgartigimod in the People's Republic of China (***PRC***) in the second quarter of 2022. The approval decision is expected in 2023.
    - Medison Pharma Ltd (***Medison***) filed for approval of efgartigimod in Israel in the second quarter of 2022. The approval decision expected in 2023.
    - Additional distribution partnership agreements for other territories were announced in 2022 to further expand global patient reach. For example, we entered into VYVGART commercial and distribution agreements with Medison in Central and Eastern Europe and with Genpharm Services FZ-LLC (***Genpharm***) for the Gulf Cooperation Council, comprising Saudi Arabia, Kuwait, the United Arab Emirates, Qatar, Bahrain and Oman (collectively, the ***GCC***).
    - Expanded large-scale manufacturing capabilities and capacity through collaboration with FUJIFILM Diosynth Biotechnologies Denmark ApS (***Fujifilm***) based in Hillerød, Denmark, to provide large-scale drug substance manufacturing of efgartigimod (in addition to Lonza Sales AG (***Lonza***)).

Pipeline of Differentiated Antibody Candidates

Efgartigimod is our first-in-class neonatal FcRn blocker. We expect our leadership in FcRn blockade to expand to include thirteen autoimmune indications in the pipeline by the end of 2023, including in our commercial franchises listed below:

- Neurology franchise:
  - ADAPT-SC: Positive topline data of SC efgartigimod, announced on March 22, 2022, followed by acceptance of a biologics license application (***BLA***) by the FDA for SC efgartigimod for gMG in adult patients. The BLA was granted a Prescription Drug User Fee Act (***PDUFA***) target action date that was recently extended by three months to June 20, 2023.
  - ADHERE: Topline data from registrational ADHERE clinical trial of SC efgartigimod for chronic inflammatory demyelinating polyneuropathy (***CIDP***) expected in thesecond quarter of 2023.
  - ALKIVIA: Registrational Phase 2/3 ALKIVIA clinical trial ongoing of SC efgartigimod for three subtypes of idiopathic inflammatory myopathies (***Myositis***), including immune-mediated necrotizing myopathy (***IMNM***), anti-synthetase syndrome (***ASyS***) and dermatomyositis (***DM***), with an analysis planned for the Phase 2 portion of the clinical trial including 30 patients of each subtype.
  - Thyroid eye disease (***TED***): Registrational clinical trial to start in TED in the fourth quarter of 2023.

- gMG data from our neuromuscular franchise presented during the American Association of Neuromuscular and Electrodiagnostic Medicine annual meeting and Myasthenia Gravis Foundation of America scientific session on September 21, 2022, including new data analyses from ADAPT+ and real-world case studies on the adult AChR antibody negative gMG patient population.

- Hematology/rheumatology franchise:
  - ADVANCE: Positive topline data of VYVGART for ITP, announced on May 5, 2022.
  - ADVANCE-SC: Topline data from the second registrational ADVANCE-SC clinical trial of SC efgartigimod for primary ITP expected in the second half of 2023.
  - Sjögren's syndrome (***Primary SjS***): Phase 2 proof-of-concept clinical trial ongoing through partnership with IQVIA Ltd (***IQVIA***) with topline results expected in 2024.
  - Post-COVID-19 Postural Orthostatic Tachycardia Syndrome (***PC-POTS***): Phase 2 proof-of-concept clinical trial ongoing through partnership with IQVIA with topline results expected in fourth quarter of 2023.
  - Anti-neutrophil cytoplasmic antibody-associated vasculitis (***AV***): Phase 2 proof-of-concept clinical trial to start in fourth quarter of 2023.

- Dermatology franchise:
  - ADDRESS: Topline data from registrational ADDRESS trial of SC efgartigimod for pemphigus vulgaris (***PV***) and pemphigus foliaceus (***PF***) expected in the second half of 2023.
  - BALLAD: Registrational Phase 2/3 BALLAD trial of SC efgartigimod in bullous pemphigoid (***BP***) ongoing with interim results after the first 40 patients expected in 2024.
  - Novel translational data from the open-label Phase 2 clinical trial of efgartigimod for the treatment of PV and PF that further support the potential role of FcRn blockade and potential of efgartigimod in autoimmune skin blistering disorders were published in the journal Frontiers of Immunology and presented during the Society for Investigative Dermatology Annual Meeting in May 2022.

- Nephrology franchise:
  - Phase 2 proof-of-concept clinical trial ongoing through partnership with Zai Lab. Membranous Nephrology (***MN***).
  - Phase 2 proof-of-concept clinical trial ongoing through partnership with Zai Lab. Lupus Nephritis (***LN***).
  - Antibody-mediated rejection (***AMR***): Phase 2 proof-of-concept clinical trial to start in the fourth quarter of 2023.

ARGX-117 (C2 inhibitor):

- ARDA: Phase 2 proof-of-concept clinical trial of ARGX-117 in multifocal motor neuropathy (***MMN***) ongoing with interim results expected in mid-2023.
- Phase 2 proof-of-concept clinical trial to start in delayed graft function (***DGF***) in the second half of 2023.
- DM was announced as the third indication for ARGX-117.

ARGX-119 (muscle-specific tyrosine kinase (***MuSK***) agonist):

- Phase 1 dose-escalation trials in healthy volunteers started in the first quarter of 2023 with subsequent Phase 1b clinical trial to assess early signal detection in patients.

LEO Pharma exercised it's exclusive, worldwide option to ARGX-112 targeting IL22 receptor, which triggered a €5.0 million payment to us.

Creation of OncoVerity, Inc. (***OncoVerity***):

- argenx, the University of Colorado Anschutz Medical Campus and the University of Colorado Health (***UCHealth***) created an asset-centric spin-off, OncoVerity, focused on optimizing and advancing the development of cusatuzumab, an 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 the experience from argenx on the CD70/CD27 pathway. OncoVerity is the fourth spin-off company from our IIP.

Corporate Achievements

Board of Directors

Appointment of Camilla Sylvest and Ana Cespedes in 2022, and Steve Krognes in the first quarter as non-executive directors to our board of directors (***Board of Directors***).

843

Employees

Expansion to 843 employees (as of December 31, 2022) to support further growth of our business, including fully staffed commercial teams in the U.S., Europe and Japan.

Hans de Haard

Prof. Hans de Haard, our chief scientific officer, retired effective January 1, 2023 and transitioned to consult within our IIP and as a strategic advisor to the research and development committee of our Board of Directors. Peter Ulrichts, Ph.D., our former head of clinical science, assumed the chief scientific officer role.

Keith Woods

Keith Woods, our chief operating officer, was succeeded as chief operating officer by Karen Massey effective March 13, 2023. Mr. Woods will transition to serve as an advisor to our Board of Directors.

Fiscal 2022

Financial Highlights

$400.7
million
Global net product VYVGART revenue

$2.2
billion
Cash

(cash, cash-equivalents and current financial assets) enabling execution of our ambitious strategy objectives.

$720.3
million
Operating loss

$709.6
million
Loss

$804.1
million
Raised

In gross proceeds in global offering of 2,683,334 ordinary shares (including ordinary shares represented by American Depositary Shares (***ADSs***)), which included the full exercise of the underwriters' option to purchase 350,000 additional ADSs.

2023 Outlook

Planned Commercial Milestones	
VYVGART gMG Approval in China	YE 2023
VYVGART gMG Approval in Canada	3Q 2023
VYVGART gMG Launch in France, UK, Italy	YE 2023
SC efgartigimod gMG PDUFA Date	June 20, 2023
SC efgartigimod gMG Approval in EU	4Q 2023
SC efgartigimod gMG Submission in Japan	1Q 2023
VYVGART ITP Submission in Japan	Mid-2023
Planned Clinical Milestones	
Efgartigimod	
ADHERE data in CIDP	2Q 2023
ADDRESS data in Pemphigus	2H 2023
ADVANCE (SC) data in ITP	2H 2023
POC data in Post-COVID POTS	4Q 2023
Initiate registrational trial in TED	4Q 2023
Initiate POC studies in ANCA and AMR	4Q 2023
Additional pipeline	
ARGX-117	
ARDA MMN interim results	Mid-2023
Initiate DGF POC study	2H 2023
ARGX-119	
Initiate Phase 1 study	1Q 2023

The table above is subject to risks and uncertainties that may materially impact the achievement of our 2023 outlook. For more information, please refer to section 2 "**Risk Factors**" of this Annual Report for a discussion of such risks and uncertainties.

The future belongs to those who dare to do more.

David

"Pemphigus is always in the back of my mind. If I have something on my skin, I look twice. If I feel a strange itch or sensation on my scalp, I wonder if that's a lesion popping up."

David was diagnosed with Pemphigus Vulgaris 18 years ago

When he started experiencing symptoms, David was a commercial airline pilot. It took almost a year to get a diagnosis, and he wondered if he'd ever be able to fly again.

What was your life like when you started experiencing symptoms and eventually got diagnosed with pemphigus vulgaris?

I'll never forget the dermatologist saying: 'I know what's wrong with you. It's very serious. But I can't treat it. You need to go see a specialist at a university.' And he wrote two words on a piece of paper, words I'd never seen before: Pemphigus vulgaris.

When the Director of Dermatology comes into your room and says, 'I've tried everything, I don't know what else to do,' that's a low point for me. I didn't know where to go from there. I needed full-time care. I walked like I was 90 years old with 70% of my body covered in open sores and I had a lot of nerve pain. I was on a fentanyl patch and it did nothing. I had to move back in with my parents. I didn't know if I'd ever get back to flying as a pilot.

How have you responded to treatments and adjusted to living with PV?

I returned to work in 2007. Not long after that I met my wife. We rode motorcycles together and we were married 12 years ago. I entered into long-term remission. I had a minor flare at the end of 2019, but this time I knew what to look for, so we caught it early.

While I wouldn't wish pemphigus vulgaris on my worst enemy, I'm actually glad I have it. It might sound strange, but it's made me who I am today. I don't know if I would have met my wife. I've made lifelong friends through other patients.

How does having PV affect your mental health?

Pemphigus is always in the back of my mind. If I have something on my skin, I look twice. If I feel a strange itch or sensation on my scalp, I wonder if that's a lesion popping up. If I get a sore, I wonder: is it pemphigus popping up? And what does that mean for the rest of my life? With pemphigus, there are worries about income and insurance. I live with these concerns and manage the stress, because stress is a big autoimmune trigger.

What are your coping mechanisms?

I love to cook. I'm into barbecue and slow smoking. A brisket can take 12-18 hours. For me the process is very soothing and cathartic. And then getting to feed my friends and family is a big stress reliever.

What advice do you have for others who are newly diagnosed with PV?

First, you need to become an expert in the disease. If you understand it and the available treatments and future treatments in development, that will help you be your own advocate. Second, you have to preserve your mental health. This disease is difficult and can lead to depression. Sometimes it helps to talk to people. Finding another PV patient can help, and so can seeing a professional.

The future belongs to those who dare to do more.

Dina

"I believe it's important that people with ITP have an accurate source of information and a way to connect with others with ITP so we can learn from each other and be with people who understand the challenges of living with ITP."

Dina is working and raising children while living with ITP

Diagnosed with immune thrombocytopenia (ITP) in 2014, Dina became her own advocate. Today she struggles with the fatigue of ITP, but still manages to work and raise her family.

How did your journey with ITP begin?

I was diagnosed with ITP in 2014. It was an accident when I was seeking treatment for a tick bite and Lyme disease. When my platelets stayed low after Lyme, a hematologist monitored me for 6 months and confirmed ITP. During this time I began my self-advocacy efforts by researching ITP on the internet and finding and reaching out to patient advocacy organizations.

How have the symptoms of ITP impacted your life?

My symptoms were atypical in that I did not experience excessive bruising while I had very low platelet levels. My most significant symptom was and is debilitating fatigue and exhaustion that impacts my ability to do my job and engage in my relationships with my family and manage my responsibilities at home. I get frustrated some days, like when I don't have the energy to prepare the evening meal for the family, so I have to rely on the ready-made meals from the store. I also struggle to do what I used to do with my family, like hiking and vacationing.

How have you relied on community to cope with ITP?

Belgium does not have an ITP patient advocacy organization of its own, but I was able to access a Platelet Disorder Support Association (PDSA) international alliance member organization in the Netherlands. In one of the organization's publications, I saw a call out to join a study for people with ITP who still had their spleen. So I reached out to the contact and was ultimately included in the study. This opportunity helped me better understand my experience with ITP, and the treatment allowed me to stop the roller coaster of ever-changing platelet levels.

It's so important that people with ITP have a way to find valid sources of information, like medical journals and organizations like PDSA or the Dutch ITP organization. We also need a way to connect with others with ITP. We can learn from one another and it helps to be with people who understand your challenges.

How else can people with ITP advocate for themselves?

It's important to be part of the decision-making process about your treatment approaches. I really embrace the idea that while my doctor may know the most about the treatment options, I know the most about my body and have to be involved in all the decisions made about what's done to my body.

The future belongs to those who dare to do more.

Mihoko

"Above all, I want to become a role model for other MG patients. We cannot recover completely, and face challenges in terms of mental health and our appearance, but we can figure out ways and means to live with the disease. I want to encourage others by sharing my experience."

I didn't even know what the next day would bring after being diagnosed with MG

Ms. Suzuki, 52 years old, was diagnosed with MG in 2008, when she was in her 30s.

I felt heaviness in my body when I travelled a long distance for a relative's wedding. I also felt my eyelids drooping and found difficulty in swallowing food. I thought I was just tired because I was very busy at work at the time and wasn't getting enough sleep. But a little later, when I was driving my car, I started to see two traffic signals or two roads. That's when I thought: 'There's something wrong with me,' so I decided to see a doctor.

After undergoing MRI scans at the department of neurosurgery, Ms. Suzuki was referred to a university hospital with a suspected disease, and was diagnosed with MG. She underwent thymectomy and began medical treatment.

When I started receiving treatment, it was hard for me not knowing when I would lose my motor functions, or even what tomorrow might bring. It was also difficult for me to make plans to meet with my friends, and I could not commit to completing tasks at work. I was in an unstable state of mind, as if I were walking down a narrow path and somehow trying to make it to tomorrow.

After ending up in the hospital due to MG symptoms, she met a doctor who changed her life.

A doctor who always reaches out to patients accepted my desire to adjust my treatment so I could go back to work. I came to think: 'This doctor is helping me stay alive!'

I also met other patients with MG at the hospital. We were able to open up to each other right away because we shared MG in common. Meeting other MG patients who had come through the same situation and being able to talk with them helped me to become more positive, and start thinking that 'I want to do something.'

With the slogan: "We are now in a dark tunnel, but one day we will pass through the tunnel and morning will surely come," they encouraged each other. "There's something fun even in the dark tunnel. Never give up hope."

I thought seriously about how to live with MG.

Ms. Suzuki was able to overcome her mental and physical suffering with the help of medical care and her friends. Despite the limitations her illness imposes, she is living her life by figuring out the best way to handle her situation.

In my daily life, I cannot cook at all. I live by myself, so I buy precooked food or ask my family to send me food. I can't go shopping frequently, so I buy things when I go out on an errand or use home delivery services.

Since I cannot hold buttons between my fingers when changing clothes, I wear mainly pullovers and shawls. In addition, I don't use an electric toothbrush because according to my doctor it could chip my teeth due to the impact of the treatment. Everything takes time, so I get up early to make sure I have enough time to do everything.

I feel happy after changing my living environment, perspective, and mindset.

Above all, I want to become a role model for other MG patients. We cannot recover completely, and face challenges in terms of mental health and our appearance, but we can figure out ways and means to live with the disease. I want to encourage others by sharing my experience.

Many MG patients may think that their future is uncertain because of their disease. Although we can't change reality, I think it is important for all of us to change our current living environment, perspective, and mindset and try to get to a place where we can achieve sufficient happiness to alleviate some of the suffering and hardship we may experience. It's not easy, but you can try it at any time you like. If you are facing a tough time, why don't you contact me as your friend? Let's go forward together without giving up!

1 Presentation of the Group

1 Presentation of the Group

1.1 Company Profile

1.1.1 General

We are a commercial-stage, global, fully-integrated biopharma company developing a deep pipeline of differentiated therapies for the treatment of severe autoimmune diseases. By combining our suite of antibody engineering technologies with the disease biology expertise of our research collaborators, we aim to translate immunology breakthroughs into a pipeline of novel antibody-based medicines through our discovery engine, the IIP. We have a particular focus on rare, autoimmune diseases that fit into our growing commercial franchises focused on neurology, hematology and rheumatology, dermatology and nephrology. Through the building and use of commercial franchises, we plan to leverage capabilities and an organizational footprint for subsequent potential launches across our broad immunology pipeline. On December 17, 2021, the FDA approved efgartigimod in the U.S., which is marketed as VYVGART (efgartigimod alfa-fcab), for the treatment of gMG in adult patients who are AChR-AB+. On January 20, 2022, MHLW approved VYVGART (efgartigimod alfa) for the treatment of adult patients with gMG who do not have sufficient response to steroids or non-steroidal ISTs. On August 11, 2022 the EU Commission granted marketing authorization for VYVGART (efgartigimod alfa-fcab) as an add-on to standard therapy for the treatment of adult patients with gMG who are AChR-AB+ in all 27 EU Member States, Iceland, Norway and Liechtenstein (collectively, with the U.S. and Japan, the ***VYVGART Approved Countries***). With these regulatory milestones, VYVGART is the first-and-only approved FcRn blocker in the U.S., Europe and Japan.

argenx was founded on April 25, 2008 and is registered with the trade register of the Dutch Chamber of Commerce under number 24435214. Our registered office is at Laarderhoogtweg 25, 1101 EB Amsterdam, the Netherlands. Our commercial name is “argenx” and, since April 26, 2017, our corporate name is “argenx SE”.

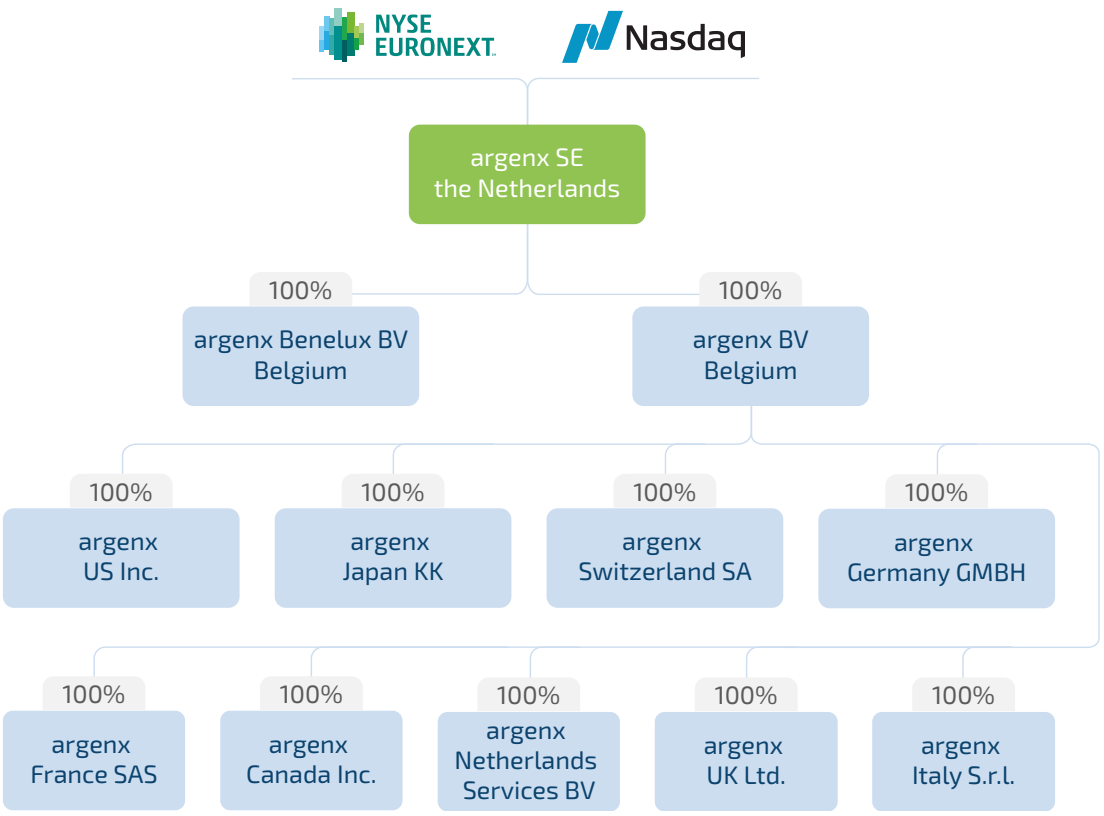
Our ordinary shares are listed on the regulated market of Euronext Brussels in Belgium under ISIN NL0010832176 under the symbol “ARGX” since 2014 and our ADSs, each representing one ordinary share in argenx (or a right to receive such share), are listed on the Nasdaq Global Select Market (***Nasdaq***)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

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

- argenx Benelux BV (prior to October 31, 2022 known as argenx IIP BV), 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, and
- argenx BV, 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 BV is the sole shareholder of:
    - 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 02110;
    - 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 Switzerland SA, incorporated under the laws of Switzerland, having its registered office in Geneva, Switzerland, and its address at Rue du Pré-de-la-Bichette 4, 1202 Geneva, Switzerland;
    - argenx France SAS, incorporated under the laws of France, having its registered office in Paris, France, and its address at rue Camille Desmoulins 13, 92130 Issy Les Moulineaux, France;
    - 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 Gerrargs Cross, SL9 0BG, UK;
    - argenx Netherlands Services BV, incorporated under the laws of the Netherlands, having its registered office in Laarderhoogtweg 25, 1101 EB Amsterdam, the Netherlands;
    - 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 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; and
    - 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, 20122 Milan, Italy.

The following chart provides an overview of the Group as of December 31, 2022 and 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 Pipeline

- Efgartigimod (FcRn blocker): efgartigimod is a human IgG1 Fc fragment that is designed to target the neonatal FcRn and reduce immunoglobulin G (***IgG***). FcRn is foundational to the immune system and functions to recycle IgG, extending its serum half-life over other Ontario 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. It has the potential to address a multitude of severe autoimmune diseases where pathogenic IgGs are believed to be mediators of disease. We are evaluating both IV efgartigimod (10 mg/kg) (VYVGART) and SC efgartigimod (1000 mg efgartigimod PH20). SC efgartigimod is co-formulated with recombinant human hyaluronidase PH20 (rHuPH20), Halozyme, Inc.'s (***Halozyme***) ENHANZE® drug delivery technology. ENHANZE® facilitates the SC injection delivery of biologics that are typically administered via IV infusion.

- gMG: In May 2020, we announced positive topline results from the Phase 3 ADAPT clinical trial of IV efgartigimod for the treatment of gMG. The topline results from the ADAPT clinical trial showed that efgartigimod was well-tolerated, demonstrated clinically meaningful improvements in strength and quality of life measures, and provided the option of an individualized dosing schedule for gMG patients. The full Phase 3 ADAPT results were published in The Lancet Neurology in July 2021. Data from the ADAPT clinical trial and the subsequent open-label extension (ADAPT+) formed the basis for the regulatory approvals of VYVGART in the U.S., Japan and the EU.
- In March 2022, we announced positive topline results from the Phase 3 ADAPT-SC study. SC efgartigimod achieved the primary endpoint of total IgG reduction from baseline at day 29, demonstrating statistical noninferiority to VYVGART IV formulation in gMG patients. Based on these results, we announced the acceptance of a BLA by the FDA with a PDUFA target action date that was recently extended by three months to June 20, 2023.
- Registrational clinical trials are ongoing in five additional autoimmune indications:
  - ITP: The ADVANCE trial of VYVGART was initiated in the fourth quarter of 2019 and positive topline data of IV efgartigimod for primary ITP were announced on March 22, 2022. The ADVANCE-SC trial of SC efgartigimod started in the fourth quarter of 2020 and topline data are expected in the second half of 2023.
  - PV and PF: The ADDRESS trial of SC efgartigimod was initiated in 2020. The topline data of SC efgartigimod for PF and PV are expected in the second half of 2023.
  - CIDP: The ADHERE trial of SC efgartigimod was initiated at the end of 2019 and topline data are expected in the second quarter of 2023.
  - BP: The BALLAD trial of SC efgartigimod in BP was initiated in the second half of 2022. An interim analysis of the first 40 patients is expected in 2024.
  - Myositis: The ALKIVIA trial of SC efgartigimod initiated in the third quarter of 2022 for three subtypes of Myositis, including IMNM, ASyS and DM. Interim analysis of the first 30 patients of each subset is expected in 2024.
- Clinical trials in four additional autoimmune indications through partnership agreements with Zai Lab and IQVIA started in 2022:
  - Zai Lab launched the Phase 2 proof-of-concept trials in two kidney indications, LN and MN.
  - IQVIA launched the Phase 2 proof-of-concept trials in Primary SjS and PC-POTS. Topline results from the PC-POTS trial are expected in the fourth quarter of 2023 and from the Primary SjS trial in 2024.

- ARGX-117 (C2 inhibitor): ARGX-117 is a novel complement inhibitor targeting C2, blocking function of both the classical and lectin pathways while leaving the alternative pathway intact. ARGX-117 has the potential to be a pipeline-in-a-product candidate with indications that fit within our commercial franchises.
  - Final Phase 1 data of ARGX-117 confirmed the interim data reported in July 2021 showing a favorable safety profile across single and multiple ascending doses (***MADs***) of both IV and SC formulations. Pharmacokinetic (***PK***) and pharmacodynamic (***PD***) profiles demonstrated potential for infrequent dosing schedules.

  - Phase 2 ARDA proof-of-concept trial started at the end of 2021 in MMN and interim data are expected in mid-2023.
  - Phase 2 proof of concept clinical trial to start in DGF following kidney transplantation in the second half of 2023.
  - DM was announced as the third indication for ARGX-117.

- ARGX-119 (MusK agonist): ARGX-119 is an agonist SIMPLE Antibody™ to the MuSK receptor with potential in multiple neuromuscular indications. Phase 1 dose-escalation clinical trial started in the first quarter of 2023 with a subsequent Phase 1b clinical trial planned to assess early signal detection in patients thereafter.

- ARGX-118 (Galectin-10): ARGX-118 is an antibody against Galectin-10, the protein of Charcot-Leyden crystals which are implicated as a major contributor to airway inflammation and to the persistence of mucus plugs.

- 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:
  - ARGX-112 (LP-0145), a SIMPLE Antibody inhibitor of interleukin-22 receptor (***IL-22R***) and out-licensed to LEO Pharma.
  - ARGX-114 (AGMB-101), a SIMPLE Antibody agonist to the mesenchymal-epithelial transition factor (***MET***) receptor and out-licensed to AgomAb Therapeutics NV (***AgomAb***).
  - ARGX-115 (ABBV-151), a SIMPLE Antibody inhibitor of glycoprotein A repetitions predominant (***GARP***)- transforming growth factor beta (***TGF-β***) and out-licensed to AbbVie S.A.R.L (***AbbVie***).
  - ARGX-116 (STT-5058), a SIMPLE Antibody inhibitor of ApoC3 and out-licensed to Staten Biotechnology B. V.
  - Cusatuzumab (Anti-CD70 Antibody): Cusatuzumab is an anti-CD70 monoclonal antibody. CD70, a tumor necrosis factor receptor ligand, and its receptor CD27 are expressed on leukemic stem cells and AML blasts but not on hematopoietic stem cells. OncoVerity, an asset-centric spin-off was created to focus on optimizing and advancing the development of cusatuzumab, a novel anti-CD70 antibody, in 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 the experience from argenx on the CD70/CD27 pathway.

Immunology Innovation Program

Our IIP is a core business strategy of co-creation and innovation. The IIP also serves as our discovery engine to identify novel targets and together, in collaboration with our scientific and academic partners, to build potential new pipeline candidates. Every current pipeline candidate from both our wholly-owned and partnered pipeline emerged from an IIP collaboration. As part of our long-term strategy, we continue to invest in the IIP.

For example:

- Efgartigimod emerged from a collaboration with Professor Sally Ward and University of Texas Southwestern Medical Center (***UT Southwestern)*** that later became one of the blueprints for our IIP collaborations. Professor Ward's research identified the crucial role that FcRn plays in maintaining and distributing IgGs throughout the body. Efgartigimod is a human IgG1 Fc fragment that is equipped with ABDEG mutations, which we in-licensed from UT Southwestern. These proprietary mutations modified efgartigimod to increase its affinity for FcRn while retaining the pH-dependent binding that is characteristic of FcRn interactions with its natural ligand, endogenous IgG.
- ARGX-117 was built in collaboration with Broteio Pharma B.V. (***Broteio***) which was launched in 2017 with support from Professor Erik Hack and the University of Utrecht, to conduct research to demonstrate preclinical proof-of-concept of the mechanism of ARGX-117. Professor Hack has done renowned research in the role of inflammation in disease, specifically in the complement system, and has contributed research and expertise to the approval of two complement inhibitors. His understanding of the mild phenotype associated with a natural C2 deficiency and C2's unique positioning at the junction of the classical and lectin pathways led to our interest in engineering ARGX-117, which is equipped with our proprietary NHANCE® mutations and LALA mutations.
- ARGX-119 was built in collaboration with the Leiden University Medical Center (***LUMC***) and New York University (***NYU***) with support from the teams led by Professor Verschuuren and Professor Steve Burden, respectively. Both groups have world-class expertise in unraveling the biological mechanism of neuromuscular disease and translating these insights from the lab to the patient.

Our Suite of Technologies

Through our IIP, we collaborate with scientific and academic partners to identify immunology breakthroughs and build potential pipeline candidates. This is done through co-creation. We bring to the collaboration our unique suite of antibody engineering technologies and experience in clinical development and our partners bring a wealth of disease and target biology expertise.

- SIMPLE Antibody platform: Our proprietary SIMPLE Antibody platform, 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 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 dehydrated hereditary stomatocytosis (***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. (***Chugai***) for the ***SMART-Ig®*** and ***ACT-Ig®*** 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. In 2020, we also entered into a non-exclusive research agreement with the Clayton Foundation under which we may access the Clayton Foundation's proprietary DHS mutations to extend the serum half-life of therapeutic antibodies.

- Halozyme's ENHANZE SC drug delivery technology: We have exclusive access to ENHANZE for the FcRn and C2 targets and four additional targets. The global collaboration and license agreement with Halozyme was announced in February 2019 and expanded in October 2020. The ENHANZE® technology has the potential to shorten drug administration time, reduce healthcare practitioner time and offer additional flexibility and convenience for patients.
- In April 2021, we entered into a collaboration and license agreement with Elektrofi, Inc. (***Elektrofi***) to explore Elektrofi's high-concentration, low-volume delivery technology for efgartigimod, and up to one additional target.

1.2 Strategy and Objectives

1.2.1 Company's Strategies

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

- Execute our global launch. With the commercial launch of VYVGART as the first-and-only approved neonatal FcRn blocker in the U.S., Japan and the EU, we have already taken the first steps in executing our plans for a global launch for VYVGART for the treatment of gMG. We aim for further approvals in additional jurisdictions in the course of 2023. We have already built our commercial infrastructure to support the commercialization of VYVGART in the U.S., Europe and Japan as well as built out additional commercialization infrastructure to support other indications in certain of these key territories if and when new indications receive approval. In 2023, we expect VYVGART approvals in Canada in the third quarter of 2023, and in the PRC and Israel by the end of 2023. We also plan to launch VYVGART in France, Italy and the UK by the end of 2023 following review of each country's respective reimbursement dossier.

- Expand applications for our lead product efgartigimod. Our goal is to maximize the commercial potential of our existing products and product candidates by exploring additional indications, as well as formulations that may expand the target patient populations within existing indications. We are further developing our lead product, efgartigimod, to market regulatory approval for the treatment of gMG, ITP, PV, CIDP, BP, Myositis, PC-POTS, Primary SjS, MN, LN, TED, AV and AMR. We expand the use of our products and product candidates in existing indications by developing new formulations, such as an SC version of efgartigimod, that may reach more patient groups by capturing different patient preferences and providing additional optionality with regards to dosing. In this respect, we announced the acceptance of a BLA by the FDA with a PDUFA target action date of June 20, 2023 for SC efgartigimod in gMG patients.

- Advance our pipeline of assets. In addition to new indications for efgartigimod, we plan to advance our other product candidates. In particular, we have advanced the clinical development of ARGX-117 in a Phase 2 proof-of-concept clinical trial in MMN and plan to advance in Phase 2 proof-of-concept clinical trials in DGF in the context of kidney transplants and DM. We have also advanced ARGX-119 into a Phase 1 clinical trial in healthy volunteers and plan to advance early-stage pipeline candidates as well as expand our pipeline of future product candidates through the IIP.

- Leverage our suite of technologies to seek strategic collaborations and maximize the value of our pipeline. Our suite of technologies and productive discovery capabilities have yielded several potential product candidates for which we seek to capture value, while maintaining our focus and discipline. We plan to collaborate on product candidates that we believe have promising utility in disease areas or patient populations but fall outside our commercial franchises or are better served by the resources of larger biopharmaceutical companies. In addition to collaborating on our products and product candidates, we may also elect to enter into collaborations for access to partner technology platforms or capabilities from which we can develop differentiated potential pipeline assets.

- Implement our "argenx 2025" vision. We hope to make efgartigimod globally available to patients across our four commercial franchises. We aspire to make efgartigimod either commercially available or in clinical development in fifteen active indications. We plan to make progress across our broader immunology pipeline with ARGX-117 in multiple late-stage clinical trials and demonstrate clinical proof-of-concept with ARGX-119. Finally, we will invest in the continued expansion of our differentiated pipeline through our IIP.

- Continue to build innovation into every step of our development, highlighted by our collaborative IIP translating immunology breakthroughs into medicines. Our IIP is our core business strategy connecting the specialized insight into disease and target biology of our external scientific and academic collaborators with our unparalleled experience as antibody engineers. Co-creation has led to a deep pipeline of highly differentiated product candidates. Through the IIP, we hope to together transcend breakthrough research and publications to our ultimate and unifying mission of creating new potential treatment options for patients.

1.2.2 Trends

Other than as disclosed in section 1 "**Presentation of the Group**" and 2 "**Risk Factors**", we are not aware of any trends, uncertainties, demands, commitments or events for the current financial period that are reasonably likely to have a material effect on our net revenues, income, profitability, liquidity, capital resources or prospects, or that caused the disclosed financial information to be not necessarily indicative of future operating results or financial conditions.

Following the approval of VYVGART for the treatment of gMG in the U.S. by the FDA on December 17, 2021, we transitioned from a clinical-stage to a commercial-stage biotechnology company, have commercialized VYVGART in the VYVGART Approved Countries and are working to expand commercialization in other jurisdictions, and to launch new products and product candidates, including new indications.

There has been no significant change in the financial performance or the financial position of the Group since the balance sheet date of December 31, 2022.

For more information, please refer to section 1 "**Presentation of the Group**", section 2 "**Risk Factors**", and to note 29 "**Commitments**" of our consolidated financial statements in section 6 "**Consolidated Financial Statements**".

1.2.3 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.

We compete with a wide range of biopharmaceutical companies, who are developing products for the treatment of gMG and other autoimmune diseases, including products that are in the same class as VYVGART, as well as products that are similar to some of our product candidates. We are aware of several FcRn inhibitors that are in clinical development. Competitive product launches may erode future sales of our products, including our existing products and those currently under development, or result in unanticipated product obsolescence. Such launches continue to occur, and potentially competitive products are in various stages of development. We could also face competition for use of limited international infusion sites, particularly in new markets as competitors launch new products. We cannot predict with accuracy the timing or impact of the introduction of competitive products that treat diseases and conditions like those treated by our products or product candidates. In addition, our competitors 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.

Competition in the autoimmune field is intense and involves multiple monoclonal antibodies, other biologics and small molecules either already marketed or in development by many different companies including large pharmaceutical companies such as AbbVie (Humira/rheumatoid arthritis), Amgen, Inc. (***Amgen***) (Enbrel/rheumatoid arthritis), Biogen, Inc. (Tysabri/multiple sclerosis), GlaxoSmithKline plc (***GSK***) (Benlysta/lupus), F. Hoffman-La Roche AG (***Roche***) (Rituxan/often used off label) and Janssen Pharmaceuticals, Inc. (***Janssen***) (Remicade/rheumatoid arthritis and Stelara/psoriasis). In addition, these and other pharmaceutical companies have monoclonal antibodies or other biologics in clinical development for the treatment of autoimmune diseases.

In addition to the current standard of care, we are aware that AstraZeneca PLC is selling Soliris and Ultomiris for the treatment of adult patients with gMG who are AChR-AB+ and that GSK, Roche, Novartis AG, CSL Behring, Grifols, S.A., BioMarin Pharmaceutical, Inc., Curavac, UCB S.A./RA Pharmaceuticals, Inc., DAS Therapeutics, Inc., Takeda Pharmaceutical Co Ltd, RemeGen Co, Immunovant, Inc., Cartesian Therapeutics, Inc., Horizon Therapeutics PLC, AstraZeneca PLC, Chugai/Genentech, Inc., Regeneron Pharmaceuticals, Inc./Alnylam Pharmaceuticals, Inc. and Johnson & Johnson Innovation, Inc., among others, are developing drugs that may have utility for the treatment of myasthenia gravis

(***MG***). 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.

1.2.4 Our Competitive Strengths

We believe that the combination of our technologies, expertise and focus will enable us to overcome many of the challenges associated with antibody drug development and positions us to be a leader in delivering therapies to patients suffering from severe auto-immune, neuromuscular, hematology, dermatology and nephrology diseases for which the current treatment paradigm is inadequate.

Productive discovery capabilities through our IIP fuel a deep pipeline of clinical and preclinical product candidates. We are advancing a deep pipeline of both clinical- and preclinical-stage product candidates for the treatment of severe autoimmune diseases. Leveraging our technology suite and clinical expertise, we have advanced several candidates and believe this level of productivity affords us a breadth of options with regard to independently advancing or partnering our pipeline assets.

In November 2020, we announced the agreement to acquire an FDA Priority Review Voucher (***PRV***) from Bayer Healthcare Pharmaceuticals, Inc. for $98.0 million. A PRV entitles the holder to FDA priority review of a single new drug application (***NDA***) or BLA, which reduces the target review time and may potentially lead to an expedited approval. During the third quarter of 2022, the Company utilized this PRV and submitted it with the BLA filing for SC efgartigimod for the treatment of gMG.

In November 2022, we announced an agreement to acquire a new PRV for $102 million, which we expect to redeem for a future marketing application for efgartigimod.

1.3 Our Products and Product Candidates

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

Breadth and Depth within Autoimmune Pipeline

Program	Indication	Preclinical	Phase 1	Proof of Concept	Registrational	Commercial
VYVGART	gMG (IV)					
Efgartigimod	gMG (SC)					
	CIDP					
	Myositis					
	Thyroid Eye Disease					
	ITP (IV)					
	ITP (SC)					
	COVID-19 Mediated POTS					
	Sjogren's Syndrome					
	Anca Vasculitis					
	Pemphigus					
	Bullous Pemphigoid					
	Membranous Nephropathy					
	Lupus Nephritis					
	Antibody Mediated Rejection					
ARGX-117	Multifocal Motor Neuropathy					
	Dermatomyositis					
	Delayed Graft Function After Kidney Transplant					
ARGX-119	Neuromuscular Indications					

NEUROLOGY | HEMATOLOGY AND RHEUMATOLOGY | DERMATOLOGY | NEPHROLOGY

1.3.1 VYVGART

Approval

On December 17, 2021, the FDA approved VYVGART for the treatment of gMG in adult patients who are AChR-AB+. These patients represent approximately 85% of the total gMG population (Behin et al. New Pathways and Therapeutics Targets in Autoimmune Myasthenia Gravis. J Neuromusc Dis 5. 2018. 265–277). On January 20, 2022, MHLW granted marketing authorization for VYVGART (efgartigimod alfa) for the treatment of adult patients with gMG who are AChR-AB+. With these regulatory milestones, VYVGART is the first-and-only approved neonatal FcRn blocker in the U.S., Japan and the EU.

gMG is a rare and chronic neuromuscular disease characterized by debilitating and potentially life-threatening muscle weakness. VYVGART is a human IgG1 antibody fragment that binds to FcRn, resulting in the reduction of circulating IgG antibodies. The action of AChR autoantibodies at the neuromuscular junction is a key driver of gMG (Howard JF Jr, Utsugisawa K, Benatar M, et al. Safety and efficacy of efficacy of eculizumab in AChR antibody-positive refractory gMG (REGAIN): a phase 3, randomized, double-blind, placebo-controlled, multicenter study. Lancet Neurol. 2017; 16: 976–86).

The approval of VYVGART is based on results from the global Phase 3 ADAPT clinical trial, which were published in the July 2021 issue of The Lancet Neurology.

We integrated input from the gMG community into the ADAPT clinical trial design. Through listening to and learning from the gMG patient community, we understand that every gMG patient experiences the course of disease differently. As a result, we designed a clinical trial to reflect the individualized nature of gMG with a dosing approach that we believe is adapted to each patient's individual response.

The Phase 3 ADAPT clinical trial was a randomized, double-blind, placebo-controlled, multi-center, global clinical trial evaluating the safety and efficacy of efgartigimod in patients with gMG. A total of 167 adult patients with gMG in North America, Europe and Japan enrolled in the clinical trial and were treated. Patients were eligible to enroll in ADAPT regardless of antibody status, including patients with AChR antibodies and patients where AChR antibodies were not detected. Patients were randomized in a 1:1 ratio to receive efgartigimod or placebo for a total of 26 weeks. ADAPT was designed to enable an individualized treatment approach with an initial treatment cycle followed by a variable number of subsequent treatment cycles.

The ADAPT clinical trial met its primary endpoint, demonstrating that significantly more anti-AChR-AB+ gMG patients were responders on the MG-activities of daily living (***MG-ADL***) scale following treatment with VYVGART compared with placebo (68% vs. 30%; $p<0.0001$). Responders were defined as having at least a two-point reduction on the MG-ADL scale sustained for four or more consecutive weeks during the first treatment cycle.

Additionally, there were significantly more responders on the quantitative myasthenia gravis (***QMG***) scale following treatment with VYVGART compared with placebo (63% vs. 14%; $p<0.0001$). Responders were defined as having at least a three-point reduction on the QMG scale sustained for four or more consecutive weeks during the first treatment cycle.

As shown in figure 1, minimal symptom expression (***MSE***) is an increasingly important data point for physicians and patients because it is a measure of symptom-free status. In ADAPT, 40% of patients achieved MSE – or an MG-ADL score of 0 or 1 – at any time during cycle one. The right side shows depth of response. Over half of patients treated with efgartigimod experienced an improvement of five points or more on the MG-ADL scale by week four.

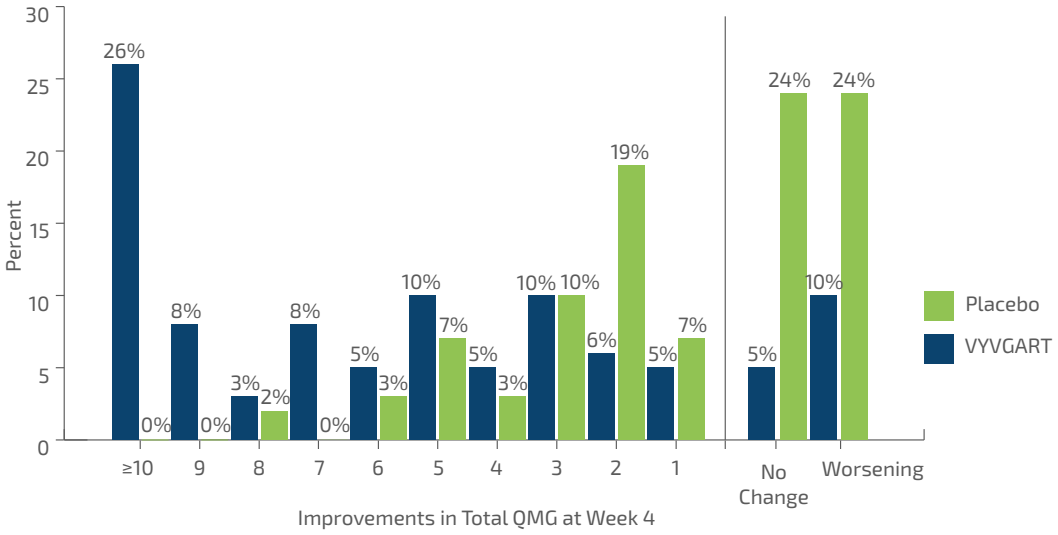


Figure 1: Percentage of patients with MG-ADL and QMG total score change four weeks after initial infusion of the first cycle in AChR-Ab+ population.

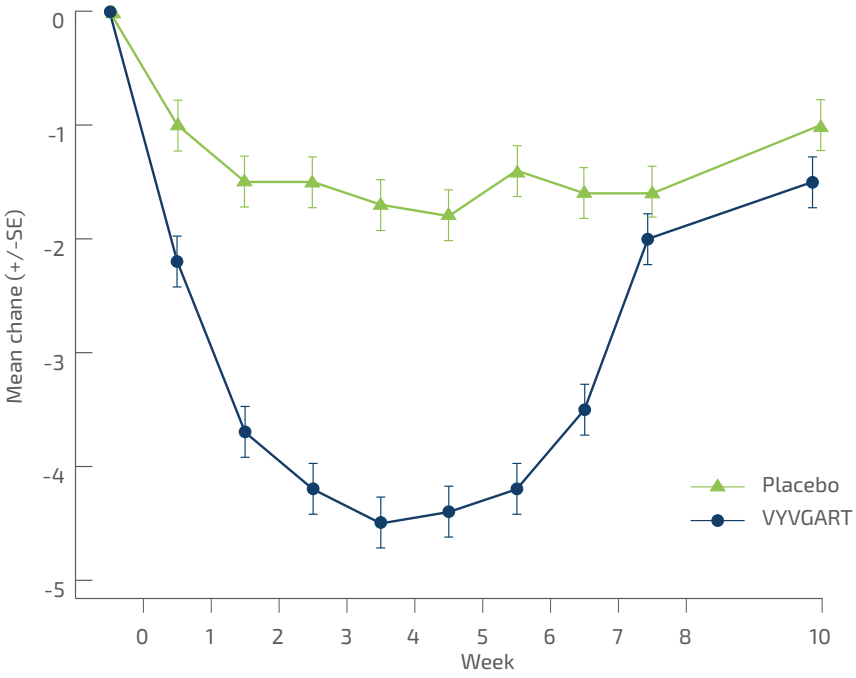


Figure 2: Mean change in total MG-ADL from cycle 1 baseline over time in AChR-Ab+ population.

VYVGART had a demonstrated safety profile in the ADAPT clinical trial. The most common adverse events in ADAPT were respiratory tract infection (33% vs 29% placebo), headache (32% vs 29% placebo), and urinary tract infection (10% vs. 5% placebo).

There is a pre-approval access program (***PAA***) for gMG patients that remains open in the EU, the UK, Hong Kong and Canada for eligible patients.

Commercialization and Regulatory Plans

VYVGART was launched in the U.S. in January 2022, in Japan in May 2022 and in Germany in September 2022 following approval in each region. The European commercial launch of VYVGART is still ongoing.

We have established our own sales force in the U.S., Japan and Europe for VYVGART for the treatment of gMG. We plan to expand our own sales and marketing capabilities and promote our products and product candidates if and when regulatory approval has been obtained in the relevant jurisdictions. For example, we established argenx Canada in the first quarter of 2022 in preparation for a potential Health Canada approval request and if granted commercial launch in Canada. We also established argenx UK in August 2022 in preparation for potential Medicines and Healthcare Products Regulatory Agency (***MHRA***) approval.

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, a commercial-stage biopharmaceutical company, for the development and commercialization of efgartigimod in Greater China (***Zai Lab Agreement***). Zai Lab filed for approval in the PRC in the second quarter of 2022. Under the Zai Lab Agreement, we received a $75.0 million upfront payment in the form of 568,182 newly issued Zai Lab shares calculated at a price of $132.0 per share, a $75.0 million guaranteed non-creditable, non-refundable development cost-sharing payment and a $25.0 million

milestone payment in connection with FDA approval of VYVGART (***Zai Lab Payments***). We will also be eligible for tiered royalties based on annual net sales of efgartigimod in Greater China.

In October 2021, we announced an exclusive distribution agreement with Medison to commercialize efgartigimod for gMG in Israel (***Medison Agreement***). Medison will also be responsible for seeking requisite regulatory approvals, and Medison filed for approval in Israel in the second quarter of 2022. On June 6, 2022 we announced an exclusive multi-regional agreement with Medison to commercialize efgartigimod in 14 countries, including Poland, Hungary, Slovenia, Czech Republic, Romania, Bulgaria, Lithuania, Croatia, Slovakia, Estonia, Latvia, Greece, and Cyprus, for the treatment of adult patients with gMG (***Medison Multi-Regional Agreement***).

In January 2022, we entered into a partnership agreement with Genpharm, under which Genpharm shall purchase VYVGART from us for the resale in the GCC on an exclusive basis for Genpharm's own account and own name (***Genpharm Agreement)***.

We intend to sign additional distribution partnerships for other territories.

For a discussion of total revenues by geographic market, please see note 18 "**Segment Reporting**" in our consolidated financial statements.

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 in autoimmunity and 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 implemented a PAA on February 21, 2022 through which investigational therapies are made available in certain circumstances to treat gMG patients who are unable to participate in an ongoing clinical trial. As of the date of this Annual Report, the PAA has approved over 150 gMG patients in ten countries. With the approval of VYVGART in the U.S., Japan and EU, the PAA program remains open only in countries where VYVGART is not yet launched or reimbursed.

1.3.2 Efgartigimod (formerly ARGX-113) Development

Mechanism of Action

As shown in figure 3, 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 Igs 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.

Compared to alternative immunosuppressive approaches, such as B-lymphocyte (***B-cell)***, depleting agents, efgartigimod acts in a highly selective manner. As of the date of this Annual Report, efgartigimod has been evaluated in over 1,300 subjects with a cumulative exposure of over 1,000 patient years. Efgartigimod has been observed to significantly reduce concentrations of all IgG subtypes without decreasing levels of other Igs or human serum albumin, which is also recycled by FcRn.

In a randomized, double-blind, placebo-controlled first-in-human study of 62 healthy volunteers, efgartigimod treatment resulted in rapid and specific clearance of serum IgG levels. Single administration of efgartigimod reduced IgG levels up to 50% while multiple dosing further lowered IgGs on average by 75% from baseline. Approximately eight weeks following the last administration, IgG levels returned to baseline. Efgartigimod did not alter homeostasis of albumin or Igs other than IgG and no serious adverse events as defined by the competent authorities related to efgartigimod infusion were observed.

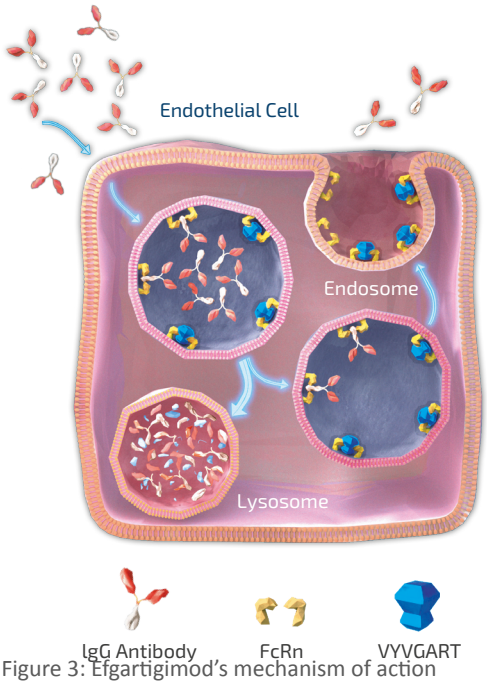


Figure 3: Efgartigimod's mechanism of action blocks the recycling of IgG antibodies and removes them from circulation

Based on its mechanism of action in targeting FcRn to selectively reducing IgGs, efgartigimod has the potential to address a multitude of severe autoimmune diseases where pathogenic IgGs are believed to be mediators of disease.

As of the date of this Annual Report, we continue to evaluate efgartigimod in ten autoimmune indications where significant unmet need exists despite the availability of commonly used therapies. These include gMG, CIDP and Myositis within our neurology franchise; ITP, PC-POTS and Primary SjS within our hematology and rheumatology franchise; PV, PF and BP within our dermatology franchise; and LN and MN within our nephrology franchise. In 2023, we announced our intention to expand efgartigimod into three new indications: TED, AV and AMR.

Indication Selection Strategy

We utilize the following strategy to select indications for efgartigimod:

- We first start with a strong, unifying biological rationale. The indications in our pipeline are unified in that there exists a wide range of supportive evidence that demonstrates that each is IgG-mediated. This ranges from published literature, clinical trials with currently used therapies such as intravenous Ig (***IVIg***), PLEX, or Rituximab, and other experiments, such as passive transfer models.
- We also look at indications where a significant clinical or commercial opportunity exists. These are disease areas where there is a significant unmet need for innovation as patients are often not well-managed by current therapies and their respective side effects. For example, steroids and ISTs are often used to treat a multitude of autoimmune diseases, but for the indications in our pipeline thus far, these have been observed to be lacking in both safety and tolerability.
- Furthermore, for each indication, there is a defined path forward with established precedent for how to run proof-of-concept and registrational clinical trials with generally accepted clinical and regulatory endpoints.

- Finally, as we work towards achieving our 'argenx 2025' vision, we select indications where there is a reasonable fit within our growing commercial franchises.

Formulations

Overview

We are developing two formulations of efgartigimod to address the needs of patients, physicians, and payors across indications and geographies, including IV efgartigimod (VYVGART) and the ENHANZE® (licensed from Halozyme) SC formulation.

IV (VYVGART)

We conducted a Phase 1 clinical trial in healthy volunteers to evaluate the safety, tolerability, PK, PD, and immunogenicity of single and multiple doses of efgartigimod. In the first part of the clinical trial, 30 subjects were randomized to receive a single dose of efgartigimod or placebo ranging from 0.2 mg/kg to 50 mg/kg. In the second part of the clinical trial, 32 subjects were randomized to receive MADs of efgartigimod or placebo up to a maximum of 25 mg/kg.

In the MAD part of the Phase 1 clinical trial, repeat administration of both 10 mg/kg and 25 mg/kg of efgartigimod every seven days, four doses in total, and 10 mg/kg every four days, six doses in total, was associated with a gradual reduction in levels of all four classes of IgG antibodies by 60% to 85%, with 10 mg/kg dose results shown in figure 4. For all doses in the MAD part of the Phase 1 clinical trial, we observed the reduction in circulating IgG antibody levels to persist for more than four weeks after the last dose with levels below 50% at approximately three weeks and did not return to baseline levels for more than one month. PK analysis of serum baseline levels of efgartigimod indicates that it has a half-life of approximately three to four days with no drug accumulation following subsequent weekly dosing. The prolonged activity on the levels of IgG antibodies is consistent with the mechanism of action of efgartigimod and the effect of our proprietary ABDEG technology (detailed in section 1.8.2 "**Platform Technologies**") on increasing the intracellular recycling of efgartigimod. In both the single and MAD portions, no significant reductions in IgM, IgA or serum albumin were observed.

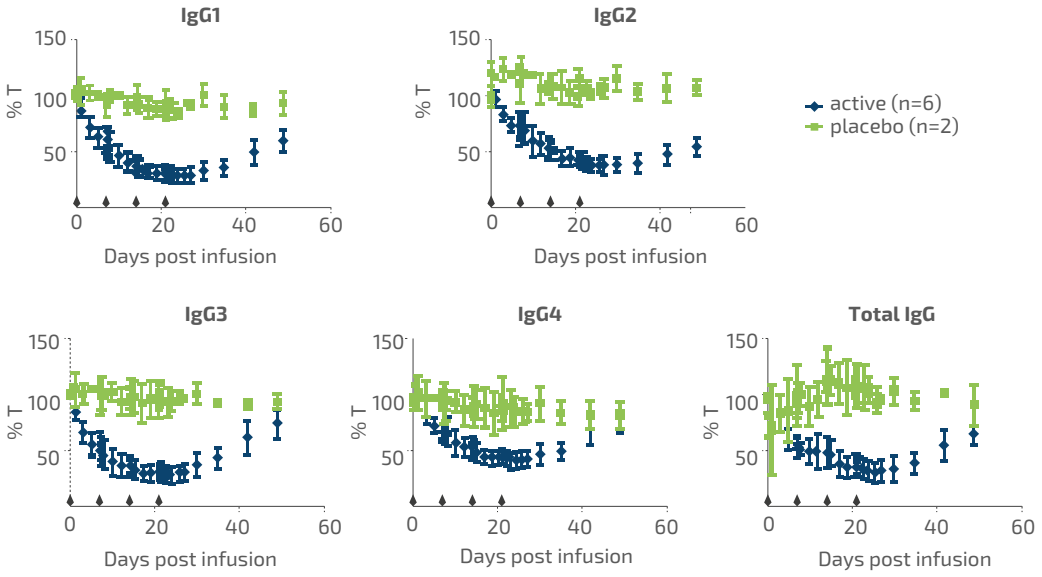


Figure 4: Reduction in the levels of four IgG antibody classes and total IgG levels in the MAD part of our Phase 1 clinical trial of efgartigimod in healthy volunteers at a dose of 10 mg/kg every seven days.

SC – Partnership with Halozyme

In 2020, we and Halozyme expanded the existing global collaboration and license agreement that was signed in February 2019. Under the expansion, we gained the ability to access Halozyme's ENHANZE® drug delivery technology for three additional exclusive targets upon nomination bringing the total to six potential targets under the collaboration. To date, two targets have been nominated including the human FcRn and C2.

In July 2019, we evaluated an SC formulation of efgartigimod that incorporates Halozyme's ENHANZE® drug delivery technology in a Phase 1 clinical trial in healthy volunteers, which demonstrated retained PD profile of IV-formulated efgartigimod.

ENHANZE® has demonstrated across multiple FDA-approved products the ability to remove traditional limitations on the volume of biologics that can be delivered subcutaneously, potentially shortening drug administration time, reducing healthcare practitioner time, and offering additional flexibility and convenience for patients.

In November 2022, we announced that the FDA accepted for priority review a BLA for SC efgartigimod (1000 mg efgartigimod-PH20) for the treatment of adult patients with gMG who are AChR-AB+. The BLA has been granted a PDUFA target action date of June 20, 2023.

SC – Partnership with Elektrofi

In April 2021, we entered into a collaboration and license agreement with Elektrofi to explore Elektrofi's high-concentration, low-volume delivery technology for efgartigimod, and up to one additional target. See section 1.5.1 "**Our Exclusive License with Elektrofi for Efgartigimod**" for more information.

1.3.3 Efgartigimod (formerly ARGX-113) Indications

gMG

Overview

gMG is a rare and chronic autoimmune disease where IgG autoantibodies disrupt communication between nerves and muscles, causing debilitating and potentially life-threatening muscle weakness.

In MG, IgG autoantibodies either bind and occupy or cross-link and internalize the receptor on the muscle cells, thereby preventing the binding of acetylcholine, the signal sent by the nerve cell. In addition, these autoantibodies can cause destruction of the neuromuscular junction by recruiting complement, a potent cell-destroying mechanism of the human immune system. The muscle weakness associated with MG usually presents initially in ocular muscles and can then spread into a generalized form affecting multiple muscles, known as gMG. Approximately 85% of people with MG progress to gMG within 24 months (source: Behin et al. New Pathways and Therapeutics Targets in Autoimmune Myasthenia Gravis. J Neuromusc Dis 5. 2018. 265–277). MG in the ocular form initially causes droopy eyelids and blurred or double vision due to partial paralysis of eye movements. As MG becomes generalized it affects muscles in the neck and jaw, causing problems in speaking, chewing and swallowing. MG can also cause weakness in

skeletal muscles leading to problems in limb function. In the most severe cases, respiratory function can be weakened to the point where it becomes life-threatening. These respiratory crises occur at least once in the lives of approximately 15% to 20% of MG patients. The U.S. prevalence of MG is estimated at approximately 20 cases per 100,000 (source: Philips et al, Ann NY Acad Sci. 2003).

Patients with confirmed AChR antibodies account for approximately 85% of the total gMG population (Behin et al. New Pathways and Therapeutics Targets in Autoimmune Myasthenia Gravis. J Neuromusc Dis 5. 2018. 265–277).

In May 2020, we announced positive topline results from the pivotal ADAPT clinical trial of efgartigimod for the treatment of gMG. The topline results from the ADAPT clinical trial showed that efgartigimod was well-tolerated, demonstrated clinically meaningful improvements in strength and quality of life measures, and provided the option of an individualized dosing schedule for gMG patients. The full Phase 3 ADAPT results were published in The Lancet Neurology in July 2021. The data from the ADAPT clinical trial and the subsequent open-label extension (ADAPT+) formed the basis for the regulatory approvals of VYVGART in the U.S., Japan and the EU.

ADAPT-SC Trial Design

In January 2021, we initiated ADAPT-SC, a registrational non-inferiority bridging study of SC efgartigimod for the treatment of gMG. The design of the bridging study is based on the demonstrated association between total IgG reduction and clinical benefit in gMG and incorporates feedback from the FDA. The study is comparing the PD effect of 1000 mg SC efgartigimod with 10 mg/kg IV efgartigimod. The primary endpoint is the percent change from baseline of total IgG levels measured at day 29.

On March 22, 2022, we announced positive topline results from the Phase 3 ADAPT-SC study. SC efgartigimod achieved the primary endpoint of total IgG reduction from baseline at day 29, demonstrating statistical noninferiority to VYVGART IV formulation in gMG patients. Based on these results, we announced the acceptance of a BLA by the FDA with a PDUFA target action date that was recently extended by three months to June 20, 2023.

Other Clinical Trials

We are currently evaluating alternative dosing regimens of efgartigimod IV in adult gMG patients in the ADAPT NXT clinical trial. In addition, a clinical trial of efgartigimod IV in pediatric gMG patients is ongoing. In 2022, a Phase 1 clinical trial evaluating the effect of efgartigimod or placebo on immune response to the polyvalent pneumococcal vaccine (PNEUMOVAX 23) was completed.

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. (sources: Current Medical Research and Opinion, 25:12, 2961–2969; Am J Hematol. 2012 Sep; 87(9): 848–852; Pediatr Blood Cancer. 2012 Feb; 58(2): 216–220).

Phase 3 ADVANCE Clinical Trials

In the fourth quarter of 2019, the first of two registrational clinical trials, the ADVANCE Phase 3 clinical trial, was initiated to evaluate 10 mg/kg IV efgartigimod (VYVGART) for the treatment of primary ITP. The second registrational ADVANCE-SC clinical trial of 1000 mg SC efgartigimod for the treatment of primary ITP was initiated in the fourth quarter of 2020. Positive phase 3 topline data for the ADVANCE clinical trial were announced on May 5, 2022. ADVANCE was the second registrational clinical trial of VYVGART and the first Phase 3 clinical trial of a neonatal FcRn blocker in ITP. The ADVANCE clinical trial enrolled 131 adult patients with chronic and persistent ITP. Patients were heavily pretreated and 67% of patients had received three or more prior ITP therapies, including 59% who had prior thrombopoietin receptor agonist (TPO-RAs) experience, 34% with prior rituximab experience and 37% with a history of splenectomy.

The clinical trial met its primary endpoint demonstrating that a significantly higher proportion of patients with chronic ITP receiving VYVGART (17/78; 21.8%) compared to placebo (2/40; 5%) achieved a sustained platelet response (p=0.0316), defined as having platelet counts greater than or equal to 50x109/L on at least four of the last six scheduled visits between weeks 19 and 24 of treatment.

Key platelet-derived secondary endpoints showed VYVGART-treated patients had a statistically significant benefit compared to placebo on (1) cumulative number of weeks where platelet counts were at least 50x109/L in the chronic ITP population (p=0.0009) and (2) sustained platelet response in the overall population, including both chronic and persistent ITP patients (p=0.0108). Numerically fewer WHO-classified bleeding events occurred in treated patients throughout the clinical trial but the difference from placebo was not statistically significant. A higher proportion of treated patients in the overall population achieved a durable, sustained platelet response compared to placebo, defined as a sustained platelet response on at least six of the last eight scheduled visits between weeks 17 and 24 of treatment (p=0.0265), but was not considered statistically significant based on hierarchical testing.

Additional secondary endpoint data from the ADVANCE clinical trial are consistent with primary and secondary platelet-derived endpoints and provide additional context on metrics that often drive treatment decisions, including on International Working Group (***IWG***) responder status:

- 51.2% of VYVGART-treated patients were classified as IWG responders and 27.9% as complete responders compared to 20% of placebo patients as IWG responders and 4.4% as complete responders.

- IWG responders are defined as having a platelet count of at least 30x109/L, a two-fold increase in platelet count from baseline, and the absence of bleeding for two separate, consecutive weekly visits. Complete responders are patients with platelet counts of 100x109/L and the absence of bleeding for two separate, consecutive weekly visits.

Mean platelet count change from baseline: VYVGART-treated patients demonstrated a rapid onset of platelet count improvement with statistically significant separation from placebo observed at week one and maintained through 20 out of 24 weeks of the clinical trial.

Ten VYVGART-treated patients switched to a biweekly (every two weeks) dosing schedule after achieving platelet counts of 100x109/L for three out of four consecutive visits, compared to one placebo patient. Nine of the ten treated patients achieved a sustained platelet response.

VYVGART was well-tolerated in this 24-week study and the observed safety and tolerability profile was consistent with previous clinical trials.

SC efgartigimod is being evaluated in a second registrational clinical trial in ITP, ADVANCE-SC topline data are expected in the second half of 2023. The clinical trial design for ADVANCE-SC is the same as for ADVANCE but the target enrollment was increased based on the results of the Phase 3 ADVANCE clinical trial.

Phase 2 Trial

We completed a randomized, double-blind, placebo-controlled Phase 2 clinical trial to evaluate the safety, efficacy and PK of efgartigimod in 38 adult primary ITP patients.

Full results from the Phase 2 clinical trial were published in the peer-reviewed American Journal of Hematology. Efgartigimod was well-tolerated and showed a correlation of reduced IgG levels, increased platelet counts and reduced bleeding in ITP patients.

The primary endpoint analysis demonstrated efgartigimod to be well-tolerated in all patients, with most treatment emergent adverse events (***TEAEs***) observed characterized as mild (Common Terminology Criteria for Adverse Events grading 1 and 2). There were no dose-related safety observations and the safety profile was consistent with previous observations in healthy volunteers and MG patients. No increased risk of infection was apparent in the efgartigimod-treated groups compared to the placebo group.

PV

Overview

PV is an autoimmune disorder associated with mucosal and skin blisters that lead to pain, difficulty swallowing and skin infection. This chronic, potentially life-threatening disease is triggered by IgG autoantibodies targeting desmoglein-1 and -3, which are present on the surface of keratinocytes and important for cell-to-cell adhesion in the epithelium. Autoantibodies targeting desmogleins result in loss of cell adhesion, the primary cause of blister formation in PV. Similar to MG and ITP, disease severity of pemphigus correlates to the amount of pathogenic IgGs targeting desmogleins. Currently, there are an estimated 19,000 pemphigus patients in the U.S., of which an estimated 13,100 patients are suffering from PV. Several disease activity measurements

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

Phase 3 ADDRESS Clinical Trial

In the fourth quarter of 2020, the registrational ADDRESS clinical trial was initiated of SC efgartigimod for the treatment of PV and PF. This is a randomized, double-blinded, placebo-controlled study, where the objective is to assess efficacy, safety and tolerability in up to 150 newly diagnosed or relapsing patients with moderate to severe pemphigus. Patients are randomized to receive either SC efgartigimod or placebo for 30 weeks. Patients start on concomitant steroids based on what we determine to be the optimized dosing regimen from the Phase 2 study. The primary endpoint will assess the proportion of patients who achieve complete remission on a minimal steroid dose at 30 weeks. The ADDRESS clinical trial will evaluate efficacy and safety, including the potential to drive fast onset of disease control and complete remission and the ability to taper corticosteroids. A relevant minority portion of the patients in the ADDRESS clinical trial are participating at sites in Ukraine or Russia. Following a risk assessment relating to the conflict between Russia and Ukraine, we increased target enrollment, which delayed expected topline data of SC efgartigimod for PV and PF to the second half of 2023.

Phase 2 Trial

We completed an open-label Phase 2 adaptive clinical trial in which, through sequential cohorts, 34 patients were dosed at 10 or 25 mg/kg IV efgartigimod (VYVGART) with various dosing frequencies, as monotherapy or add-on therapy to low dose oral prednisone. The primary endpoint of the clinical trial was safety and tolerability. The full Phase 2 clinical trial results were published in The British Journal of Dermatology.

In this clinical trial, we observed:

- a favorable tolerability profile, consistent with data from previous efgartigimod studies and those adverse events were mostly mild;
- a major decrease in serum total IgG and anti-desmoglein autoantibodies and correlated with improved PDAI scores;
- that 90% (28/31) of patients demonstrated early disease control; median time to disease control for monotherapy and combination therapy was 17 days;
- complete clinical remission in 64% (14/22) of patients receiving optimized prolonged treatment with efgartigimod in combination with a median dose of 0.26 mg/kg/day prednisone within 2–41 weeks; and
- a favorable tolerability profile, consistent with data from previous efgartigimod studies.

Novel translational data from the open-label Phase 2 study of efgartigimod for the treatment of PV that further support the potential role of FcRn blockade and potential of efgartigimod in autoimmune skin blistering disorders were published in the journal Frontiers of Immunology and presented during the Society for Investigative Dermatology annual meeting in May 2022.

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. CIDP affects approximately 16,000 patients in the U.S.

Most CIDP patients require treatment and IVIg which is the preferred first-line therapy. Glucocorticoids and plasma exchange are used to a lesser extent as they are either limited by side effects upon chronic use, in the case of glucocorticoids, or invasiveness of the procedure and access, which is restricted to specialized centers in case of plasma exchange. Alternative immunosuppressant agents are typically reserved for patients ineligible for or refractory to IVIg, glucocorticoids or plasma exchange.

ADHERE Clinical Trial

At the end of 2019, we initiated the registrational ADHERE clinical trial evaluating SC efgartigimod for the treatment of CIDP. The ADHERE clinical trial is a randomized, withdrawal study evaluating 1000 mg weekly SC efgartigimod expected to enroll approximately 130 patients. The clinical trial consists of an open-label Stage A followed by a randomized, placebo-controlled Stage B with a planned interim responder analysis after the first 30 patients enroll in Stage A. In order to enter Stage A and receive efgartigimod, both patients who are treatment-naïve or on therapy must first receive a confirmed diagnosis of CIDP by an independent panel of experts and demonstrate active disease. To show active disease, patients who are on current CIDP therapy have to demonstrate a minimal clinically meaningful worsening after treatment withdrawal based on at least one CIDP clinical assessment tool, including the Inflammatory Neuropathy Cause and Treatment Disability Score (***INCAT Disability Score***), Inflammatory Rasch-built Overall Disability Scale (***I-RODS***) or mean grip strength. To advance to Stage B, patients need to demonstrate a minimal clinically meaningful response to efgartigimod equivalent with the loss observed on the same efficacy scale on which worsening is observed during the withdrawal period. In Stage B, patients are randomized to either SC efgartigimod or placebo for up to 48 weeks. The primary endpoint is event-driven and based on the adjusted INCAT Disability Score in Stage B.

Interim Analysis from ADHERE Clinical Trial

In February 2021, we announced a “go” decision to transition into the second, placebo-controlled stage of this clinical trial based on a planned efficacy and safety assessment following the enrollment of 30 patients into the initial part of the ADHERE clinical trial. The ADHERE clinical trial is expected to enroll at least 130 patients in total to support potential registration of SC efgartigimod for the treatment of CIDP. The interim analysis achieved the pre-defined threshold for continuation, which was based on response rates seen in precedent clinical trials of current standard of care in CIDP. The decision to continue enrollment was confirmed by an independent data monitoring committee. In addition, the safety and tolerability data observed to date is consistent with that of efgartigimod in other clinical trials.

We expect to announce the topline data of the ADHERE clinical trial in the second quarter of 2023.

Idiopathic Inflammatory Myopathies (Myositis)

Overview

Myositis are a rare group of autoimmune diseases that can be muscle specific or affect multiple organs including the skin, joints, lung, gastrointestinal tract and heart. Myositis can be very severe and disabling and have a material impact on quality of life. Initially these Myositis were classified as either DM or polymyositis, but as the underlying pathophysiology of Myositis has become better understood, including through the identification of characteristic autoantibodies, new polymyositis subgroups have emerged. Two of these subtypes are IMNM and ASyS. Proximal muscle weakness is a unifying feature of each Myositis subset.

- IMNM is characterized by skeletal muscle weakness due to muscle cell necrosis. The muscle weakness is typically symmetrical – on both sides of the body – and affects proximal muscles including hips, thighs, upper arms, shoulder and neck. The muscle weakness can be severe and lead to difficulty in completing daily tasks. Characteristic autoantibodies of IMNM, include anti-signal recognition particle and anti-3-hydroxy-3-methylglutaryl-coenzyme A reductase autoantibodies.

- ASyS is characterized by muscle inflammation, inflammatory arthritis, interstitial lung disease, thickening and cracking of the hands ("mechanic's hands") and Raynaud phenomenon. Autoantibodies associated with ASyS attack tRNA synthetase enzymes and include anti-Jo-1 and anti-PL1 and PL-12 most commonly.

- DM is characterized by muscle inflammation and degeneration and skin abnormalities, including heliotrope rash, Gottron papules, erythematous, calcinosis and edema. DM is associated with Myositis-specific autoantibodies, including anti-Mi-2, anti-MDA-5, anti-TIF-1γ and others.

There are no current FDA-approved therapies for IMNM or ASyS. IVIg (Octagam 10%) was approved by the FDA for the treatment of DM in July 2021. Myositis patients are most often treated with high-dose steroids.

ALKIVIA Clinical Trial

We initiated the registrational ALKIVIA clinical trial of SC efgartigimod for the treatment of Myositis in the third quarter of 2022. The study plans to enroll approximately 240 patients in three Myositis subtypes, IMNM, ASys and DM. The study will be conducted in 2 phases, with an analysis of the Phase 2 portion of the clinical trial, including 30 patients of each subtype, followed by conduct of the Phase 3 portion of the clinical trial.

The primary endpoint is the total improvement score (***TIS***) at the end of the treatment period. Key secondary endpoints include response rates at the end of treatment, time to response, and duration of response in TIS, as well as change from baseline in individual TIS components. Other secondary endpoints include quality of life and other functional scores.

An interim analysis of the first 30 patients in each subset is expected in 2024.

BP

Overview

BP is the most common autoimmune blistering disease and is driven by autoantibodies affecting the skin. The disease typically affects elderly people and early key symptoms are itch and rash and patients develop fluid-filled blisters during disease progression. The prevalence of BP is twelve per 100,000 adults and the incidence increases with age. BP is associated with a high disease burden and can have a significant impact on the quality of life of patients. The mortality of BP in the U.S. is 2.4% or higher than the mortality in the general population of the same age. There are currently no approved therapies available for BP. First line treatment consists of topical or systemic cortico-steroids, which result in substantial morbidity and increased mortality, conventional immunosuppressants as corticosteroid-sparing agents, rituximab and IVIg.

BP is a well characterized autoimmune disease in which the binding of autoantibodies to hemidesmosomal proteins, BP180 and BP230, initiates a cascade of inflammatory events resulting in blister formation. BP180 and BP230 are involved in the stable attachment of keratinocyte to the underlying matrix. The autoantibody actions include mechanical disruption of keratinocyte adhesion and cytokine release. Immune complex formation initiates complement activation leading to the recruitment mast cells, neutrophils, eosinophils and other immune cells and to the release of proteases and inflammatory mediators. All these effects, which start with the binding of the autoantibodies, induce the blistering observed in BP.

BALLAD Trial

We initiated the Phase 2/3 BALLAD registrational clinical trial evaluating SC efgartigimod in BP in the second half of 2022, in which we plan to enroll 160 patients.

The clinical trial population are newly diagnosed and relapsing patients within one year from diagnosis. Patients will be randomized 1-to-1 to receive efgartigimod or placebo for total duration of 36 weeks. The primary endpoint is the proportion of participants in complete remission while off oral corticosteroids for at least eight weeks at week 36. Secondary endpoints relate to cumulative steroid doses, IGA BP score, time to achieving control of disease activity, change from baseline in average itch, and quality of life measures. In our Half Year 2022 report, we announced that the registrational BALLAD clinical trial is ongoing of SC efgartigimod for BP with interim analysis planned of first 40 patients in 2024.

New Efgartigimod Indications

We are also evaluating four indications in proof-of-concept clinical trials through our partnerships with Zai Lab and IQVIA:

- MN is an autoimmune, glomerular disease and the most frequent cause of nephrotic syndrome. MN is characterized by thickening of the glomerular capillary walls caused by immune complex deposition. 70% of MN patients have IgG autoantibodies against PLA2R. In patients without PLA2R autoantibodies, there can be detectable anti-THSd7A or anti-NELL1 antibodies. 20–30% of patients progress to end-stage renal disease. There are no current approved therapies for MN.

- LN is a glomerulonephritis and one of the most severe and common organ manifestations of the autoimmune disease systemic lupus erythematosus (***SLE***). LN is a substantial cause of morbidity and death among patients with SLE.

Autoantibodies associated with LN include anti-dsDNA and anti-nuclear antibodies. 5–20% of LN patients progress to end-stage renal disease. Oral corticosteroids and broad immunosuppressants are current standard of care but are not uniformly effective.

- Primary SjS is a systemic autoimmune disease of the exocrine glands that can affect salivary and lacrimal glands, mostly, and result in severe dryness of mucosal surfaces, primarily in the eyes and mouth. In addition to sicca symptoms, patients can experience significant fatigue, chronic pain, major organ involvement, neuropathies and lymphomas. Autoantibodies are present in the majority of patients and include antinuclear antibodies and antibodies against Primary SjS-related antigen A and B (anti-SSA Ro and SSB La). There are no current FDA-approved therapies and patients are most often treated with IVIg, in severe cases, or eyes drops and corticosteroids in more mild to moderate patients.

- PC-POTS has been emerging after resolution of COVID-19 infection in previously healthy patients. PC-POTS is a disorder of the autonomic nervous system that is characterized by a rise in heart rate when moving to a standing position and additional symptoms of shortness of breath, headache, fatigue, poor concentration, weakness and anxiety. The large majority of patients are women between 15 and 50 years of age. There is a strong association of PC-POTS to activating autoantibodies to autonomic G-protein coupled receptors, including the β1 and β2-adrenergic receptors and M2 and M3 muscarinic receptors. There are no current FDA-approved therapies and symptomatic treatments focus on blood volume, kidney sodium levels, heart rate reduction and vessel constriction.

Zai Lab Limited

Our Zai Lab strategic collaboration allows us to accelerate development of efgartigimod into new autoimmune indications with Zai Lab taking operational leadership of the Phase 2 proof-of-concept clinical trials.

Zai Lab initiated the Phase 2 proof-of-concept clinical trials in 2022 in MN and LN, which both fall within our emerging nephrology franchise.

IQVIA

On December 2, 2021 we entered into a strategic asset development agreement (***Asset Development Agreement***) with IQVIA. Pursuant to the Asset Development Agreement, IQVIA shall perform asset and indication development services for efgartigimod through an advanced outsourcing model. Such services include, but are not limited to, overall product indication development strategy, design of clinical trial protocol, set-up, execution and oversight of clinical development plans for an indication for efgartigimod selected by us.

To enable and encourage fast and innovative delivery of the services by IQVIA, the Asset Development Agreement contains an innovative earn-back and bonus plan based upon the performance of IQVIA.

Primary SjS and PC-POTS are the first indications we identified to be further developed under the Asset Development Agreement.

In 2022, IQVIA launched the Phase 2 clinical trials in Primary SjS and PC-POTS.

Additional Efgartigimod Indications

In January 2023, we announced our plans to launch clinical trials in three new indications including a registrational clinical trial in TED and proof-of-concept clinical trials in AV and AMR.

1.3.4 ARGX-117 Development

ARGX-117 is a highly differentiated therapeutic monoclonal antibody 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 ARGX-117 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.

ARGX-117 exhibits both pH- and calcium dependent binding. These unique characteristics enable ARGX-117 to capture free C2 in circulation and release it in the endosome to be sorted for degradation in the lysosome. ARGX-117 is equipped with NHANCE mutations increasing its affinity for FcRn and allowing it to recycle back into circulation to capture more C2.

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

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

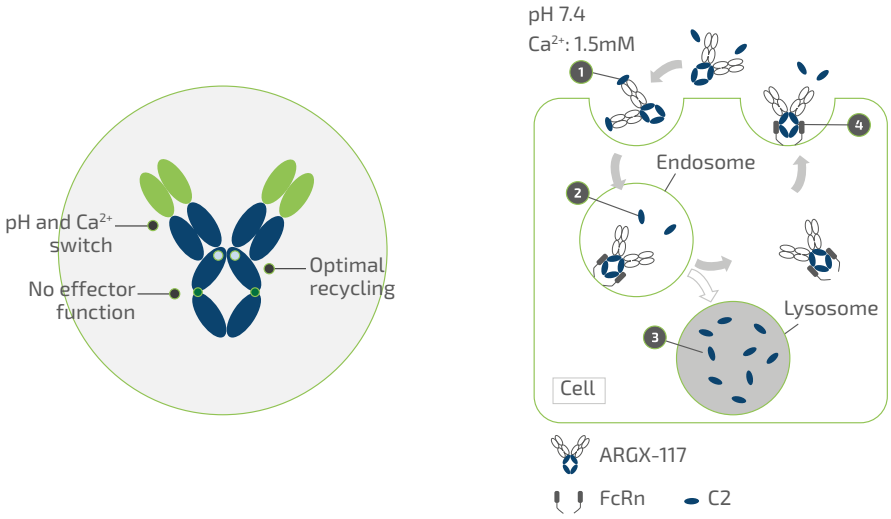


Figure 5

Phase 1 Data

We conducted a Phase 1 healthy volunteer clinical trial of IV and SC ARGX-117. This first-in-human clinical trial was a double-blind placebo-controlled study designed to assess the safety, tolerability, PK and PD of a broad dose range of ARGX-117 in 102 healthy subjects. In the single ascending dose part, we evaluated 70 subjects and tested up to 80 mg/kg administered IV and up to 60 mg/kg administered SC. In the MAD part of the study, we evaluated 32 subjects to understand the safety and tolerability of repeated administrations and in particular to generate a data-set to optimally inform a PK/PD model.

The majority of the observed TEAEs were categorized as grade 1 (or mild). Few grade 2 (or moderate) TEAE were observed and, in the MAD part of the study, no grade 2 or higher TEAEs were observed. Overall, we concluded that single and multiple administrations of ARGX-117 or placebo have a favorable safety and tolerability profile supporting the investigation of study drug in patient studies.

We observed a dose-dependent reduction of free C2 levels. After one dose of 30 mg/kg ARGX-117, free C2 levels were reduced by 95% for more than 100 days. In the MAD part of the study, we could reach full complement blockade with more than 99% reduction of free C2 levels.

Following analysis of Phase 1 data, and the observed favorable safety and tolerability profile and consistent PK/PD profile, we launched a Phase 2 proof-of-concept clinical trial in MMN in the fourth quarter of 2021 within our neuromuscular franchise. Proof-of-concept ARDA clinical trial is ongoing to evaluate safety, tolerability, and potential dosing regimen in MMN. Interim data from ARDA are expected in mid-2023.

Overview of MMN and Current Treatment

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 usually misdiagnosed as amyotrophic lateral sclerosis (***ALS***). There are estimated to be around 13,000 patients with MMN in the U.S. and this number is increasing.

Specific pathophysiologic characteristics of MMN include the presence of IG M (***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 regularly to address the disease's progressive nature.

DGF and/or Allograft Failure

We intend to start a phase 2 proof-of-concept clinical trial in the second half of 2023 to evaluate ARGX-117 for the prevention of DGF (n) and/or allograft failure after kidney transplantation. This occurs in up to 40% of kidney transplant recipients and is often a result of ischemia reperfusion injury.

There is compelling evidence from kidney biopsies of mannose-binding lectin and C4d co-staining indicating involvement of both the classical and lectin pathways, making C2 an ideal target. Furthermore, there is a well-established process to measure kidney function and establish proof-of-concept and achieve registration. On this basis, combined with the significant unmet medical need, we have chosen DGF (n) and allograft failure after kidney transplantation as second indication for ARGX-117.

Dermatomyositis

In January 2023, we announced DM as the third indication for ARGX-117.

1.3.5 Immunology Innovation Program

Overview

Our IIP is a core business strategy of co-creation and innovation. The IIP also serves as our discovery engine to identify novel targets and together, in collaboration with our scientific and academic partners, to build potential new pipeline candidates. The IIP has been foundational in building our pipeline, and every current pipeline candidate from both our wholly-owned and partnered pipeline emerged from an IIP collaboration. As part of our long-term strategy, we have committed to continued investment in the IIP.

Our Suite of Technologies

Through our IIP, we collaborate with scientific and academic partners to identify immunology breakthroughs and build potential pipeline candidates. This is done through co-creation where we bring to the collaboration our unique suite of antibody engineering technologies and experience in clinical development and our partners bring a wealth of disease and target biology expertise.

Together with our antibody discovery and development expertise, this suite of technologies has enabled us to build our broad pipeline of products and product candidates, across all stages of development and we believe will ensure continuous development of innovative and relevant programs. Our key technologies are outlined below:

Antibody Engineering and Other Technology Capabilities

Our Proprietary SIMPLE Antibody Platform

Our proprietary SIMPLE Antibody platform sources V-regions from conventional antibodies existing in the immune system of outbred llamas. Outbred llamas are those that have been bred from genetically diverse parents, and each has a different genetic background. The llama produces highly diverse panels of antibodies with a high human homology in their V-regions when immunized with human disease targets. We then combine these llama V-regions with Fc regions of fully human antibodies, resulting in antibodies that we then produce in industry-validated production cell lines. The resulting antibodies are diverse and, due to their similarity to human antibodies, we believe they are well suited to human therapeutic use. With this breadth of antibodies, we are able to test many different epitopes. Being able to test many different epitopes with our antibodies enables us to search for an optimized combination of safety, potency and species cross-reactivity with the potential for maximum therapeutic effect on disease. These antibodies are often cross-reactive with the rodent version of chosen disease targets. This rodent cross-reactivity enables more efficient preclinical development of our product candidates because most animal efficacy models are rodent-based. By contrast,

most other antibody discovery platforms start with antibodies generated in inbred mice or synthetic antibody libraries, approaches that we believe are limited by insufficient antibody repertoires and limited diversity, respectively. Our SIMPLE Antibody platform allows us to access and explore a broad target universe, including novel and complex targets, while minimizing the long timelines associated with generating antibody candidates using traditional methods.

Our Fc Engineering Technologies

Our antibody engineering technologies – NHance, ABDEG, POTELLIGENT and DHS mutations – focus on engineering the Fc region of antibodies in order to augment their interactions with components of the immune system, thereby potentially expanding the therapeutic index of our product candidates by modifying their half-life, tissue penetration, rate of disease target clearance and potency. In addition, we obtained a non-exclusive research license and option for the SMART-Ig and ACT-Ig technologies. For example, our NHance and ABDEG engineering technologies enable us to modulate the interaction of the Fc region with FcRn, which is responsible for regulating half-life, tissue distribution and PD properties of IgG antibodies. Similarly, the POTELLIGENT engineering technology modulates the interaction of the antibody Fc region with receptors located on specialized immune cells known as natural killer (***NK***) cells. These NK cells can destroy the target cell, resulting in enhanced antibody-dependent cell-mediated cytotoxicity (***ADCC***).
NHance and ABDEG: Modulation of Fc Interaction with FcRn.

An illustration of the FcRn-mediated antibody recycling mechanism is shown in figure 6. [1] Serum proteins, including IgG antibodies, are routinely removed from the circulation by cell uptake. [2] Antibodies can bind to FcRn, which serves as a dedicated recycling receptor in the endosomes, which have an acidic environment, and then [3A] return to the circulation by binding with their Fc region to FcRn. [3B] Unbound antibodies end up in the lysosomes and are degraded by enzymes. Because this Fc/FcRn interaction is highly pH-dependent, antibodies tightly bind to FcRn at acidic pH (pH 6.0) in the endosomes but release again at neutral pH (pH 7. 4) in the circulation.

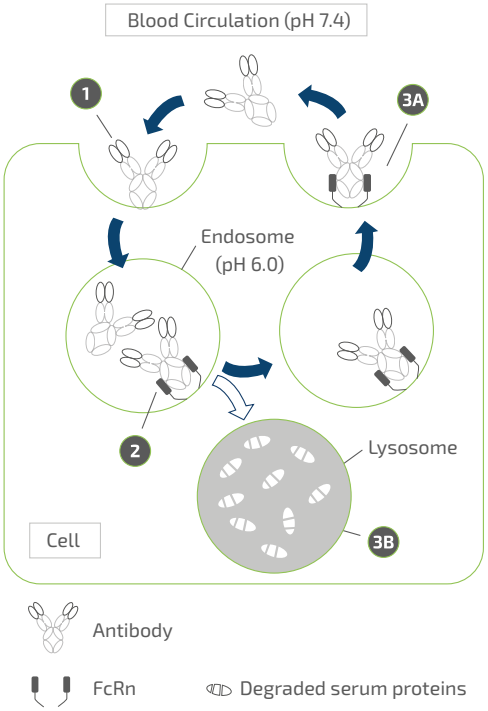


Figure 6: The FcRn-mediated recycling mechanism

NHANCE

NHance refers to two mutations that we introduce into the Fc region of an IgG antibody. NHance is designed to extend antibody serum half-life and increase tissue penetration. In certain cases, it is advantageous to engineer antibodies that remain in the circulation longer, allowing them to potentially exert a greater therapeutic effect or be dosed less frequently. As shown in figure 7, [1] NHance antibodies bind to FcRn with higher affinity, specifically under acidic pH conditions. [2]

Due to these tighter bonds, NHance FcRn-mediated antibody recycling is strongly favored over lysosomal degradation, although some degradation does occur. [3] NHance allows a greater proportion of antibodies to return to the circulation potentially resulting in increased bioavailability and reduced dosing frequency. ARGX-109, ARGX-111, ARGX-117 and a number of our discovery-stage programs utilize NHance.

ABDEG

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

As shown in figure 8, our ABDEG technology can also be used with our pH-dependent SIMPLE Antibodies in a mechanism referred to as sweeping. Certain SIMPLE Antibodies bind to their target in a pH-dependent manner. These antibodies [1] bind tightly to a target at neutral pH while in circulation, and [2] release the target at acidic pH in the endosome. [3] The unbound target is degraded in the lysosome. [4] However, when equipped with our ABDEG technology, the therapeutic antibodies remain tightly bound to FcRn at all pH levels and are not degraded themselves. Instead, they are returned to the circulation where they can bind new targets. We believe this is especially useful in situations where high levels of the target are circulating or where the target needs to be cleared very quickly from the system.

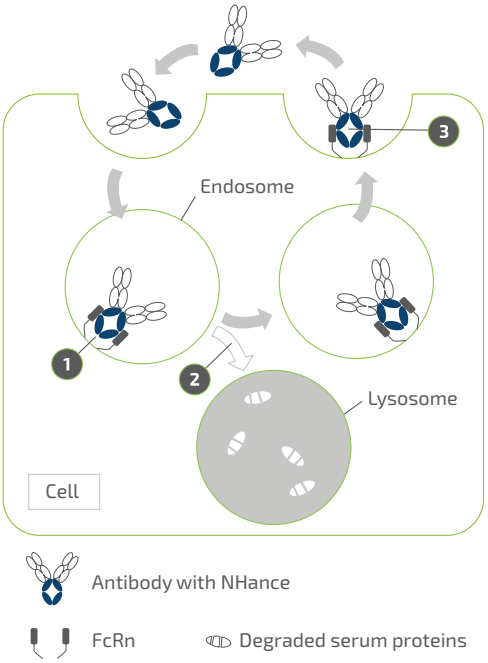


Figure 7

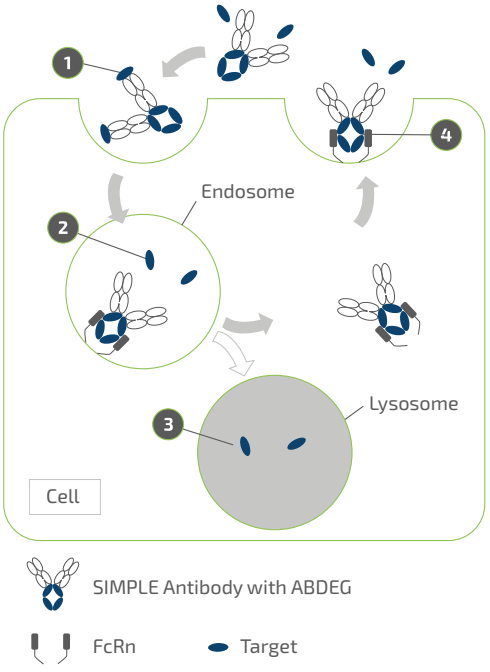


Figure 8: SIMPLE Antibody and ABDEG technologies work in concert to sweep diseases targets.

POTELLIGENT

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

Chugai and Clayton

In 2020, we entered into a research license and option agreement with Chugai under which we may access Chugai's SMART-Ig ("Recycling Antibody" and part of "Sweeping Antibody" technology) and ACT-Ig (Antibody half-life extending technology). In 2020, we also entered into a non-exclusive research agreement with the Clayton Foundation under which we may access the Clayton Foundation's proprietary DHS mutations to extend the serum half-life of therapeutic antibodies.

SC Drug Delivery Technologies

We have exclusive access to Halozyme's ENHANZE® SC drug delivery technology for the FcRn and C2 targets and four additional targets. The ENHANZE® has the potential to shorten drug administration time, reduce healthcare practitioner time, and offer additional flexibility and convenience for patients.

In addition, in April 2021, we entered into a collaboration and license agreement with Elektrofi to explore new SC formulations utilizing Elektrofi's small volume injection technology for efgartigimod, and up to one additional target.

For more information on our collaborations, see section 1.4 "**Collaboration Agreements**".

Other IIP Programs

ARGX-119

In January 2022, we announced that ARGX-119 is an antibody that targets MuSK, a protein located at the neuromuscular junction, in an agonistic or activating manner. We intend to develop ARGX-119 in a range of neuromuscular diseases, potentially including congenital MG, a rare hereditary subtype of MG, MuSK-associated MG, a rare autoimmune subtype of MG, spinal muscular atrophy and ALS, both rare, severe neuromuscular indications.

Phase 1 dose-escalation clinical trial in healthy volunteers started in the first quarter of 2023, with a subsequent Phase 1b clinical trial to assess early signal detection in patients thereafter.

ARGX-118

We have exercised our option to exclusively acquire rights to ARGX-118, a highly differentiated antibody against Galectin-10, the protein of Charcot-Leyden crystals, which are implicated as a major contributor to severe asthma and to the persistence of mucus plugs.

argenx and VIB vzw (***VIB***) continue to pursue pre-clinical development of the program under the collaboration.

Other Partnered Programs

See sections 1.4 "**Collaboration Agreements**" and 1.5 "**License Agreements**" for a description of collaboration and license agreements that we have entered into to further leverage our IIP.

1.4 Collaboration Agreements

We follow a disciplined strategy to maximize the value of our pipeline. We plan to retain all development and commercialization rights to those products and product candidates that we believe we can commercialize successfully, if approved.

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

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

In April 2016, we entered into a collaboration agreement with AbbVie to develop and commercialize ARGX-115 (ABBV-151) as a cancer immunotherapy against the novel target GARP (the ***AbbVie Collaboration Agreement***). ARGX-115 (ABBV-151) employs our SIMPLE Antibody technology and works by stimulating a patient's immune system after a tumor has suppressed the immune system by co-opting immunosuppressive cells such as regulatory T cells. Under the terms of the AbbVie Collaboration Agreement, we were responsible for conducting and funding all ARGX-115 (ABBV-151) research and development activities up to completion of investigational new drug (***IND***)-enabling studies.

AbbVie has an exclusive option to obtain a worldwide, exclusive license to the ARGX-115 (ABBV-151) program to develop and commercialize products and has now assumed development obligations, including the sole responsibility for all research, development and regulatory costs relating to ARGX-115 (ABBV-151)-based products. Subject to the continuing progress of ARGX-115 (ABBV-151) by AbbVie, we are eligible to receive development, regulatory and commercial milestone payments in aggregate amounts of up to $110 million, $190 million and $325 million, respectively, as well as tiered royalties on product sales at percentages ranging from the mid-single digits to the lower teens, subject to customary reductions.

Pursuant to the AbbVie Collaboration Agreement, we have the right, on a product-by-product basis, to co-promote ARGX-115 (ABBV-151) based products in the European Economic Area (***EEA***) and Switzerland and to combine the product with our own future oncology programs (if any). The co-promotion effort would be governed by a co-promotion agreement negotiated in good faith by the parties.

Unless earlier terminated upon mutual agreement, for material breach or as otherwise specified in the AbbVie Collaboration Agreement, the term of the option and license agreement ends, with respect to the ARGX-115 (ABBV-151) program, upon the earliest of (i) a technical failure of the IND-enabling studies which is outside of our control, (ii) AbbVie's election to not exercise its option or (iii) following AbbVie's exercise of the option, fulfilment of all payment obligations under the agreement.

AbbVie may terminate the AbbVie Collaboration Agreement for any reason upon prior written notice to us. AbbVie's royalty payment obligations expire, on a product-by-product and country-by-country basis, on the date that is the later of (i) such time as there are no valid claims covering such product, (ii) expiration of regulatory or market exclusivity in respect of such product or (iii) ten years after the first commercial sale of such product sold in that country under the AbbVie Collaboration Agreement.

1.4.2 Our Strategic Partnership with Zai Lab for Efgartigimod

Pursuant to the Zai Lab Agreement, Zai Lab obtains the exclusive right to develop and commercialize efgartigimod in the aforementioned countries. Zai Lab will also contribute patients to our global Phase 3 clinical trials of efgartigimod. Additionally, the collaboration with Zai Lab is expected to accelerate efgartigimod global development by initiating multiple Phase 2 proof-of-concept clinical trials in new autoimmune indications under our supervision; first indications for such proof-of-concepts studies are kidney conditions LN and MN.

Pursuant to the Zai Lab Agreement, we have received value worth $175.0 million from the Zai Lab Payments. We are also eligible to receive tiered royalties (mid-teen to low-twenties on a percentage basis) based on annual net sales of efgartigimod in the PRC.

1.4.3 Our Strategic Partnership with LEO Pharma for ARGX-112 (LP0145)

In May 2015, we entered into a collaboration agreement with LEO Pharma A/S (***LEO Pharma***) to develop and commercialize ARGX-112 (LP0145) for the treatment of dermatologic indications involving inflammation (***LEO Pharma Collaboration Agreement***). ARGX-112 (LP0145) employs our SIMPLE Antibody technology and blocks the IL-22R in order to neutralize the signaling of cytokines implicated in autoimmune diseases of the skin. LEO Pharma funded more than half of all product development costs up to clinical trial application (***CTA***) approval of a first product in a Phase 1 clinical trial, with our share of such costs capped, which was achieved in April 2018. Since then, LEO Pharma has been solely responsible for funding the clinical development of the program. In May 2021, clinical trial application CTA approval of a Phase 2a clinical trial for LP0145 was received.

LEO Pharma, against payment of an option fee to us, was granted an option to obtain an exclusive, worldwide license to further develop and commercialize a product, following the exercise of the option, LEO Pharma will assume full responsibility for the continued development, manufacture and commercialization of such product and be subject to diligence obligations in respect of continuation of development and commercialization of such product. We are eligible to receive additional development, regulatory and commercial milestone payments in aggregate amount of up to €120.0 million, as well as tiered royalties on product sales at percentages ranging from the low single digits to the low teens, subject to customary reductions.

Unless earlier terminated, the term of the LEO Pharma Collaboration Agreement ends upon the later of (i) the expiration of the last license granted under the agreement, and (ii) the fulfilment of all payment obligations under the agreement. LEO Pharma may terminate the LEO Pharma Collaboration Agreement for any reason upon prior written notice to us. LEO Pharma's royalty payment obligations expire, on a product-by-product and country-by-country basis, upon the later of (i) a time when no valid claims covering such product, and (ii) (a) in major market countries with no composition of matter patent covering such product, the expiration of the data exclusivity period or (b) in countries that are not major market countries, a double-digit number of years after the first commercial sale of such product sold in that country.

In 2021, we signed two amendments to the LEO Pharma Collaboration Agreement, to extend LEO Pharma's option period with six months, to allow LEO Pharma to undertake chemistry, manufacturing and control development work in advance of the exercise by LEO Pharma of its option, and updating the provisions regarding the management of patents.

In September 2022, LEO Pharma exercised its option and has assumed full responsibility of the program for the continued development, manufacture and commercialization of such product and be subject to diligence obligations in respect of continuation of development and commercialization of such product, which triggered a milestone payment of €5.0 million.

1.4.4 Our Strategic Collaboration with Shire

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

Up through a specified period, we have granted Shire an exclusive option, against payment of a one-time option fee, to obtain all right, title and interest in any antibodies discovered under a study and to obtain an exclusive, worldwide license under our intellectual property which is necessary to further develop and commercialize products incorporating such antibodies. Following such exercise, Shire has the diligence obligation to continue to develop and commercialize at least one licensed product.

Shire may exercise exclusive options to develop and commercialize programs arising under our expanded agreement against an option fee. In July 2018, Shire exercised such an exclusive option to in-license an antibody discovered and developed using our licensed technologies, triggering a milestone payment by Shire to us.

In addition to option fees, Shire is obligated to pay us on a per-product basis upon achievement of specified development, regulatory and commercial milestones and a percentage of net sales as a royalty. Accordingly, we are eligible to receive payments in aggregate amounts of up to $3.8 million, $4.5 million and $22.5 million, upon achievement of development, regulatory and commercial milestones, respectively, for a product generated against one of the three initial targets named in the Shire Collaboration Agreement. For products generated against additional targets, development and regulatory milestone payments remain the same, and we are eligible to receive payments in aggregate amounts of up to $60.0 million for achievement of commercial milestones. The royalties payable to us are tiered, single digit and are subject to customary reductions.

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

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

1.4.5 Creation of OncoVerity for Cusatuzumab

In 2022, we, the University of Colorado Anschutz Medical Campus and UCHealth created an asset-centric spin-off, OncoVerity, focused on optimizing and advancing the development of cusatuzumab, a novel anti-CD70 antibody, in 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 the experience from argenx on the CD70/CD27 pathway.

1.5 License Agreements

We are party to several license agreements 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 Fc 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.

1.5.1 Our Exclusive License with Elektrofi for Efgartigimod

In April 2021, we entered into a collaboration and license agreement with Elektrofi to explore new SC formulations utilizing Elektrofi's small volume injection technology for efgartigimod, and up to one additional target (the ***Elektrofi Agreement***). The Elektrofi-enabled formulations are aimed to promote additional optionality for patients through at-home and self-administration capabilities.

Under the terms of the Elektrofi Agreement, we made an upfront payment and future milestones payments across both targets pending achievement of pre-defined development, regulatory, and commercial milestones. Elektrofi will also receive a mid-single digit royalty on sales of commercialized products.

1.5.2 Our Non-Exclusive Research License with Chugai for SMART-Ig and ACT-Ig

In September 2020, we entered into a non-exclusive research license and option agreement with Chugai, allowing us to access Chugai's SMART-Ig and ACT-Ig Fc engineering technologies for conducting feasibility studies. 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.

1.5.3 Our Non-Exclusive License with the Clayton Foundation for DHS Mutations

In October 2020, we entered into a non-exclusive research agreement with the Clayton Foundation relating to the non-exclusive in-license for the Clayton Foundation's proprietary DHS mutations to extend the serum half-life of therapeutic candidates.

1.5.4 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 ARGX-117, 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.

In October 2020, we expanded our collaboration with Halozyme for ENHANZE® drug delivery technology to include three additional exclusive targets upon nomination bringing the total to six potential targets. From the effective date of the ENHANZE License Agreement, we have a seven-year period in which to conduct research and preclinical studies on other target-specific molecules in combination with ENHANZE® and may nominate up to four additional targets we have not yet nominated for an exclusive commercial license.

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

In return for achieving the first patient dosed with SC efgartigimod in the Phase 3 study for ITP, we made a $15.0 million milestone payment in February 2021. Upon nomination of any future target for an exclusive commercialization license and confirmation by Halozyme that such a license is available, we will pay $12.5 million to Halozyme per target. We will be obligated to pay clinical development, regulatory and commercial milestones totaling $160.0 million for the first product that uses ENHANZE® and is specific for a given target. Throughout the term of the ENHANZE License Agreement, we must provide Halozyme on an annual basis a guidance forecast setting out all projected milestone payments for products for the following four calendar quarters. We are also obligated to pay Halozyme a percentage of net sales as a royalty of any licensed product that uses ENHANZE®. This royalty varies with net sales volume, ranging from the low to

mid-single digits, and it is reduced by a maximum of 50% if following ten years from the first commercial sale of the product in a country, the last valid claim within the licensed ENHANZE® patent(s) expires. We have diligence obligations with respect to the continuation of development and commercialization of product candidates, but we are not obligated to utilize ENHANZE® for every product candidate directed to a given exclusive target(s).

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.

As also set out in section 3 "**Corporate Governance**", our non-executive director James M. Daly is also a non-executive member of the board of directors of Halozyme. The ENHANZE License Agreement with Halozyme was not a related party transaction in accordance with IAS 24 – Related Party Disclosures, since Mr. Daly, in his role as non-executive director, does not control or have significant influence over argenx or Halozyme. However, the ENHANZE License Agreement does constitute a related party transaction under the applicable SEC rules and will therefore be reported as such in our annual report on Form 20-F for the fiscal year ended December 31, 2022. Mr. Daly did not participate in any discussions and decision making relating to the ENHANZE License Agreement. Consequently, no further disclosures regarding Halozyme have been added in section 5.10.2 "**Related Party Transactions**".

In March 2022, we announced our Phase 3 ADAPT-SC clinical trial evaluating SC efgartigimod achieved the primary endpoint of total IgG reduction from baseline at day 29, demonstrating statistical non-inferiority to VYVGART (efgartigimod alfa-fcab) IV formulation in gMG patients. Based on these results, we submitted a BLA to the FDA on September 21, 2022. The BLA has been granted a PDUFA target action date of June 20, 2023.

1.5.5 Our Exclusive License with AgomAb for ARGX-114 (AGMB-101)

In March 2019, we entered into an exclusive out-license with AgomAb for the use of certain patent rights relating to our proprietary suite of technologies for the development and commercialization of a series of agonistic anti-MET SIMPLE Antibodies, including ARGX-114 (AGMB-101), a halofuginone-mimetic SIMPLE Antibody directed against the MET receptor. AgomAb is required to use commercially reasonable efforts to develop and commercialize at least one licensed product. In connection with our entry into this agreement, we received a profit-sharing certificate which entitles us to 20% of all distributions to AgomAb's shareholders (which shall be reduced to 10% following the filing of an IND and is subject to further adjustment upon the occurrence of certain financings). Upon the occurrence of a qualified initial public offering of AgomAb, the

profit-sharing certificate will automatically be converted into the equivalent number of ordinary shares in AgomAb. This agreement is subject to mutual termination for material breach or insolvency and automatically expires upon the expiration of the last to expire of our licensed patent rights.

1.5.6 Our Exclusive License with Broteio for ARGX-117

In March 2017, we entered into a collaboration with Broteio in connection with our IIP, to develop an antibody against a novel target in the complement cascade, ARGX-117 (***Broteio Agreement***). Under the Broteio Agreement, we and Broteio jointly developed the complement-targeted antibody to seek to establish preclinical proof-of-concept using our proprietary suite of technologies. Upon successful completion of these studies, we exercised an exclusive option to in-license the program in March 2018 and assumed responsibility for further development and commercialization. Pursuant to the Broteio Agreement, we are obligated to make milestone payments upon the occurrence of certain development milestones (up to an aggregate of €4.0 million), commercialization milestones (up to an aggregate of €10.0 million) and pay tiered royalties on net sales in the low single digits. We may terminate the Broteio Agreement for convenience upon 90 days prior written notice. The Broteio Agreement is also subject to mutual termination for material breach or insolvency and automatically expires upon the expiration of our financial obligations thereunder.

1.5.7 Our Exclusive License with VIB for ARGX-118

In November 2016, we entered into a collaboration under our IIP with VIB to develop antibodies against Galectin-10, the protein of Charcot-Leyden Crystals, which play a major role in severe asthma and the persistence of mucus plugs, including ARGX-118 (***VIB Agreement***). Pursuant to the VIB Agreement, we and VIB jointly developed antibodies against Galectin-10 using our proprietary suite of technologies. Upon successful completion of this initial research, we exercised an exclusive option to in-license the program and assumed responsibility for further development and commercialization. Under the VIB Agreement, including as amended in November 2018, we are obligated to make milestone payments upon the occurrence of certain development milestones (up to an aggregate of €4.0 million), commercialization milestones (up to an aggregate of €11.0 million) and pay tiered royalties on net sales in the low single digits. We may terminate the VIB Agreement for convenience upon 90 days prior written notice. The VIB Agreement is also subject to mutual termination for material breach, insolvency or certain patent challenges and automatically expires upon the expiration of VIB's licensed patent rights.

1.5.8 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 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.

1.5.9 Our Non-Exclusive License with BioWa and Non-Exclusive Commercial Licenses with BioWa and Lonza for POTELLIGENT

In October 2010, we entered into a non-exclusive license agreement with BioWa, Inc. (***BioWa***) for the use of certain patents and know-how owned by BioWa and relating to its POTELLIGENT platform technology, for use in the field of prevention and treatment of human diseases (the ***BioWa Agreement***). Pursuant to the BioWa Agreement, we are granted a non-exclusive right to use POTELLIGENT to research and develop antibodies and products containing such antibodies using POTELLIGENT.

In 2013 and 2014, we entered into non-exclusive license agreements for POTELLIGENT CHOK1SV with BioWa and Lonza for the further development, manufacturing and commercialization of ARGX-110 and ARGX-111, respectively (the ***POTELLIGENT License Agreements***).

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

Pursuant to the POTELLIGENT License Agreements, we have the right to grant sublicenses to third parties. BioWa retains a right of first negotiation for the exclusive right to develop and commercialize, in certain countries only, any product we develop using POTELLIGENT.

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

1.5.10 Our Non-Exclusive License with Lonza for Multi-Product GS Xceed-License

On February 4, 2015, we entered into a non-exclusive multi-product in-license agreement with Lonza (the ***Multi-Product License***) for use of Lonza's proprietary glutamine synthetase gene expression system known as GS Xceed™ consisting of Chinese hamster ovary cell line and the vectors for the manufacturing of drug substance (the ***System***). The System is used for the manufacturing of, amongst others, efgartigimod, ARGX-117 and ARGX-119.

Pursuant to the Multi-Product License, we have the right to grant sublicenses to certain pre-approved third parties without prior written consent of Lonza, but otherwise must obtain Lonza's prior written consent.

We have assumed certain development, regulatory and commercial milestone payment obligations to Lonza. We are required to pay such milestones using the System. We are obligated to make development, regulatory and commercial milestone payments to Lonza. Through December 31, 2022, we paid Lonza an aggregate amount of £0.6 million,

which includes milestone payments made under the Multi-Product License. Upon commercialization of our products developed using the System, we are obligated to pay Lonza a percentage of net sales as a royalty for each product manufactured, except for ARGX-109, which is wholly-owned, and next generation efgartigimod. The Lonza royalty is tiered, ranging in the low single digits and is reduced by half if the product in a country is not protected by a valid claim. During 2022, we made an aggregate payment of $1.7 million to Lonza for the royalty on net sales for manufacturing of efgartigimod.

We may terminate the Multi-Product License on a product-by-product basis by giving Lonza prior written notice. Lonza may terminate the Multi-Product License solely in case of breach or insolvency events. Absent early termination, the Multi-Product License will automatically expire upon the expiry of the last valid claim for such product. We or our strategic partners would retain the right to sell the respective products then on hand post-termination.

1.5.11 Our Collaboration with Université Catholique de Louvain (UCL) and Sopartec S.A. (Sopartec) for GARP

In January 2013, we entered into a collaboration and exclusive product license agreement with UCL and its technology transfer company Sopartec to discover and develop novel human therapeutic antibodies against GARP (***GARP Agreement***). Pursuant to the GARP Agreement, each party is responsible for all of its own costs in connection with the activities assigned to it under a mutually agreed research plan.

In January 2015, we exercised the option we were granted under the GARP Agreement to enter into an exclusive, worldwide commercial in-license for use of certain GARP-related intellectual property rights owned by UCL and the Ludwig Institute for Cancer Research to further develop and commercialize licensed products, including the GARP-neutralizing antibody ARGX-115 (ABBV-151) which was discovered under the original collaboration (***GARP License***). Upon the expiration of the GARP Agreement, the GARP License will become a fully paid-up, perpetual worldwide exclusive license under the GARP intellectual property for any purpose, subject to UCL's retention of non-commercial research rights.

Pursuant to the GARP License, we may grant sublicenses to third parties and affiliates of such third parties. In 2016, we entered into an exclusive collaboration and license agreement with AbbVie regarding ARGX-115. From any income we receive in connection with these sublicenses, such as in connection with AbbVie Collaboration Agreement, we must pay Sopartec a percentage of that income in the lower teen digit range. Royalty payment obligations expire on a product-by-product and country-by-country basis when there are no valid claims covering the ARGX-115 (ABBV-151) product. We also have diligence obligations with respect to the continued development and commercialization of ARGX-115 (ABBV-151) products.

1.5.12 Our Exclusive License with NYU Langone Health and LUMC for ARGX-119

In 2019 and 2020, we entered into collaboration and exclusive license agreements with NYU Langone Health and LUMC under our IIP to develop antibodies targeting the MuSK, for the treatment neuromuscular diseases, which play a major role at the neuromuscular junction (***NYU and LUMC Agreements***). Pursuant to the NYU and LUMC Agreements, we, NYU and LUMC jointly developed antibodies against MuSK using our proprietary suite of technologies. Under the NYU and LUMC Agreements, as amended, we are obligated to make milestone payments upon the occurrence of certain development milestones, commercialization milestones and pay tiered royalties on net sales in the low single digits.

1.6 Distribution Agreements

We are parties to the Medison Agreement, the Medison Multi-Regional Agreement and the Genpharm Agreeement.

1.7 Manufacturing and Supply

We utilize third-party contract manufacturers who act in accordance with the FDA's good laboratory practices (***GLPs***) and current good manufacturing practices (***cGMPs***) for the manufacture of drug substance and drug product. We continue to build our global network of contract manufacturers to support the development and commercialization of our products. We contract with Lonza based in Slough, UK, Portsmouth, U.S. and Singapore 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 contracted with Fujifilm based in Hillerød, Denmark, for activities relating to the large-scale manufacturing of efgartigimod drug substance. We use additional contract manufacturers to fill, label, package, store and distribute (investigational) drug products.

1.8 Intellectual Property

1.8.1 Introduction

We strive to protect the proprietary technologies that we believe are important to our business, including pursuing and maintaining patent protection intended to cover the platform technologies incorporated into, or used to produce, our product candidates, the compositions of matter of our product candidates and their methods of use, as well as other inventions that are important to our business. In addition to patent protection, we also rely on 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 patent and other proprietary protection for commercially important technologies, inventions and know-how related to our business, defend and enforce our intellectual property rights, particularly our patent rights, preserve the confidentiality of our trade secrets and operate without infringing valid and enforceable intellectual property rights of others. Specifically, we are materially dependent on patent and other proprietary protection related to our core platform technologies, described in section 1.8.2 "**Platform Technologies**", and our product candidates, as described in section 1.8.3 "**Our Internal Programs**" and section 1.8.4 "**Our Partnered Programs**".

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

As of January 1, 2023, our patent portfolio (which includes both proprietary and in-licensed patent families) comprised approximately 433 granted patents and approximately 402 pending patent applications, including approximately 46 issued U.S. patents, approximately 17 granted European patents and approximately 370 issued patents in other jurisdictions.

1.8.2 Platform Technologies

With regard to our platform technologies, we own or have intellectual property rights directed to our SIMPLE Antibody discovery platform, the ABDEG and NHance technologies.

With regard to our SIMPLE Antibody discovery platform, we own a patent family containing six issued U.S. patents with composition of matter claims directed to chimeric antibodies containing variable domains comprising complementary determining regions (***CDRs***) obtained from conventional heterotetrameric llama antibodies fused to one or more domains of a human antibody, polynucleotides encoding such chimeric antibodies, libraries of expression vectors comprising cDNA sequences encoding camelid antibodies, method claims directed to the preparation of such chimeric antibodies, and methods of modulating the binding of a human target antigen to its ligand or receptor by administering such a chimeric antibody. The U.S. patents are expected to expire in 2029 to 2033. In addition, the patent family contains patents that have been granted in Australia, Canada, Europe, the UK, Israel, India and Japan, and pending applications in the PRC and Japan (divisional). In addition, we have a second patent family containing patents granted in the U.S. (two), Australia, Europe, the UK, Israel, India and Japan, and one patent application pending in Canada, with composition of matter claims directed to

a chimeric antibody containing variable regions with CDRs derived from a llama antibody and certain amino acid substitutions corresponding to amino acids present in a human germline variable region. The granted patents have a basic patent expiry date in 2031.

With regard to the ABDEG™ platform, we co-own with, and exclusively license from, UT Southwestern, a patent family containing a granted U.S. patent with composition of matter claims directed to an isolated FcRn-antagonist comprising a variant Ig Fc region having an increased affinity for an Fc gamma receptor relative to a wild-type IgG1 Fc region, and method of use claims directed to a method of using such an FcRn-antagonist to treat certain antibody-mediated disorders. The U.S. parent patent expires in 2036 (including patent term adjustment). In addition, in this patent family, we also have granted patents in Australia, the PRC, Eurasia, Europe, Japan, Macao, Mexico, New Zealand and Singapore, and we have multiple patent applications pending in the U.S. (divisional) and various other countries and regions in North America, South America, Europe, Asia and South Africa. The granted patents have a basic expiry date in 2034. In addition, we own a second patent family containing pending patent applications in the U.S. and 15 other jurisdictions with claims directed to methods of reducing the serum levels of an Fc-containing agent in a subject by administering to the subject an FcRn-antagonist containing a variant Ig Fc region containing certain amino acid substitutions. A U.S. patent, if issued from the U.S. patent application, is expected to expire in 2036.

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

1.8.3 Our Internal Programs

Efgartigimod

efgartigimod incorporates the ABDEG platform technology.

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. This patent family has granted patents in Australia, Canada, Chile, the PRC, Colombia, Hong Kong, Israel, Japan, Mexico, New Zealand, Russia, the U.S. and South Africa, and pending patent applications in Brazil, India and the U.S. (divisional application). The patent family has a basic expiry date in 2033. Furthermore, ARGX-109 incorporates or employs the SIMPLE Antibody platform technology and the NHance platform technology.

Our ARGX-117 Product Candidate

With regard to the ARGX-117 product candidate, we own or have rights in three patent families (including one in-licensed patent family from Broteio) with several granted patents and pending patent applications in multiple jurisdictions in North America, South America, Europe and Asia, directed to composition of matter claims and method of treatment claims. The in-licensed patent family from Broteio has granted patents in Australia, the PRC, Europe, Hong Kong, Mexico and the U.S. (two issued patents in the

U.S.), which have a basic expiry date in 2034. The other two patent families have basic expiry dates in 2039 and 2040. ARGX-117 product candidate incorporates or employs the NHance® platform technology.

Our ARGX-119 Product Candidate

With regard to the ARGX-119 product candidate, we in-licensed two patent families from/with NYU Langone Health, a U.S. medical center based in New York, and three patent families from/with the LUMC, with one U.S. granted patent and several pending applications in multiple jurisdictions.

Our ARGX-118 Product Candidate

With regard to the ARGX-118 product candidate, we co-own one patent family 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, Europe and Asia. The patent family has a basic expiry date in 2039.

1.8.4 Our Partnered Programs

Our Cusatuzumab (ARGX-110) Product Candidate

With regard to the cusatuzumab product candidate, we have five issued U.S. patents, including, one U.S. granted patent with composition of matter claims directed to the cusatuzumab antibody, one U.S. granted patent with claims directed to the epitope cusatuzumab binds to, one U.S. granted patent with claims directed to a polynucleotide that encodes antibodies that bind to the epitope cusatuzumab binds to, and, one U.S. granted patent and one U.S. granted patent with method of use claims directed to the treatment of cancer and immunological disorders with the cusatuzumab antibody. The issued U.S. patents expire in 2032 and 2033, without taking a potential patent term extension into account. In addition, we have patents that have been granted in Australia, Canada, the PRC, Europe, Indonesia, Israel, India, Japan and Russia and patent applications pending in Brazil and the U.S. (divisional application). 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 granted U.S. patent with composition of matter claims directed to an antibody that binds GARP the presence of TGF-β and method of use claims directed to the use of such an antibody in the treatment of cancer. The U.S. patent has a basic expiry date in 2034, without taking a potential patent term extension into account. In addition, the patent family contains at least 18 patent applications pending in U.S. (continuation-in-part) and various other countries and regions in North America, South America, Europe and Asia. Further, we co-own with, and exclusively license from, UCL two more patent families with composition of matter claims directed to an antibody that binds an epitope of a complex formed by human GARP and TGF-β as well as method of use claims directed to the use of such an antibody in the treatment of cancer. These two patent families have basic expiry dates 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 basic expiry date in 2037. Furthermore, ARGX-112 (LP-0145) incorporates the SIMPLE Antibody platform technology.

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

In the 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 1.9.1 "**Licensure and Regulation of Biologics in the U.S.**". Similar provisions are available in Europe and in certain other jurisdictions to extend the term of a patent that covers an approved drug. It is possible that issued U.S. patents covering each of our product candidates may be entitled to patent term extensions. If our product candidates receive FDA approval, we intend to apply for patent term extensions, if available, to extend the term of patents that cover the approved product candidates. We also intend to seek patent term extensions in any jurisdictions where they are available, however, there is no guarantee that the applicable authorities, including the FDA, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions.

1.8.5 Trade Secret Protection

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

1.9 Regulation

Government authorities in the U.S., at the federal, state and local level, and in the EU and other countries and jurisdictions, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products, including biological products. In addition, some jurisdictions regulate the pricing of pharmaceutical products. The processes for obtaining marketing approvals in the 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 time and financial resources.

1.9.1 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, with the exception that the section of the FDCA that governs the approval of drugs via NDAs does not apply to the approval of biologics. Biologics are approved for marketing under provisions of the Public Health Service Act (***PHSA***) via BLAs. However, the application process and requirements for approval of BLAs are very similar to those for NDAs. The failure to comply with the applicable U.S. requirements at any time during the product development process, including preclinical testing and clinical testing, the approval process or post-approval process may subject an applicant to delays in the conduct of a study, regulatory review and approval, and/or administrative or judicial sanctions. These sanctions may include, but are not limited to, the FDA's refusal to allow an applicant to proceed with clinical testing, refusal to approve pending applications, license suspension or revocation, warning or untitled letters, adverse publicity, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines and civil or criminal investigations and penalties brought by the FDA or the Department of Justice or other governmental entities.

An applicant seeking approval to market and distribute a new biologic in the 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 regulations, including the GLPs;
- submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may begin;
- approval by an institutional review board (***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, strength, quality and purity;
- FDA audits of the clinical trial sites to assure compliance with GCPs, and the integrity of clinical data in support of the BLA;
- payment of user fees and securing FDA approval of the BLA and licensure of the new 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.

Preclinical Studies and INDs

Before testing any biological product candidate in humans, the product candidate must undergo preclinical testing. Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as animal studies to evaluate the potential for activity and toxicity. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND application. The IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about the product candidate or conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks, and places the proposed clinical trial on clinical hold. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns before the clinical trial can begin.

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

Human Clinical Trials in Support of a BLA

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

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

Further, each clinical trial must be reviewed and approved by the IRB either centrally or individually at each institution at which the clinical trial will be conducted. The IRB will consider, among other things, clinical trial design, patient informed consent, ethical

factors and the safety of human subjects. An IRB must operate in compliance with FDA regulations. The FDA, IRB, or the clinical trial sponsor may suspend or discontinue a clinical trial at any time for various reasons, including a finding that the clinical trial is not being conducted in accordance with FDA requirements or the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive GCPs and the requirements for informed consent. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group may recommend continuation of the study as planned, changes in study conduct, or cessation of the study at designated check points based on access to certain data from the study.

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

- Phase 1 clinical trials are initially conducted in a limited population to test the product candidate for safety, including adverse effects, dose tolerance, absorption, metabolism, distribution, excretion and PD in healthy humans or, on occasion, in patients, such as cancer patients.

- Phase 2 clinical trials are generally conducted in a limited patient population to identify possible adverse effects and safety risks, evaluate the efficacy of the product candidate for specific targeted indications and determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger Phase 3 clinical trials.

- Phase 3 clinical trials proceed if the Phase 2 clinical trials demonstrate that a dose range of the product candidate is potentially effective and has an acceptable safety profile. Phase 3 clinical trials are undertaken within an expanded patient population to gather additional information about safety and effectiveness necessary to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling.

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

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and the investigators fifteen days after the clinical trial sponsor determines the information qualifies for reporting for serious and unexpected suspected adverse events, findings from other studies or animal or in vitro testing that suggest a significant risk for human subjects and any clinically important increase in the rate of a

serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must also notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than seven calendar days after the sponsor's initial receipt of the information.

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

Compliance with cGMP Requirements

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

Manufacturers and others involved in the manufacture and distribution of products must also register their establishments with the FDA and certain state agencies. Both domestic and foreign manufacturing establishments must register and provide additional information to the FDA upon their initial participation in the manufacturing process. Establishments may be subject to periodic unannounced inspections by government authorities to ensure compliance with the FDCA, cGMPs and other requirements. Manufacturers may have to provide, on request, electronic or physical records regarding their establishments.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including biological products, are required to register and disclose certain clinical trial information on the **website**. Information related to the product, patient population, phase of investigation, clinical trial sites and investigators, and other aspects of a clinical trial are then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of clinical trials can be delayed in certain circumstances for up to two years after the date of completion of the clinical trial. Competitors may use this publicly available information to gain knowledge regarding the progress of clinical development programs as well as clinical trial design.

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 must contain extensive manufacturing information and detailed information on the composition of the product and proposed labeling as well as payment of a user fee.

The FDA has 60 days after submission of the application to conduct an initial review to determine whether the BLA is sufficient to 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 ten 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 a priority review of an application, if the BLA is not filed under the program. If the BLA is submitted under the program, additional 2 months are added to the review clock, whether standard or priority review for a total review time of 12 or 8 months, respectively. The FDA does not always meet its PDUFA goal dates for standard and priority reviews. The review process and the PDUFA goal date may also be extended by three months if the FDA so requests or if the applicant otherwise provides additional information or clarification regarding information already provided in the submission which may be deemed as substantial information.

After the FDA's evaluation of the application and accompanying information, including the results of any potential inspections of the manufacturing facilities and any FDA audits of clinical trial sites to assure compliance with GCPs, 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 and the conditions that must be met in order to secure approval of the application, and when possible, will outline recommended actions the sponsor might take to obtain approval of the application. Sponsors that receive a complete response letter may submit to the FDA information that represents a complete response to the issues identified by the FDA, withdraw the application or request a hearing. The FDA will not approve an application until issues identified in the complete response letter have been addressed.

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

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

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

Such regulatory reviews can result in denial or modification of the planned changes, or requirements to conduct additional tests or evaluations that can substantially delay or increase the cost of the planned changes.

Fast Track, Breakthrough Therapy and Priority Review Designations

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

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

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

lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

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

Accelerated Approval Pathway

The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit 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, 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 FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a product.

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

and describe the product's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. 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 approval. 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 regulations are subject to prior review by the agency. The Food and Drug Omnibus Reform Act (***FDORA***) was recently enacted and includes provisions related to the accelerated approval pathway. Pursuant to FDORA, the FDA is authorized to require a post-approval study to be underway prior to approval or within a specified time period following approval. FDORA also requires the FDA to specify the conditions of any required post-approval study not later than 180 days following approval and not less frequently than every 180 days thereafter until completion or termination of such study. Such conditions may include imposing milestones such as a target date of study completion or requiring sponsors to submit progress reports. FDORA also enables the FDA to initiate enforcement actions or criminal prosecutions for the failure to conduct with due diligence a required post-approval study, including a failure to meet any required conditions specified by the FDA or to submit timely reports.

Orphan Drug Designation

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.

Orphan drug designation qualifies a company for tax credits and market exclusivity for seven years following the date of the product's marketing approval if granted by the FDA and if it is the first FDA approval for that product for the disease for which it has such designation. 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. The product must then go through the review and approval process like any other product in order to be marketed.

A sponsor may request orphan drug designation of a previously unapproved product or new orphan indication for an already marketed product. In addition, a sponsor of a product that is otherwise the same product as an already approved orphan drug may seek and obtain orphan drug designation for the subsequent product for the same rare disease or condition if it can present a plausible hypothesis that its product may be clinically superior to the first drug. Whether a large molecule product (i.e., a biological product) is the same as another product is based on whether the two products have the same principal molecular structural features. More than one sponsor may receive orphan drug designation for the same product for the same rare disease or condition, but each sponsor seeking orphan drug designation must file a complete request for designation.

If orphan drug exclusivity is granted by the FDA, the period of exclusivity begins on the date that the marketing application is approved by the FDA and applies only to the indication for which the product has been designated. The FDA may approve a second application for the same product for a different use or a second application for a clinically superior version of the product for the same use. The FDA cannot, however, approve the same product made by another sponsor for the same indication during the market exclusivity period unless it has the consent of the sponsor or the sponsor is unable to provide sufficient quantities of the product.

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 as well as any post-approval requirements that the FDA has imposed as part of the approval process. The sponsor will be required to report certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling. Manufacturers and other parties involved in the drug supply chain for prescription drug and biological products must also comply with product tracking and tracing requirements and for notifying 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, which impose certain procedural and documentation requirements upon manufacturers. Accordingly, the sponsor and its third-party manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with 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 pharmaceutical products. Any distribution of prescription biological products and pharmaceutical samples must comply with the U.S. Prescription Drug Marketing Act and the PHSA.

Once an approval is granted, the FDA may revoke or suspend the approval of the BLA 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 or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Pharmaceutical products may be promoted only for the approved indications and in accordance with the provisions of the approved labeling. Although physicians may prescribe legally available products for unapproved uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), companies with approved products may not market or promote such off-label uses. The FDA does not regulate the behavior of physicians in their choice of treatments, but the FDA regulations do impose stringent restrictions on manufacturers' communications regarding off-label uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities. Prescription biological product promotional materials must be submitted to the FDA in conjunction with their first use or first publication.

Pediatric Studies and Exclusivity

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

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Unless otherwise required by regulation, 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 marketing exclusivity in the U.S. and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity. This six-month exclusivity may be granted if a BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity cover the product are extended by six months.

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

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date of approval of the reference product. The FDA may not approve a biosimilar product until twelve 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. However, to rely on such exclusivities for establishing or protecting our market position is not without risk, as such laws are subject to changes by the legislature. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

U.S. Patent Term Restoration

Depending upon the timing, duration and specifics of FDA 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 prior to the expiration of the patent. The 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 its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

1.9.2 Regulation and Procedures Governing Approval of Medicinal Products in the EU and the UK

In order to market any medicinal product outside of the U.S., a company also must comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable regulatory authorities before it can initiate clinical trials or marketing of the product in those countries or jurisdictions. Specifically, no medicinal product may be placed on the market of an EU member state unless a marketing authorization has been issued by the competent authorities of that member state in accordance with Directive 2001/83/EC or a centralized marketing authorization has been granted in accordance with Regulation (EC) No 726/2004, read in conjunction with Regulation (EC) No 1901/2006 and Regulation (EC) No 1394/2007. The process governing approval of medicinal products in the EU and the UK generally follows the same lines as in the U.S. It entails satisfactory completion of pharmaceutical development, pre-clinical studies 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 the submission to relevant competent authorities for clinical trials authorization and to the European Medicines Agency (***EMA***) or to competent authorities in EU Member States of a marketing authorization application (***MAA***) and granting of such MAA by these authorities before the product can be marketed and sold in the EU. Following the UK's departure from the EU, a separate MAA is required in order to place medicinal products on the market in the Great Britain (England, Wales and Scotland) (under the Northern Ireland Protocol, the EU regulatory framework will continue to apply in Northern Ireland in this regard and centralized EU marketing authorizations will continue to be recognized).

Clinical Trial Approval

In April 2014, the EU adopted the new Clinical Trials Regulation (EU) No 536/2014, which replaced the Clinical Trials Directive 2001/20/EC as of January 31, 2022. The transitional provisions of the new Regulation offered sponsors the possibility to choose between the requirements of the previous Directive and the new Regulation if the request for authorization of a clinical trial was submitted by January 30, 2023. If the sponsor chose to submit under the previous Directive, the clinical trial continues to be governed by the

Directive until three years after the new Regulation became applicable (i.e., January 31, 2025). If a clinical trial continues for more than three years after the Regulation became applicable, the new Regulation will at that time begin to apply to the clinical trial. The new Regulation (EU), which is directly applicable in all EU Member States, aims to simplify and streamline the approval of clinical trials in the EU. The main characteristics of the new Regulation include: a streamlined application procedure via a single-entry point through the Clinical Trials Information System; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts (Part I contains scientific and medicinal product documentation and Part II contains the national and patient-level documentation). Part I is assessed by a coordinated review by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (***Concerned Member States***) of a draft report prepared by a reference member state. Part II is assessed separately by each Concerned Member State. Strict deadlines have also been established for the assessment of CTAs.

Prior to its exit from the EU, the UK implemented Directive 2001/20/EC into national law through the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended). However, implementation of the new EU Clinical Trials Regulation took place after the UK's departure from the EU, and so the new Clinical Trial Regulation described in the preceding paragraph does not apply to Great Britain. The MHRA, the UK medicines regulator, ran a consultation on reforms to the UK clinical trials legislation which closed in March 2022. The outcome of that consultation has not yet been published and the future regulatory framework for clinical trials in the UK is currently uncertain.

Orphan Designation and Exclusivity

Regulation (EC) No. 141/2000 and Regulation (EC) No. 847/2000 provide that a product can be designated as an orphan drug by the EU Commission if its sponsor can establish: (1) that the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition, (2) either (i) the prevalence of the condition is not more than five in ten thousand persons in the EU when the application is made, or (ii) 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 (3) 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 a marketing authorization is granted for an orphan medicinal product, this results in a ten-year period of market exclusivity. During this market exclusivity period, neither the EMA, the European Commission nor the EU Member States can accept an application or grant a marketing authorization for a "similar medicinal product". A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The market exclusivity period for the authorized therapeutic indication may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation because, for example, the product is sufficiently profitable not to justify market exclusivity. 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 marketing authorization holder for the authorized orphan product consents to the second orphan application; or (iii) the marketing authorization holder for the authorized orphan product cannot supply enough orphan medicinal product. Orphan designation must be requested before submitting an application for marketing approval. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Since January 1, 2021, a separate process for orphan designation has applied in Great Britain. There is now no pre-marketing authorization orphan designation (as there is in the EU) and the application for orphan designation will be reviewed by the MHRA, at the time of an MAA for a UK or Great Britain marketing authorization. The criteria are the same as in the EU, save that they apply to Great Britain only (e.g., there must be no satisfactory method of diagnosis, prevention or treatment of the condition concerned in Great Britain, as opposed to the EU, and the prevalence of the condition must be no more than five in 10,000 persons in Great Britain).

Marketing Authorization

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

The centralized procedure provides for the grant of a single marketing authorization by the EU Commission that is valid for all EEA Member States. Pursuant to Regulation (EC) No. 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy 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 products that contain a new active substance for any other indications, which are a significant therapeutic, scientific or technical innovation and whose authorization would be in the interest of public health in the EU.

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 EU 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. Clock stops may extend the timeframe of evaluation of an MAA considerably beyond 210 days. Accelerated evaluation may be granted by the CHMP in exceptional cases, when a medicinal product is of major

interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts such a request, the time limit of 210 days will be reduced to 150 days (excluding clock stops), but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that it is no longer appropriate to conduct an accelerated assessment.

Following the departure of the UK from the EU, Great Britain is no longer covered by centralized marketing authorizations (under the Northern Ireland Protocol, centralized EU authorizations will continue to be recognized in Northern Ireland). However, all medicinal products with a current centralized authorization were automatically converted to UK marketing authorizations on January 1, 2021, and there is a further period, recently extended to December 31, 2023, during which the MHRA may rely on a decision taken by the EU Commission on the approval of a new marketing authorization in the centralized procedure, in order to more quickly grant a new Great Britain marketing authorization. A separate application is, however, still required.

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 marketing authorization and an additional two years of market exclusivity. 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 marketing authorization 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 eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains a marketing authorization 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 a marketing authorization based on an MAA with a complete independent data package of pharmaceutical tests, preclinical tests and clinical trials. Similar arrangements apply in the UK.

Periods of Authorization and Renewals

A marketing authorization is valid for five years, in principle, and it may be renewed after five years on the basis of a reevaluation of the risk benefit balance by the EMA for a centrally authorized product, or by the competent authority of the authorizing member state for a nationally authorized product. Once renewed, the marketing authorization is valid for an unlimited period, unless the EU Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any marketing authorization that is not followed by the placement of the drug on the EU market (in the case of the centralized procedure) or on the market of the authorizing member state (for a nationally authorized product) within

three years after authorization, or if the drug is removed from the market for three consecutive years, ceases to be valid. In Great Britain, centrally authorized products converted from EU to UK marketing authorizations will have the same renewal date.

Regulatory Requirements after Marketing Authorization

Following approval, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of the medicinal product. These include compliance with the EU's stringent pharmacovigilance or safety reporting rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed. In addition, the manufacturing of authorized products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the EMA's GMP requirements and comparable requirements of other regulatory bodies in the EU, which mandate the methods, facilities and controls used in manufacturing, processing and packing of products to assure their safety and identity. Finally, the marketing and promotion of authorized products, including industry-sponsored continuing medical education and advertising directed toward the prescribers of products and/or the general public, are strictly regulated in the EU under Directive 2001/83EC, as amended.

The aforementioned EU rules are generally applicable in the EEA, and similar arrangements apply in the UK.

Brexit and the Regulatory Framework in the UK

In June 2016, the electorate in the UK voted in favor of leaving the EU (commonly referred to as "Brexit"), and the UK officially withdrew from the EU on January 31, 2020. Pursuant to the formal withdrawal arrangements agreed between the UK and the EU, the UK was subject to a transition period until December 31, 2020, during which EU rules continued to apply. However, the EU and the UK concluded a trade and cooperation agreement (***TCA***), which was provisionally applicable since January 1, 2021 and has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not foresee wholesale mutual recognition of UK and EU pharmaceutical regulations. The UK has implemented EU legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended) and has not yet enacted significant legislative change in this area following its exit from the EU. The regulatory regime in Great Britain therefore largely aligns with current EU regulations. However, these regimes may diverge increasingly as time passes, now that Great Britain's regulatory system is independent from the EU, and the TCA does not provide for mutual recognition of UK and EU pharmaceutical legislation. For example, as already explained, the new Clinical Trials Regulation which became effective in the EU on January 31, 2022 has not been implemented into UK law, and a separate application will need to be submitted for clinical trial authorization in the UK. Furthermore, the position in Northern Ireland differs in certain respects from that of the rest of the UK (England, Wales and Scotland) as some EU rules continue to be applicable to Northern Ireland following the UK's departure from the EU.

1.9.3 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 in Japan 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 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 person is required to obtain from the MHLW a marketing license in order to conduct the business of marketing, leasing or providing medical products that are manufactured (or outsourced to a third party for manufacturing) or imported by such person.

Also, in order to conduct the business of manufacturing medical products which will be marketed in Japan, a person is required to obtain from the MHLW a manufacturing license for each manufacturing site.

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. Also, the data of clinical trials and other pertinent data, which must be attached for 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 marketing license-holder that has obtained marketing approval for a new pharmaceutical must have that pharmaceutical re-examined by the PMDA for a specified period after receiving marketing approval. Such re-examination period for VYVGART is stated to be ten (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 marketing license-holder the obligation to gather clinical data for a certain period after the marketing approval was granted so that the PMDA has the opportunity to re-examine the product. Results of usage and other pertinent data must be attached for an application for a re-examination. A marketing license holder

that has obtained a marketing approval is also required to investigate, among other things, the results of usage and to periodically report to the PMDA pursuant to the Pharmaceutical and Medical Devices Act.

Price Regulation

In Japan, 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, a marketing license-holder of medical products must first have a new medical product listed on the NHI price list in order to obtain its coverage under the public medical insurance system. The NHI price list listed VYVGART in April 2022.

The NHI price of a medical product is determined either by price comparison of comparable medical products with necessary adjustments for innovativeness, 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 will be subject to revision, generally once every year, on the basis of the actual prices at which the medical products are purchased by medical institutions.

1.9.4 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. 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. Each plan determines whether or not it will provide coverage for a product, what amount it will pay the manufacturer for the product, on what tier of its formulary the product will be placed and whether to require step therapy. The position of a product on a formulary generally determines the co-payment that a patient will need to make to obtain the product and can strongly influence the adoption of a product by patients and physicians. 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. For example, the payor may require co-payments that patients find unacceptably high. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor.

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

In the PRC, the newly created National Healthcare Security Administration (***NHSA***) an agency responsible for administering the PRC's social security system, organized a price negotiation with drug companies for certain new drugs that had not been included in

the national Reimbursable Drug List (***RDL***) at the time of the negotiation in November 2019, which resulted in an average price reduction by over 60% for 70 of the 119 drugs that passed the negotiation. NHSA, together with other government authorities, review the inclusion or removal of drugs from the PRC's National Drug Catalog for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance, or provincial or local medical insurance catalogues for the national medical insurance program regularly, and the tier under which a drug or device will be classified, both of which affect the amounts reimbursable to program participants for their purchases of those drugs. These determinations are made based on a number of factors, including price and efficacy. We may also be invited to attend the price negotiation with NHSA upon receiving regulatory approval in the PRC, but we will likely need to significantly reduce our prices, and to negotiate with each of the provincial healthcare security administrations on reimbursement ratios. On the other hand, if the NHSA or any of its local counterpart includes our drugs and devices in the national RDL or provincial RDL, which may increase the demand for our drug candidates and devices, our potential revenue from the sales of our drug candidates and devices may still decrease as a result of lower prices. Moreover, eligibility for reimbursement in the PRC does not imply that any drug or device will be paid for in all cases or at a rate that covers our costs, including licensing fees, research, development, manufacture, sale and distribution.

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. Further, due to the COVID-19 pandemic, millions of individuals have lost/will lose employer-based insurance coverage, which may adversely affect our ability to commercialize our products. 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. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our potential revenue from the sale of any products for which we may obtain approval. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more of our products for which we or our collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Obtaining and maintaining reimbursement status is time-consuming and costly.

In the EU, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies (so called health technology assessments) in order to obtain reimbursement or pricing approval. For example, the EU provides options for its Member States to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. 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 product on the market. Other Member States allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the EU have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the EU. The downward pressure on healthcare costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various 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 drugs. Inclusion of orphan drugs in reimbursement systems tend to focus on the medical usefulness, need, quality and economic benefits to patients and the healthcare system as for any drug. Acceptance of any medicinal product for reimbursement may come with cost, use and often volume restrictions, which again can vary by country. In addition, results-based rules of reimbursement may apply. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products, if approved in those countries. Historically, products launched in the EU do not follow price structures of the U.S. and generally prices tend to be significantly lower.

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.

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

1.9.5 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 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. For non-innovator products, generally generic drugs marketed under abbreviated NDAs, the rebate amount is 13% of the average manufacturer price (***AMP***) for the quarter. The AMP is the weighted average of prices paid to the manufacturer (1) directly by retail community pharmacies and (2) by wholesalers for drugs distributed to retail community pharmacies. For innovator products (i.e., drugs that are marketed under NDAs or BLAs), the rebate amount is the greater of 23.1% of the AMP for the quarter or the difference between such AMP and the best price for that same quarter. The best price is essentially the lowest price available to non-governmental entities. Innovator products may also be subject to an additional rebate that is based on the amount, if any, by which the product's AMP for a given quarter exceeds the inflation-adjusted baseline AMP, which for most drugs is the AMP for the first full quarter after launch. Since 2017, non-innovator products are also subject to an additional rebate. To date, the rebate amount for a drug has been capped at 100% of the AMP; however, effective January 1, 2024, this cap will be eliminated, which means that a manufacturer could pay a 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 drugs 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 (***HRSA***) on a quarterly basis. HRSA 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, 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. 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.

Recently, the Infrastructure Investment and Jobs Act, effective January 1, 2023, added a requirement for manufacturers of certain single-source drugs (including biologics and biosimilars) separately paid for under Medicare Part B for at least 18 months and marketed in single-dose containers or packages (known as refundable single-dose containers or single-use package drugs) to provide annual refunds if those portions of the dispensed drug that are unused and discarded exceed an applicable percentage defined by statute or regulation. Manufacturers will be subject to periodic audits and those that fail to pay refunds for their refundable single-dose containers or single-use package drugs shall be subject to civil monetary penalties.

Medicare Part D provides prescription drug benefits for seniors and people with disabilities. Medicare Part D enrollees once had a gap in their coverage (between the initial coverage limit and the point at which catastrophic coverage begins) where Medicare did not cover their prescription drug costs, known as the coverage gap. However, beginning in 2019, Medicare Part D enrollees paid 25% of brand drug costs after they reached the initial coverage limit – the same percentage they were responsible for before they reached that limit – thereby closing the coverage gap from the enrollee's point of view. Most of the cost of closing the coverage gap is being borne by innovator companies and the government through subsidies. Each manufacturer of drugs approved under NDAs or BLAs is required to enter into a Medicare Part D coverage gap discount agreement and provide a 70% discount on those drugs dispensed to Medicare Part D enrollees in the coverage gap, in order for its drugs to be reimbursed by Medicare Part D. Beginning in 2025, the Inflation Reduction Act (***IRA***) eliminates the coverage gap under Medicare Part D by significantly lowering the enrollee maximum out-of-pocket cost and requiring manufacturers to subsidize, through a newly established manufacturer discount program, 10% of Part D enrollees' prescription costs for brand drugs below the out-of-pocket maximum, and 20% once the out-of-pocket maximum has been reached. Although these discounts represent a lower percentage of enrollees' costs than the current discounts required below the out-of-pocket maximum (that is, in the coverage gap phase of Part D coverage), the new manufacturer contribution required above the out-of-pocket maximum could be considerable for very high-cost patients and the total contributions by manufacturers to a Part D enrollee's drug expenses may exceed those currently provided.

The IRA will also allow HHS to negotiate the selling price of certain drugs and biologics that CMS reimburses under Medicare Part B and Part D, although only high-expenditure single-source biologics that have been approved for at least 11 years (7 years for drugs) can be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price. Beginning in October 2022 for Medicare Part D and January 2023 for Medicare Part B, the IRA will also penalize drug manufacturers that increase prices of Medicare Part D and Part B drugs at a rate greater than the rate of inflation.

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.

1.9.6 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, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. 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. On December 2, 2020, the Office of Inspector General (***OIG***) published further modifications to the AKS. Under the final rules, OIG added safe harbor protections

under the AKS for certain coordinated care and value-based arrangements among clinicians, providers, and others. This rule (with exceptions) became effective January 19, 2021. We continue to evaluate what effect, if any, the rule will have on our business;

- 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 laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; 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.

Some state laws require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on

Interactions with Healthcare Professionals, in addition to requiring pharmaceutical manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state and require the registration of pharmaceutical sales representatives State and foreign laws, including for example the EU General Data Protection Regulation, which became effective May 2018, 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 OIG 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. 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 OIG 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.

On December 2, 2020, the HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers (***PBMs***), unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between PBMs and manufacturers. Implementation of this change and new safe harbors for point-of-sale reductions in price for prescription pharmaceutical products and PBM service fees has been delayed until January 1, 2032. Further, on December 31, 2020, CMS published a new rule, effective January 1, 2023, requiring manufacturers to ensure the full value of co-pay assistance is passed on to the patient or these dollars will count toward the AMP and Best Price calculation of the drug. On May 21, 2021, PhRMA sued the HHS in the U.S. District Court for the District of Columbia, to stop the implementation of the rule claiming that the rule contradicts federal law surrounding Medicaid rebates, and on May 17, 2022, the court vacated the rule.

Violations of these laws can subject us to criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment and exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become

subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm, and we may be required to curtail or restructure our operations. Moreover, we expect that there will continue to be federal and state laws and regulations, proposed and implemented, that could impact our future operations and business.

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.

1.9.7 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, in March 2010, the ACA entered into force. The ACA is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

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. On September 9, 2021, the Biden administration published a wide-ranging list of policy proposals, most

of which would need to be carried out by Congress, to reduce drug prices and drug payment. The HHS plan includes, among other reform measures, proposals to lower prescription drug prices, including by allowing Medicare to negotiate prices and disincentivize price increases, and to support market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase price transparency. As discussed above, these initiatives recently culminated in the enactment of the IRA in August 2022, which will, among other things, allow HHS to negotiate the selling price of certain drugs and biologics that CMS reimburses under Medicare Part B and Part D, although only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for biologics) can be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price. Beginning in January 2023 for Medicare Part B and October 2022 for Medicare Part D, the IRA will also penalize drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. 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. These provisions will take effect progressively starting in 2023, although they may be subject to legal challenges.

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

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

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

1.9.8 Environmental Issues 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.

2 Risk Factors

2 Risk Factors

The occurrence of any of the events or circumstances described in these risk factors, individually or together with other circumstances, could have a material adverse effect on the business, results of operations, financial condition and prospects of argenx. These are not the only risks argenx faces. Additional risks and uncertainties not presently known to argenx or that it currently considers immaterial or not specific may also impair its business, results of operation and financial condition.

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

2.1.1 We have Incurred Significant Losses Since our Inception and Expect to Incur Losses for the Foreseeable Future. We may Never Achieve or Sustain Profitability.

Since our inception, we have incurred significant operating losses, totaling $2,109.8 million of cumulative losses. To date we have commercialized VYVGART for the treatment of gMG in the VYVGART Approved Countries (see section **1.1.1** above). We do not currently have any marketing approvals for any other product candidates or VYVGART in other indications. Our losses resulted principally from costs incurred in research and development, preclinical testing and clinical development of our research programs, and from general and administrative costs associated with our operations. We intend to continue to conduct research and development, preclinical testing, clinical trials and regulatory compliance activities as well as the continued commercialization of VYVGART and other products candidates, for current and future indications, and we intend to continue our efforts to expand our sales, marketing and distribution infrastructure. These expenses, together with anticipated general and administrative expenses, may result in incurring further significant losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we execute our strategic objectives and as we experience delays or encounter issues relating thereto, including failed clinical trials, ambiguous clinical trial results, safety issues or other regulatory challenges.

Although we have generated revenue of $400.7 million from global product net sales of VYVGART in fiscal year 2022, we can provide no assurances that we will be able to achieve or sustain profitability based on sales in that indication alone or that we will be

able to receive regulatory approval of and commercialize VYVGART in other indications or in other countries. To become and remain profitable, we must succeed in developing and commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our products and our product candidates, including new indications, discovering and developing additional products and product candidates, including new indications, obtaining regulatory approval for any product candidates that successfully complete clinical trials, establishing manufacturing and marketing capabilities, obtaining funding or reimbursement for our products, and ultimately selling products for which we may obtain regulatory approval. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability.

2.1.2 We may Need to Raise Substantial Additional Funding Which may not be Available to us on Acceptable Terms or at all.

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

To finance our operations, we may need to raise additional capital through a combination of public or private equity or debt financings or other sources, which may include collaborations with third parties. Our ability to raise additional funds on acceptable terms or at all will depend on financial, economic and market conditions and other factors, over which we may have no or limited control. If we are unable to raise additional capital if and when needed, or if the terms are not acceptable, our business strategy could be impacted, and we may be forced to delay, reduce or terminate the one or

more of our research or development programs or the commercialization of any of our products or product candidates, including new indications, or be unable to expand our operations or otherwise capitalize on our business opportunities, all of which may have a material adverse impact on our business, financial condition and results of operations.

2.1.3 Our Assets, Earnings and Cash Flows and the Investment of our Cash and Cash Equivalents may be Subject to Risks Which may Cause Losses and Affect the Liquidity of these Investments.

As of December 31, 2022, we had cash and cash equivalents and current financial assets of $2,192.5 million compared to $2,336.7 million in December 31, 2021. We historically have invested substantially all of our available cash and cash equivalents and current financial assets in either current accounts, savings accounts, term accounts or highly liquid money market funds, pending their use in our business. For example, we have invested in USD denominated cash deposit accounts and in current financial assets with a significant portion of the proceeds from our U.S. public offerings. Any future investments may include term deposits, corporate bonds, commercial paper, certificates of deposit, government securities and money market funds in accordance with our cash management policy. These investments may be subject to general credit, liquidity, market, inflation and interest rate risks and we may realize losses in the fair value of these investments or a complete loss of these investments, which would have a negative effect on our financial condition. The market risks associated with our cash flows and investment portfolio may adversely affect our results of operations, liquidity and financial condition.

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

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

2.2.1 We will Face Significant Challenges in Successfully Commercializing our Products and Additional Product Candidates After they are Launched.

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

Even if we successfully expand our sales and marketing capabilities, either on our own or in collaboration with third parties, we may fail to launch or market our products effectively. Recruiting and training a specialized sales force is expensive and the costs of expanding an independent sales, marketing and/or promotion organization could be greater than we anticipate. We could further encounter difficulties in our sales or marketing, due to regulatory actions, shut-downs, work stoppages or strikes, approval delays, withdrawals, recalls, penalties, supply disruptions, shortages or stock-outs at our facilities or third-party facilities that we rely on, reputational harm, the impact to our facilities due to pandemics or natural or man-made disasters, including as a result of climate change, product liability, and/or unanticipated costs. In addition, recruiting and training a sales force is time-consuming and could delay any product launch. In the event that any such launch is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

We have entered into distribution agreements with Medison, Zai Lab and Genpharm to perform sales and marketing services in Israel and Central and Eastern Europe, the PRC and the GCC, respectively. Under these agreements, our product revenues or the profitability of these product revenues could be lower than if we were to market and sell the products that we develop ourselves. Such distribution agreements may place the commercialization of our products outside of our control, including over the amount or timing of resources that our distribution partners devote to our products. Furthermore,

our distributors' willingness or ability to comply with and complete their obligations under our arrangements may be adversely affected by business combinations or significant changes in our distributors' business strategies. In addition, we may not succeed in entering into arrangements with third parties to sell and market our products or may be unable to do so on terms that are favorable to us.

2.2.2 The Commercial Success of our Products and Product Candidates, Including in New Indications or Methods of Administration, will Depend on the Degree of Market Acceptance.

Our products and product candidates, including for new indications or methods of administration, if and when approved and available on the market, may never achieve an adequate level of acceptance by physicians, patients, the medical community, or healthcare payors for us to be profitable. This will depend on a number of factors, many of which are beyond our control, including, but not limited to:

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

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

Moreover, efforts to educate the medical community and third-party payors on the benefits of our products may require significant resources and may never be successful. If our product candidates or methods of use of existing products or new indications fail to gain market acceptance, this will have a material adverse impact on our ability to generate revenues. Even if some products achieve market acceptance, they may not be able to retain market acceptance and/or the market may prove not to be large enough to allow us to generate significant revenues.

2.2.3 We Face Significant Competition for our Drug Discovery and Development Efforts.

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

There can be no assurance that our competitors are not currently developing, or will not in the future develop, technologies and products that are equally or more effective, are more economically attractive, and can be administered more easily than any of our current or future technologies or products.

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

2.2.4 Our Products, Product Candidates and new Indications for Which we have Obtained or Intend to Seek Approval as Biological Products, Including for New Indications, may Face Competition Sooner than Anticipated.

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

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the twelve-year period of exclusivity, as was the case with VYVGART. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for competition by biosimilar products sooner than anticipated. Moreover, an interchangeable biosimilar product, once approved, may be substituted under existing state law for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products. Any non-interchangeable biosimilar products may also be substituted by a healthcare provider but, under existing law, will not be automatically substituted at the pharmacy. The extent of the impact of such substitution will depend on a number of marketplace and regulatory factors that are still developing.

In the EU, biosimilars are evaluated for marketing authorization pursuant to a set of general and product class-specific guidelines. In addition, in an effort to spur biosimilar utilization and/or increase potential healthcare savings, some EU Member States have adopted, or are considering the adoption of, biosimilar uptake measures such as

physician prescribing quotas or automatic pharmacy substitution of biosimilars for the corresponding reference products. Some EU Member States impose automatic price reductions upon market entry of one or more biosimilar competitors. While the degree of competitive effects of biosimilar competition differs among EU Member States and among products, the overall use of biosimilars and the rate at which product sales of innovative products are being affected by biosimilar competition is increasing.

2.2.5 Enacted and Future Legislation could Impact Demand for our Products Which could Impact our Business and Future Results of Operations.

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

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

The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with IRA may be subject to various penalties, including civil monetary penalties. IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. These provisions will take effect progressively starting in 2023, although they may be subject to legal challenges. The full economic impact of IRA is unknown at this time, but the law's passage is likely to affect the pricing of our products and product candidates. The adoption of restrictive price controls in new jurisdictions, more restrictive controls in existing jurisdictions or the failure to obtain or maintain timely or adequate pricing could also adversely impact revenue. We expect pricing pressures will continue globally.

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

2.2.6 We are Subject to Government Pricing Laws, Regulation and Enforcement. These Laws Affect the Prices we may Charge the Government for our Products and the Reimbursement our Customers may Obtain from the Government. Our Failure to Comply with these Laws could Harm our Results of Operations and Financial Conditions.

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

The calculations are complex and are often subject to interpretation by us, governmental agencies and the courts. If we determine that the prices we reported were in error, we may be required to restate those prices and pay additional rebates or refunds

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

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

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

2.2.7 We may not Obtain or Maintain Adequate Coverage or Reimbursement Status for our Products and Product Candidates.

Sales of VYVGART for gMG and our product candidates, if approved, will depend, in part, on the extent to which third-party payors, including government health programs in the U.S. (such as Medicare Parts B and D and Medicaid) and other countries, commercial health insurers, and managed care organizations, provide coverage and establish adequate reimbursement levels for such products and product candidates. In the U.S., no

uniform policy of coverage and reimbursement for products exists among commercial third-party payors. Commercial third-party payors decide which products they will pay for and establish reimbursement levels. Commercial payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidate that we develop through approval will be made on a plan-by-plan basis. One commercial payor's determination to provide coverage for a product does not assure that other commercial payors will also provide coverage and adequate reimbursement for the product. Additionally, a commercial third-party payor's decision to provide coverage for a drug does not imply that an adequate reimbursement rate will be approved. Each plan determines whether or not it will provide coverage for a product, what amount it will pay the manufacturer for the product, on what tier of its formulary the product will be placed and whether to require step therapy. The position of a product on a formulary generally determines the co-payment that a patient will need to make to obtain the product and can strongly influence the adoption of a product by patients and physicians.

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

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

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

Moreover, coverage policies and third-party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained

for one or more products for which we receive marketing approval in one or more indications, less favorable coverage policies and reimbursement rates may be implemented in the future. For instance, even though favorable coverage and reimbursement status has been attained for VYVGART for the treatment of gMG in the U.S., access to VYVGART for the treatment of gMG or for any other indication may be reduced or restricted by limited payer coverage due to treatment criteria, which may prevent us from realizing its full commercial potential. In addition, the coverage and reimbursement levels for our products for the treatment in one indication may have an adverse impact on the coverage and reimbursement levels of such products or product candidates in other indications for which marketing approval has previously been or may subsequently be obtained. Inadequate coverage or reimbursement may diminish or prevent altogether any significant demand for our products and/or may prevent us entirely from entering certain markets or indications, which would prevent us from generating significant revenues or becoming profitable, which would adversely affect our business, financials and results of operations.

2.2.8 If we Fail to Obtain Orphan Drug Designation or Obtain or Maintain Orphan Drug Exclusivity for our Products or Product Candidates, our Competitors may Sell Products to Treat the same Conditions and our Revenue will be Reduced.

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

In the U.S., orphan drug designation entitles a party to financial incentives such as tax advantages and user fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application submitted by another applicant to market a same or similar biological product for the same indication for a period of seven years, except in limited circumstances. Whether a biological product is the same as another product is based on whether the two products have the same principal molecular structural features. Orphan designation does not, however, truncate the duration of the regulatory review and approval process.

In the EU, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. If we fail to obtain or if we lose orphan drug status for one or more of our products and product candidates, the aforementioned incentives and market exclusivity may not or no longer be available to us, which is likely to increase the overall cost of development and to decrease the competitive position of such product and product candidate including from biosimilars. Similar considerations apply in the UK.

We may from time to time seek orphan drug designation in the U.S. or Europe for certain indications addressed by our products and product candidates. For example, in September 2017, the FDA granted orphan drug designation for the use of efgartigimod for gMG, and upon approval of VYVGART, the FDA granted seven years of orphan drug exclusivity for VYVGART for the treatment of gMG in adult patients who are AChR-AB+. In July 2022, the FDA granted orphan drug designation for the use of efgartigimod co-formulated with rHuPH20 for the treatment of gMG, and we expect to obtain orphan drug exclusivity for this product with this use if our BLA is approved. In January 2019, the FDA granted orphan drug designation for the use of efgartigimod for the treatment of ITP and for the use of cusatuzumab for the treatment of AML, and in August 2021, the FDA granted orphan drug designation for the use of efgartigimod co-formulated with rHuPH20 for the treatment of CIDP. In December 2022, the MHLW granted orphan drug designation for the use of efgartigimod for the treatment of ITP. With regard to these designations or future designations we may obtain, we may not be the first to obtain marketing approval of these drugs for such indication due to the uncertainties associated with developing therapeutic products, and we may not obtain orphan designation upon approval. In addition, exclusive marketing rights in the U.S. may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties or different principal molecular structural features can be approved for the same condition. Even after an orphan drug is approved, the FDA, EMA or other foreign regulator can subsequently approve the same drug with the same principal molecular structural features for the same condition if the regulator concludes that the later drug is safer, more effective, or makes a major contribution to patient care.

2.3 Risk Factors Related to Other Government Regulations

2.3.1 We are Subject to Healthcare Laws, Regulation and Enforcement. The Failure to Comply with these Laws could Harm our Results of Operations and Financial Conditions.

Our current and future operations may be directly, or indirectly through our customers and third-party payors, subject to various U.S. federal and state, EU, Japanese, Chinese, UK, Canadian and other jurisdictions' healthcare laws including anti-kickback statutes, anti-bribery, anti-corruption provisions, false claims acts, including the AKS, Food, Drug & Cosmetic Act, False Claims Act and more. Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. These laws may impact, among other things, our proposed sales, marketing and education programs and constrain our business and financial arrangements with third-party payors, healthcare professionals who participate in our clinical research programs, healthcare professionals and others who recommend, purchase, or provide our approved products, and other parties through which we market, sell and distribute our products for which we obtain marketing approval.

In addition, our current and future operations are subject to other healthcare-related statutory and regulatory requirements and enforcement by regulatory authorities in jurisdictions in which we conduct our business. For example, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medical products is generally not permitted in the countries that form part of the EU. Some EU Member States have enacted laws explicitly prohibiting the provision of these types of benefits and advantages to induce or reward improper performance generally, and the UK has enacted similar restrictions through the Bribery Act 2010. Infringements of these laws can result in substantial fines and imprisonment, as well as associated reputational harm. We are also subject to EU Directive 2001/83/EC and the Human Medicines Regulations 2012. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

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

that our policies and procedures will be followed at all times or will effectively detect and/or prevent all compliance violations by our employees, consultants, subcontractors, agents and partners.

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

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

2.3.2 All Aspects of our Business Ranging from Preclinical, Clinical Trials, Marketing and Commercialization are Highly Regulated and any Delay by Relevant Regulatory Authorities could Jeopardize our Development and Approval Process or Result in Other Suspensions, Refusals or Withdrawal of Approvals.

Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned IND applications in the

U.S. or Japan, or our CTAs in the UK or in the EU, or a comparable application in other jurisdictions. We cannot be sure that we will be able to submit INDs or CTAs or comparable applications for our preclinical programs on the timelines we expect, if at all. We also cannot guarantee that submission of INDs or CTAs or comparable applications will result in the MHRA, EMA, FDA, MHLW (collectively, the ***Relevant Regulatory Authorities***) or other regulatory authorities allowing clinical trials to even begin.

Clinical trials must be conducted in accordance with Relevant Regulatory Authorities and other applicable regulatory authorities' legal requirements and regulations and are subject to oversight by these governmental agencies and IRBs and ethics committees at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted in compliance with GCPs and with supplies of our products and product candidates produced under cGMPs and other regulations. We could encounter delays if a clinical trial is suspended or terminated, by us, by the IRBs or ethics committees of the institutions in which such clinical trials are being conducted, by the data review committee or data safety monitoring board for such clinical trial by the Relevant Regulatory Authorities or other comparable regulatory authorities. Such authorities may impose a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or clinical trial site by the Relevant Regulatory Authorities or other applicable authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, including those relating to the class to which our products and product candidates belong, failure to demonstrate a benefit from using the product or product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

If we experience delays in the completion of, or termination of, any clinical trial of our products or product candidates, the costs to our clinical trials will increase, the commercial prospects of our products and product candidates may be harmed, our ability to generate product revenues from any of these products and product candidates will be delayed and our product candidate development and approval process may be jeopardized. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our products and product candidates.

Moreover, we must obtain separate regulatory approvals in each jurisdiction where we want to market and approval by one regulatory authority does not ensure approval by any other regulatory authority. As approval procedures can vary among countries and may change over time, this can require additional clinical testing and the time required to obtain approval may differ. For instance, only VYVGART for the treatment of gMG has obtained regulatory approval in the VYVGART Approved Countries. Efgartigimod was recently awarded a positive scientific opinion under the Early Access to Schemes program by the MHRA. Zai Lab and Medison have submitted a request for approval of VYVGART in gMG in the PRC and Israel, respectively. We can provide no assurances that such approval will be obtained on the timeline that we expect or at all. In addition, we anticipate to file requests for approval of VYVGART in new indications, but can provide no assurances that such requests will be accepted or that we will receive approval on our anticipated timeline, or at all.

If VYVGART™ or any new formulations of VYVGART are not approved in one or more jurisdictions including beyond the VYVGART Approved Countries, or if such approvals are significantly delayed, it could have a material adverse effect on our business. It is possible that none of our other existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval in any other jurisdiction or indication.

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

- may withdraw an approval or revoke a license;
- may refuse to grant approval, or may require additional data before granting approval, notwithstanding that approval may have been granted by another comparable foreign authority;
- may approve a product candidate for fewer or more limited indications or patient sub-segments than requested; or
- may grant approval contingent on the performance of costly post-marketing clinical trials, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate; or
- may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

The costs of compliance with all Relevant Regulatory Authorities and applicable authorities regulations, requirements or guidelines could be substantial, and failure to comply could result in sanctions, including fines, injunctions, civil penalties, denial of applications for marketing authorization of our products, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly increase our collaborative partners' costs or delay the development and commercialization of our product candidates. At this time, we cannot guarantee or know the exact nature, precise timing and detailed costs of the efforts that will be necessary to complete the remainder of the development of our research programs and product candidates.

2.3.3 We are Subject to Privacy Laws, Regulation and Potential Enforcement. Our Failure to Comply with these Laws could Harm our Results of Operations and Financial Conditions.

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

The EU General Data Protection Regulation (***GDPR***) imposes a broad range of strict requirements on companies, including with respect to cross-border transfers of personal data. The GDPR allows the imposition of substantial penalties in the event of non-compliance, including fines of up to €10,000,000 or up to 2% of total worldwide annual turnover for certain comparatively minor offenses, or up to €20,000,000 or up to 4% of total worldwide annual turnover for more serious offenses. We face uncertainty as to the exact interpretation of the requirements under the GDPR, and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the GDPR.

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

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

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

Beyond the EU and UK, privacy and data protection laws and regulations continue to develop and expand around the world, including in other jurisdictions in which we operate, such as the U.S., Japan, and Canada. Such laws and regulations impose increasing restrictions and obligations on the processing of personal data, including sensitive personal data such as genetic data. For example, in the U.S., the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information and the California Consumer Privacy Act of 2018 imposes obligations on covered businesses, including, but not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. If we are investigated by a data protection authority, we may face fines and other penalties. Any such investigation or charges by such data protection authorities could have a negative effect on our existing business and on our ability to attract and retain new clients or pharmaceutical partners. We may also experience hesitancy, reluctance, or refusal by clients or pharmaceutical partners to continue to use our products and solutions due to the potential risk exposure as a result of the current (and, in particular, future) data protection obligations imposed on them by certain data protection authorities in interpretation of current law. Such clients or pharmaceutical partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally

uncertain, or otherwise objectionable and therefore decide not to do business with us. Any of the foregoing could harm our business, prospects, financial condition and results of operations.

2.3.4 Failure to Comply with Anti-Corruption Laws and Regulations, Anti-Money Laundering Laws and Regulations, Economic Sanctions, and/or Export Control Regulations could have an Adverse Impact on our Business.

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

We have mechanisms in place to ensure compliance with applicable anti-corruption, anti-money laundering, and economic sanctions rules and regulations. However, there can be no assurance that our policies and procedures will be followed at all times or will effectively detect and/or prevent violations of applicable compliance regimes by our employees, consultants, sub-contractors, agents and partners. As a result, in the event of non-compliance, we could be subject to substantial civil or criminal penalties, including economic sanctions against us, incarceration for responsible employees and managers, the possible loss of export or import privileges, reputational harm, and resulting loss of revenue and profits, which could have a material adverse impact on our business, financial conditions and operations.

2.3.5 We may Become Exposed to Liability and Substantial Expenses in Connection with Environmental Compliance or Remediation Activities.

Our operations, including our research, development, testing and third-party manufacturing activities, are subject to numerous environmental, health and safety laws and regulations and for which we may become liable.

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

Furthermore, environmental, health and safety laws and regulations are becoming more stringent. Our CMOs may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case, our production and development efforts may be interrupted or delayed, and our financial condition and results of operations may be materially adversely affected.

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

2.4.1 Failure to Successfully Identify, Select and Develop Efgartigimod in Other Indications, Additional Products or Product Candidates could Impair our Ability to Grow.

Our long-term growth strategy entails developing and marketing additional products and product candidates, including efgartigimod in new indications, which requires substantial resources, whether or not any product candidates or new indications are ultimately identified. The success of this strategy depends partly upon our ability to identify, select, develop, and ultimately, commercialize promising product candidates. We are heavily dependent on precise, accurate and reliable scientific data to identify, select and develop promising product candidates and products. Our business decisions may therefore be adversely influenced by improper or fraudulent scientific data sourced from third parties. Any irregularities in the scientific data used by us to determine our focus in research

and development of product and product candidates, could impair our ability to grow. Even with accurate scientific data, our technology platforms may fail to discover and to generate additional products and products candidates, that are suitable for further development.

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

2.4.2 VYVGART for the Treatment of gMG is our Only Product that has Obtained Regulatory Approval in the VYVGART Approved Countries. Our Other Products and Product Candidates – including Additional Indications or Methods of Use for Efgartigimod, ARGX-117 and ARGX-119 – are Either in Preclinical or Clinical Development or are Pending Marketing Approval.

To obtain the requisite regulatory approvals to market and sell any of our products and product candidates, we or our collaborators for such candidates must successfully demonstrate that our products are safe, pure, and effective in humans. Clinical trials are expensive and can take many years to complete, and their outcome is inherently uncertain. Further, success in early clinical trials or in one indication does not guarantee success in later clinical trials or in other indications.

The time required to obtain approval by the Relevant Regulatory Authorities is unpredictable but typically takes many years, if obtained at all, following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market any of our product candidates, including for new indications. We may experience delays in our ongoing or planned clinical trials, for a large variety of reasons outside our control in complying with regulatory approvals which can adversely affect the timing of trials, including as described in the header " – All aspects of our business ranging from preclinical, clinical trials, marketing and commercialization are highly regulated and any delay by relevant regulatory authorities could jeopardize our development and approval process or result in other suspensions, refusals or withdrawal of approvals."

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

2.4.3 Our Clinical Trials may Fail, and Even if they Succeed, we may not Obtain Regulatory Approval for our Products and Product Candidates or Regulatory Approval may be Delayed.

Even if clinical trials are initiated, our development efforts may not be successful. Many of our clinical trials are blinded, which may cause us to incur significant expenses without any visibility as to the likelihood of successful results. Even if we obtain positive results from preclinical studies or initial clinical trials, we may not achieve the same success in future trials.

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

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

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

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

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

sales and generate revenues. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates or result in the development of our product candidates being stopped early. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our products and product candidates.

2.4.4 If we Decide to Pursue Accelerated Approval for any of our Product Candidates, it may not Lead to a Faster Development or Regulatory Review or Approval Process and does not Increase the Likelihood that our Product Candidates will Receive Marketing Approval. If we are Unable to Obtain Approval Under an Accelerated Pathway, we may be Required to Conduct Additional Clinical Trials Beyond those that we Contemplate, Which could Increase the Expense of Obtaining, Reduce the Likelihood of Obtaining, and/or Delay the Timing of Obtaining, Necessary Marketing Approvals.

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

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

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

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

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

2.4.5 Our Products and Product Candidates may have Serious Adverse, Undesirable or Unacceptable Side Effects or Even Cause Death, and we or Others may Identify Undesirable or Unacceptable Side Effects Caused by VYVGART or any of our Products or Product Candidates After they have Received Marketing Approval.

Undesirable side effects that may be caused by our product candidates, or by the combination of our product candidates with other medical products could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in more restrictive labeling or the delay or denial of regulatory approval by the Relevant Regulatory Authorities. While our preclinical studies and clinical trials for our product candidates to date show that our product candidates have generally been well tolerated from a risk-benefit perspective, we have observed adverse events and TEAEs in our clinical trials to date, and we may see additional adverse events and TEAEs in our ongoing

and future clinical trials. Such side effects may be more serious than those observed to date, and as a result, our ongoing and future clinical trials may be negatively impacted. Moreover, as we seek to develop product candidates, including products in new indications, patients may experience new or more serious effects. Drug-related side effects could affect patient recruitment, the ability of enrolled patients to complete the clinical trial, result in potential product liability claims, damage sales of our existing products, result in significant reputational damage for us and our product development, and other issues including the delay of other programs.

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

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

Any of these events could negatively impact us, our collaborators or our potential future partners. Further, we are developing an SC formulation of efgartigimod co-formulated with rHuPH20, an SC drug delivery technology, for the treatment of gMG and other indications, and side effects or adverse events associated with rHuPH20, may affect multiple of our products, and our product candidates. Further, the Relevant Regulatory Authorities could require a change of label or even revoke the license, which could harm our reputation and have a material adverse effect on our ability to commercialize VYVGART.

2.4.6 If our Target Patient Population is Smaller than Expected, we are Unable to Successfully Enroll and Retain Patients in our Clinical Trials, or Experience Significant Delays in Doing so, we may not Realize the Full Commercial Potential of any Products or Product Candidates.

Currently, we mainly develop products or product candidates for the treatment of rare diseases for which the target patient population can be small. If the actual number of

patients with these disorders is smaller than we expected, we may encounter difficulties in enrolling sufficient patients in our clinical trials, thereby delaying or preventing development and approval of our products or product candidates. Physicians, who are an important source of referral of patients for clinical trials, may also be less familiar with these rare diseases and may therefore fail to identify these conditions in their patients and therefore may not refer them to our clinical trials.

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

Even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our clinical trials. In addition, any negative results we may report in clinical trials of our drug candidates may make it difficult or impossible to recruit and retain patients in other clinical trials of that same drug candidate. Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, some of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

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

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

2.5.1 We Rely, and Expect to Continue to Rely, on Third Parties to Conduct Some of our Research Activities and Clinical Trials and for Parts of the Development and Commercialization of our Existing and Future Research Programs, Products and Product Candidates. If our Relationships with such Third Parties are not Successful, our Business may be Adversely Affected.

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators, CROs, CMOs and other third-party service providers, to assist us in the conduct of certain of our research activities and clinical trials and to monitor and manage data for our ongoing preclinical studies and clinical trials. We also depend on our collaborators and on medical institutions and CROs to conduct our research activities and clinical trials in compliance with regulatory and legal requirements, including GCPs or GMPs, our standard operating procedures and our applicable protocols. Nevertheless, we are responsible for ensuring that each of our studies and clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. To the extent our collaborators or the CROs or investigators fail to enroll participants for our clinical trials, fail to conduct the clinical trial to GCP standards or in full compliance with legal and regulatory requirements or are delayed for a significant time in the execution of clinical trials, including achieving full enrollment, we may be affected by increased costs, program delays or both, which may harm our business.

In addition, we are, and expect to continue to be, dependent on partnerships with partners and licensees relating to the development and commercialization of our existing and future research programs, products and product candidates. We currently have collaborative research relationships with various pharmaceutical companies such as AbbVie, Zai Lab and with various academic and research institutions worldwide for the development of product candidates resulting from such collaborations. We also have distribution agreements with Medison and Genpharm for the distribution of VYVGART. We had, have and will continue to have discussions on potential partnering opportunities with various pharmaceutical companies. If we fail to enter into or maintain collaborations on reasonable terms or at all, our ability to develop our existing or future research programs and product candidates and to commercialize our existing or future

products could be delayed, the commercial potential of our products could change and our costs of development and commercialization could increase.

While we have agreements governing our relationships with these third parties, we have limited influence over their actual performance and control only certain aspects of their activities. If independent investigators, third-party service providers or CROs fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of any product candidates that we develop. In addition, regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we, our investigators or any of our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the Relevant Regulatory Authorities or comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Upon inspection by a given regulatory authority, such regulatory authority may determine that our clinical trials do not fully comply with GCP regulations, which may require us to repeat clinical trials and delay the regulatory approval process. Our collaborative partners may not adhere or terminate collaboration agreements with all associated consequences or disagree on the interpretation of contractual terms. We may not be able to control our collaborative partners' compliance with all applicable requirements for the commercialization of our products, which could adversely affect such commercialization and the profitability of such products. Failures by our collaborative partners to meet their contractual, regulatory, or other obligations to us or any disruption in the relationships between us and our collaborative partners, could have a material adverse effect on our product pipeline and business.

We face significant competition in establishing successful relationships with third-party service providers and appropriate collaborative partners. These third-party service providers may have contractual relationships with other entities, some of which may be our competitors, which may draw their time and resources away from our programs. In addition, some of our third-party service providers or CROs have the ability to terminate their respective agreements with us, and if such agreements terminate, we may not be able to enter into arrangements with alternative CROs or investigators or to do so on commercially reasonable terms. In addition, we may not be able to find appropriate collaboration partners. Our ability to reach a definitive agreement for a partnership will depend, among other things, upon an assessment of the collaborator's resources and expertise, the terms and conditions of the proposed partnership and the proposed collaborator's evaluation of a number of factors. These factors may include the design or results of clinical trials, the likelihood of regulatory approval, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership regardless of the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a partnership could be more attractive than the one with us.

2.5.2 Disruptions Caused by our Reliance on Third Parties for our Manufacturing Process may Delay or Disrupt our Business, Product Development and Commercialization Efforts.

We do not have the ability to internally source the raw materials necessary to produce our product or product candidates, and do not currently have, nor do we plan to acquire, the infrastructure or capability internally to manufacture our products or product candidates and depend on a worldwide supply chain and third parties for both. Disruptions caused by our reliance on such third-party suppliers, service providers and manufacturers may delay or disrupt our business, product development and commercialization efforts.

Reliance on Third-Party Suppliers and Service Providers

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

Additionally, certain of the raw materials required in the manufacture and the formulation of our products and product candidates may be derived from biological sources, including mammalian tissues, bovine serum and human serum albumin. There are certain European regulatory restrictions on using these biological source materials including rigorous testing requirements, which could limit or delay production. If there are changes in the regulation requirements that our suppliers are unable to meet, our clinical development or commercial activities may be delayed or interrupted.

We may not be able to engage a back-up or alternative supplier or service provider in a timely manner or at all if any of these third parties were to cease or interrupt production or otherwise fail to supply these materials, products, or services to us for any reasons, including due to regulatory requirements or actions (including recalls), adverse financial developments at or affecting the supplier, failure by the supplier to comply with cGMPs, contamination, business interruptions, or labor shortages or disputes. Interruptions in the supply of these materials, products or services may also result from international conflict, trade disputes or economic sanctions enacted by, or imposed on, the U.S., the UK, the EU or any other country or region.

Reliance on Third-Party Manufacturing

We rely on and expect to continue to rely on CMOs. We also rely on certain third parties to perform filling, finishing, distribution, laboratory testing and other services related to the manufacture of our products and product candidates.

Although we do not control the manufacturing process at our CMOs and are completely dependent on them for the production of our products and product candidates in

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

We contract with Lonza based in Slough, UK, Portsmouth, U.S. and Singapore and Fujifilm for activities relating to the development of cell banks, development of our manufacturing processes and the manufacturing of drug substance, and use additional contract manufacturers to fill, test, label, package, store and distribute our (investigational) drug products. Our products and product candidates are biologics and require multiple processing steps that are more difficult than those required for most small molecule chemical pharmaceuticals. Problems with these manufacturing processes, such as capacity issues, or even minor deviations from the normal process or from the materials used in the manufacturing process, which may not be detectable by us in a timely manner, could lead to manufacturing failures or product defects, resulting in lot failures, product recalls, product liability claims and insufficient inventory.

We face risks inherent in relying on limited CMOs, as any failure in their ability to successfully manufacture our products or product candidates as described above or any disruption, such as a fire, pandemic, natural hazards or vandalism at the CMO could significantly interrupt our manufacturing capability. Alternative production plans in place or disaster-recovery facilities available to us may not be sufficient. In case of a disruption, we may have to establish additional alternative manufacturing sources. This would require substantial investment on our part, which we may not be able to obtain on commercially acceptable terms or at all. Additionally, we may experience significant manufacturing delays as we build or locate replacement facilities and seek and obtain necessary regulatory approvals. If this occurs, we will be unable to satisfy manufacturing needs on a timely basis, if at all. Also, operating any new facilities may be more expensive than operating at our current facilities. Further, business interruption insurance may not adequately compensate us for any losses that may occur, and we would have to bear the additional cost of any disruption. For these reasons, a significant disruptive event of the manufacturing facility could have drastic consequences, including placing our financial stability at risk.

2.5.3 Accuracy and Timing of our Financial Reporting is Partially Dependent on Information Received from Third-Party Partners, Which we do not Control.

We have collaborated, and plan to continue to collaborate, with third parties, including distributor and licensing partners, on certain product candidates. As part of some of these collaborations, our collaboration partners are responsible for providing us with financial information regarding specific projects, including funds spent, liabilities incurred and expected future costs, on which we rely for our own financial reporting. If our collaboration partners fail to provide us with the necessary financial information within the agreed upon timeframes, or if such financial information proves inaccurate, it would adversely impact the timing and accuracy of our own financial reporting. Any inaccuracy in our financial reporting could cause investors to lose confidence in our financial reporting. This in turn may lead to reputational damage or affect our ability to obtain, and the terms of, any future financing, which may harm our business.

2.5.4 We and our Third-Party Manufacturers and Suppliers may Become Exposed to Liability, Fines, Penalties or Other Sanctions and Substantial Expenses in Connection with Environmental Compliance or Remediation Activities.

Our and our third-party manufacturers and suppliers operations, including research, development, testing and manufacturing activities, are subject to numerous environmental, health and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, handling, release and disposal of and the maintenance of a registry for, hazardous materials and biological materials, laboratory procedures and exposure to pathogens. We do not have control over our manufacturers' or suppliers' compliance with environmental, health and safety laws and regulations. If we, or they fail to comply with such laws and regulations, we could be subject to liability, fines, penalties or other sanctions and incur substantial expenses to comply or remediate the activities.

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

2.6 Risk Factors Related to argenx's Business and Industry

2.6.1 Our Employees may Engage in Misconduct or Other Improper Activities, Including Noncompliance with Regulatory Standards and Requirements, or Consider Trading Violations, Which could Significantly Harm our Business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with governmental regulations, comply with healthcare fraud and abuse and anti-kickback laws and regulations in the U.S. and other markets, or failure to report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of, including improper trading based upon, information obtained in the course of clinical studies, which could result in regulatory sanctions and serious harm to our reputation. We maintain a global compliance program and remain focused on its evolution and enhancement. Our program includes efforts such as risk assessment and monitoring, fostering a culture encouraging employees and third parties to raise good faith questions or concerns, and defined processes and systems for reviewing and remediating allegations and identified potential concerns. It is not always possible, however, to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

2.6.2 We may Become Exposed to Costly and Damaging Liability Claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products and marketing of human therapeutic products. The current and future use of products and product candidates by us and our collaborators in clinical trials and the sale of any approved products may further expose us to liability claims. If any of our

products or product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. These claims might be made by patients who use the product, healthcare providers, pharmaceutical companies, physicians, payors, caregivers, investors, employees, government agencies, or our collaborators or others selling such products. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially adversely affect the market for our products and product candidates or any prospects for commercialization of our products and product candidates. Any such claims, regardless of their merit, could also adversely affect our reputation and the trust that physician and patients place in our products.

Regardless of the merits or eventual outcome litigation or liability claims may result in:

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

Although we maintain product liability insurance, we may not be able to maintain insurance coverage at a reasonable cost or to obtain adequate insurance coverage to satisfy any liability that may arise. Product liability claims could delay or prevent completion of our clinical development programs. In addition, claims made by patients, healthcare professionals or others might not be fully covered by product liability insurance and could result in investigations of the safety of our products or product candidates or may result in recalls. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business, financial condition and results of operations would be adversely affected.

2.6.3 We may Engage in Strategic Transactions, Including Acquisitions, Collaborations, Licenses or Investments in Other Companies or Technologies, and we may not Realize the Benefits of such Transactions.

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

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

2.6.4 Our Business and Operations Could Suffer in the Event of System Failures or Unauthorized or Inappropriate Use of or Access to our Systems.

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

be vulnerable to such attacks or may be breached, including due to employee error or malfeasance.

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

2.6.5 We are Highly Dependent on Public Perception of our Products.

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

2.7 Risk Factors Related to argenx's Intellectual Property

2.7.1 Failure to Adequately Enforce or Protect our Intellectual Property Rights in Products, Product Candidates and Platform Technologies could Adversely Affect our Ability to Develop and Market our Products and Product Candidates.

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

We cannot be certain that patents will be issued or granted with respect to applications that are currently pending. The scope of patent protection that the European Patent Office and the U.S. Patent and Trademark Office (***USPTO***) will grant with respect to the antibodies in our product pipeline is uncertain and may vary by jurisdiction. It is possible that the European Patent Office and the USPTO will not allow broad antibody claims that cover antibodies closely related to our products and product candidates as well as the specific antibody. As a result, upon receipt of EMA or FDA approval, competitors may be free to market antibodies almost identical to ours thereby decreasing our market potential.

We and our current or future licensors, licensees or collaboration partners may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Further, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors', licensees' or collaboration partners' patent rights are highly uncertain. Moreover, in some circumstances, we may need to rely on patent procurement activities of our licensors, licensees or collaboration partners or obtain additional costly licenses. Such parties may not fully comply with applicable patent rules or disagree with us as to the prosecution, maintenance or enforcement of any patent rights. Even if patents do issue and such patents cover our products and product candidates, third parties may initiate proceedings challenging the validity, enforceability or scope of such patents, which may result in the patent claims being narrowed or invalidated. Our and our licensors', licensees' or collaboration partners' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology.

Furthermore, because patent applications are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our licensors were the first to file any patent application related to a product and product candidate. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing our invention where the other party can show that they used the invention in commerce before our filing date, or if the other party is able to obtain a compulsory license. Any of the aforementioned situations could cause harm to our ability to protect our intellectual property, which in turn would allow competitors to market comparable products which could materially adversely affect our competitive position and as such our business, financial condition and results of operation.

We enjoy only limited geographical protection with respect to certain patents and may face difficulties in certain jurisdictions. We often file our first patent application (i.e., priority filing) at the UK Intellectual Property Office, the European Patent Office or the USPTO. International applications under the Patent Cooperation Treaty are usually filed within twelve months after the priority filing. We have so far not filed for patent protection in all national and regional jurisdictions where such protection may be available. If we fail to timely file a patent application in any such country or major market, we may be precluded from doing so at a later date. In addition, the grant proceeding of each national/regional patent may lead to situations in which applications might in some jurisdictions be refused by the relevant patent offices, while granted by others. Furthermore, competitors may use our and our licensors' or collaboration partners' technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we and our licensors or collaboration partners have patent protection, but enforcement is not as strong as that in the U.S., UK and the EU. Finally, some countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties, and other countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent.

2.7.2 Issued Patents could be Found Invalid or Unenforceable if Challenged in the Applicable Patent Office or Court.

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

To protect our competitive position, we may from time to time need to resort to litigation in order to enforce or defend any intellectual property rights owned by or licensed to us, or to determine or challenge the scope or validity of intellectual property rights of third parties. Enforcement of intellectual property rights is difficult, unpredictable and expensive, and many of our or our licensors' or collaboration partners' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors or collaboration partners can.

In addition, litigation involving our patents carries the risk that one or more of our patents will be held invalid or held unenforceable. Such an adverse court ruling could allow third parties to commercialize our products or use our platform technologies, and then compete directly with us, without payment to us.

2.7.3 We may be Subject to Claims Challenging the Inventorship or Ownership of our Intellectual Property or be Required to Make Additional Payments to Secure Intellectual Property from Collaborators.

Many of our consultants and employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these consultants and employees executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our consultants and employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these consultants and employees have used or disclosed confidential information or intellectual property of any such consultant's or employee's former employer or have breached their non-competition agreement. Additionally, many of our collaborators do not commit to assigning all intellectual property arising out of the collaboration to us and, instead, grant us options to acquire intellectual property or commit to making such intellectual property available to us at a fair price. As such, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our products and product candidates.

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

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

2.7.4 Third-Party Intellectual Property Rights could Adversely Affect our Ability to Commercialize our Products and Product Candidates.

Our competitive position may suffer if third-party intellectual property rights cover our products or product candidates or our manufacture or uses relevant to our development plans. In such cases, we may not be in a position to develop or commercialize products or product candidates unless we successfully pursue costly and time-consuming litigation to nullify or invalidate the third-party intellectual property right concerned or enter into a license agreement with the intellectual property right holder. We are aware of certain U.S. issued patents held by third parties that arguably cover certain aspects of our product candidates, including cusatuzumab. One such third-party patent family of potential relevance to cusatuzumab is scheduled to expire in 2028. In the event that a patent has not expired at the time of approval of such product candidate and the patent owner were to bring an infringement action against us, we may have to argue that our product, its manufacture or use does not infringe a valid claim of the patent in question. Alternatively, if we were to challenge the validity of any issued U.S. patent in court, we would need to overcome a statutory presumption of validity that attaches to every U.S. patent. In the event that a patent is successfully asserted against us such that the patent is found to be valid and enforceable and infringed by our product, unless we obtain a license to such a patent, we could be prevented from continuing to develop or commercialize our product. Similarly, other companies have filed patent applications or have patents on the targets for certain of our products or their uses. There can be no assurance any such patents will not be asserted against us or that we will not need to seek licenses from such third parties.

It is also possible that we are unaware of relevant patents or applications or of relevant scientific discoveries. In general, patent applications in the U.S. and elsewhere are published approximately 18 months after the earliest filing from which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Additionally, publications of discoveries in scientific literature often lag behind the actual discoveries. Therefore, patent applications covering our products, product candidates or platform technology could have been filed by others and relevant discoveries may have been made without our knowledge. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our products or platform technologies.

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

If we fail in any such dispute, we or our licensees may be temporarily or permanently prohibited from commercializing any of our products and product candidates that are held to be infringing. We might, if possible, also be forced to redesign products and product candidates so that we no longer infringe the third-party intellectual property rights. We may be required to seek a license to any such technology that we are found to infringe, which license may not be available on commercially reasonable terms, or

at all. Even if we or our licensors or collaboration partners obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors or collaboration partners. In addition, if the breadth or strength of protection provided by our or our licensors' or collaboration partners' patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current products and product candidates. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

2.7.5 We may not be Successful in Obtaining or Maintaining Necessary Rights to our Products and Product Candidates Through Acquisitions and In-Licenses.

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

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

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment, in which case we may have to abandon development of that product candidate or program.

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

Further, if disputes over intellectual property that we have licensed or our associated obligations prevent or impair our ability to maintain our current licensing arrangements

on acceptable terms, we may be unable to successfully develop and commercialize the affected products and product candidates.

2.7.6 If our Trademarks and Trade Names are not Adequately Protected, we may not be Able to Build Name Recognition in our Markets of Interest.

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

2.7.7 We may not be Able to Obtain Protection Under the Hatch-Waxman Act and Similar Non-U.S. Legislation for Extending the Term of Patents Covering Each of our Products and Product Candidates.

Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act and similar legislation in the EU and the Asia Pacific region. The Hatch-Waxman Act permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. The patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent applicable to an approved drug may be extended. However, we may not receive an extension if we fail to apply within applicable deadlines or prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce

our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner than we expect.

2.7.8 Changes in Patent Laws or Patent Jurisprudence could Diminish the Value of Patents in General, Thereby Impairing our Ability to Protect our Products.

Changes in patent law and regulations in the various countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces them may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Such changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

2.7.9 We may be Unable to Protect the Confidentiality of our Trade Secrets and Know-How.

In addition to patent protection, we rely on trade secret protection for our proprietary information, including, for example, certain aspects of our llama immunization and antibody affinity maturation approaches. However, trade secrets are difficult to protect, and we have limited control over the protection of trade secrets used by our numerous licensors, collaborators and suppliers.

We require our employees, consultants, advisors and potential collaborators to enter into confidentiality agreements. Moreover, we put in place appropriate procedures to identify confidential material and restrict access to documentation. However, current or former employees, consultants, advisors and potential collaborators may unintentionally or willfully disclose our confidential information to competitors despite these procedures or in violation of our confidentiality agreements. In addition, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known to our competitors or inadvertently incorporated into the technology of others. Any disclosure, either intentional or unintentional, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements.

Enforcing a claim that a third party illegally obtained and is using trade secrets is expensive, time-consuming and the outcome is unpredictable, and the enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. Moreover, if

any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us.

2.8 Risk Factors Related to argenx's Organization and Operations

2.8.1 Our Future Growth and Ability to Compete Depends on Retaining our Key Personnel and Recruiting Additional Qualified Personnel.

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

As a Dutch company listed on Euronext Brussels in addition to Nasdaq, our remuneration practices and policies may be limited by local governance rules or shareholder guidance for EU companies. Such limitations may make it more difficult to successfully compete for key talent in a number of markets that have differing remuneration practices and policies as we are bound by more restrictive remuneration practices than our competitors. For example, the Dutch Corporate Governance Code 2016 (***DCGC***) places certain limitations on the ability to grant equity incentives to non-executive directors, while Belgian law requires non-executive directors to receive part of their remuneration in the forms of shares, but not stock options. The DCGC also places limitations on amount of severance payment permitted in the event of dismissal. In addition, the U.S. has proposed legislation that imposes restrictions on our ability to prevent departing employees from competing with us following their departure. If finalized, such legislation could also adversely affect our ability to retain employees who may go to competitors with more resources than us and who are not bound by similar remuneration policies.

Many other biotechnology and pharmaceutical companies and academic institutions that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. Additionally, an inflationary environment, combined with the tight labor market for the recruitment and retention of skilled workers, could make it more costly for us to attract

or retain employees. In order to meet the compensation expectations of our prospective and current employees due to inflationary factors, we may be required to increase our operating costs. Therefore, we might not be able to attract or retain these key persons on conditions that are economically acceptable.

2.8.2 Global Geo- and Socio-Political Threats and Macro-Economic Uncertainty and Other Unforeseen Political Crises could Materially and Adversely Affect our Business and Financial Performance.

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

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

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

- the destruction or disruption of our data centers or our critical business or information technology systems; or
- the ability to submit data collected at Russian or Ukrainian sites due to the incompleteness or the fact that auditing by regulatory authorities was not fully possible.

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

2.8.3 We Face Risks Related to Natural Disasters and Public Health Issues, such as the COVID-19 Pandemic, that could Negatively Affect our Business and Financial Condition.

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

For example, the manufacturing of all of our products and product candidates requires using cells which are stored in a cell bank. We have one master cell bank for each product manufactured in accordance with cGMPs. However, it is possible that we could lose multiple cell banks and have our manufacturing significantly impacted by the need to replace these cell banks, which could materially adversely affect our business, prospects, financial condition and results of operations.

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

pandemic or otherwise, we would not be entitled to some or all of the future payments which we are eligible to receive under the collaboration agreement with such partner.

The COVID-19 pandemic has also impacted third parties in a number of different ways. For example, we were informed by our drug substance and drug product manufacturing partners about potential limitations in the availability of critical manufacturing materials due to the demand outweighing the available manufacturing capacity for these materials and prioritizations imposed by the U.S. government on the manufacturing of COVID-19 vaccines and therapeutics. Moreover, as of the date of this Annual Report, the FDA is subject to ongoing travel restrictions that impact FDA oversight operations. Should the FDA determine that an inspection is necessary for approval of a marketing application and an inspection cannot be completed during the review cycle due to restrictions on travel, the FDA has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. While the number of FDA inspection-related delays decreased in 2022, there is a risk that such delays may occur again. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. Such restrictions and delays could adversely affect our ability to obtain regulatory approval for and to commercialize our products and product candidates and have a material adverse effect on our business and financial results.

2.8.4 We may Encounter Difficulties Efficiently Managing our Growth and our Increasing Development, Regulatory and Sales and Marketing Capabilities, which could Disrupt our Operations.

We have grown significantly in the number of employees and scope of operations over recent years and expect to experience significant growth in the number of our employees and the scope of our operations also in the near future, particularly in the areas of drug research, drug development, regulatory affairs and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. In particular, we must efficiently leverage our own sales and marketing capabilities in order to launch or market our products candidates effectively.

Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. Our limited financial, manufacturing and management resources, could cause us to forgo or delay the pursuit of opportunities with potential product candidates that later prove to have greater market potential, fail to capitalize on viable commercial products or profitable market opportunities or relinquish rights to such product candidates through collaborations, licensing or royalty arrangements in circumstances where it would have been more advantageous for us to retain sole development and commercialization rights. Any inability to manage growth could delay the execution

of our strategic objectives or disrupt our operations, which in turn could materially harm our business and prospects.

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

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

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

The determination of our provision for income taxes and other tax liabilities requires significant judgment, including the adoption of certain accounting policies and our determination of whether our deferred tax assets are, and will remain, fully available in future periods. We cannot guarantee that our interpretation of applicable tax laws or our structure will not be questioned by the relevant tax authorities, or that the relevant tax laws and regulations, or the interpretation thereof, including through tax rulings,

by the relevant tax authorities, will not be subject to change. Any adverse outcome of such a review or change in law may lead to adjustments in the amounts recorded in our financial statements and could have a materially adverse effect on our operating results and financial condition.

Dealings between current and former group companies as well as additional companies that may form part of our group in the future are subject to transfer pricing regulations, which may be subject to change and could affect us. Compliance with these laws and regulations will be more challenging as we expand our international operations, including in connection with potential approvals of our products and product candidates in Europe, the U.S. and elsewhere.

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

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

In addition, we may not be able to use, or changes in tax regulations may affect the use of, certain unrecognized tax assets or credits that we have built over the years. For instance, we have considerable material tax assets in Belgium and some of these tax assets may be forfeited in whole, or in part, as a result of various transactions, including corporate reorganizations or transactions relating to our shareholding structure, or their utilization may be restricted by statutory law in the relevant jurisdiction.

3 Corporate Governance

3 Corporate Governance

3.1 Dutch Corporate Governance Code "Comply or Explain"

As a Dutch company, we are subject to the DCGC. A copy of the DCGC can be found on **www.mccg.nl** .The DCGC is based on the notion that a company is a long-term alliance between the various stakeholders of the company. Stakeholders are groups and individuals who, directly or indirectly, influence – or are influenced by – the attainment of our objectives: employees, shareholders and other lenders, suppliers, customers and other stakeholders. Our Board of Directors has responsibility for weighing these interests, generally with a view to ensuring our and our subsidiaries' continuity of us and our subsidiaries, as we seek to create long-term value. If stakeholders are to cooperate within and with the company, they need to be confident that their interests are duly taken into consideration. Good entrepreneurship and effective supervision are essential conditions for stakeholder confidence in management and supervision. This includes integrity and transparency of the actions of, and accountability for the supervision by, the Board of Directors.

The DCGC is based on a "comply or explain" principle. Accordingly, companies are required to state the extent to which they comply with the principles and best practice provisions of the DCGC in their annual report and, where they do not comply with them, why and to what extent they deviate from them.

We acknowledge the importance of good corporate governance and we fully endorse the underlying principles of the DCGC, which is reflected in a policy that complies with the best practice provisions as stated in the DCGC (the ***Board By-Laws***). The Board By-Laws are available on our website (**www.argenx.com/investors**). However, we deviate from the best practice provisions in the areas set out below, for the reasons explained in this section. These deviations all relate to our remuneration practices, which are in line with our remuneration policy as approved by our annual general meeting of shareholders held in 2021 (***2021 General Meeting***).

- Pursuant to best practice provisions 3.1.2 under vi of the DCGC, shares should be held for at least five years after they are awarded. In accordance with our remuneration policy, pursuant to our equity incentive plan (***Equity Incentive Plan***), restricted stock units (***RSUs***) vest in four equal tranches, which means that one fourth of the RSUs granted are settled at each anniversary of the date of grant, and no lock-up period applies to any shares acquired at such settlement, except as may be applicable pursuant to our minimum equity holding guidelines for directors and senior management personnel further specified in section 3.4.2 "**Changes to our remuneration practices in response to shareholder dissent**". Our Equity Incentive Plan was crafted recognizing that equity incentives are an important factor in the key jurisdictions in which we operate for attracting and retaining qualified personnel. The Equity Incentive Plan is regularly reviewed by our Board of Directors and our remuneration and nomination committee in particular, based on external benchmarking done by an independent third party. The main purpose of such review

and benchmark is to test whether the Equity Incentive Plan, including the type, size and conditions of grants and their vesting and exercisability thereunder, is fair and competitive in the key markets where we compete for talent and as such can support our ability to attract and retain talent in such markets. Hence, we deviate from best practice provision 3.1.2 under vi to allow for a competitive equity incentive plan. At the same time, we believe our current Equity Incentive Plan promotes long-term value creation. For instance, the four-year vesting period of the RSUs ensures that a RSU package granted cannot be fully settled within four years after the grant date. In 2021, our Board of Directors amended our Equity Incentive Plan in line with our updated remuneration policy, adding specifically the granting of RSUs to the equity incentive scheme and including the aforementioned vesting schemes. In 2023, our Board of Directors adopted equity holding guidelines for our Board of Directors and senior management team. Considering the importance of competitive remuneration for our ability to attract and retain highly qualified persons, alignment with the reference group is prioritized over compliance with this best practice provision 3.1.2. We will continue to review our Equity Incentive Plan conditions against our reference group, and if our benchmark exercise shows that a five-year lockup period as prescribed by the DCGC becomes competitive practice in our key talent markets, we will consider adhering in full to this best practice principle.

- Pursuant to best practice provision 3.2.3. of the DCGC, the severance payment in the event of dismissal should not exceed one year's base compensation. Our remuneration policy provides that a severance payment equal to 18 months base compensation to our chief executive officer (***CEO***). The severance component of the remuneration package is, like all other components, benchmarked against and aligned with the severance components as identified within the reference group. On this topic, considering the importance of competitive remuneration for our ability to attract and retain highly qualified persons, alignment with the reference group is prioritized over compliance with this best practice provision 3.2.3. We currently do not envision to change our practice in this respect.

- Pursuant to best practice provision 3.3.2. of the DCGC, non-executive directors should not be granted any shares or rights to shares as remuneration. We note that the 'best practices' and usages regarding granting equity incentives to non-executive directors vary significantly between the key jurisdictions in which we operate. For example, we conduct a significant part of our operations in Belgium and the Belgian Corporate Governance Code requires that non-executive directors receive part of their remuneration in the form of shares, but not stock options. Our benchmarking confirms that offering equity incentives to non-executive directors in the form of options and/or shares is on the other hand widely accepted market practice in the U.S., with over 90% of our U.S. reference group companies granting stock options to directors (benchmark of September 2022). We believe it is in the interest of our stakeholders that we are equipped to recruit the talent on our Board of Directors proportionate to our international ambitions. For this reason, we aligned our remuneration practices with those prevalent in the key markets in which we need to compete for talent. Considering specifically our significant activities in the U.S. and the specialized knowledge and experience needed on our Board of Directors to maximize our chances of success in this region, we need to align our remuneration practices for non-executive directors with the U.S. companies in our reference group, meaning we offer share options and/or restricted share units to our non-executive

directors. We believe this is a conscious and well-considered deviation from the DCGC that is required to serve our long-term global goals and ambitions. On this topic, considering the importance of competitive remuneration for our ability to attract and retain highly qualified persons, alignment with the reference group is prioritized over compliance with this best practice provision 3.3.2. We currently do not envision to change our practice in this respect, unless the practice in our reference group changes. If our benchmark exercise shows that offering only cash (no equity incentives) or equity excluding stock options becomes competitive practice in our key markets, we will consider adhering in full to this best practice principle.

3.2 Management Structure

3.2.1 General

We have a one-tier board structure consisting of one executive director and eight non-executive directors (as of December 31, 2022), and a senior management team (consisting of our CEO and senior personnel reporting directly to the CEO) responsible for the day-to-day operations. We have opted for this structure to allow for a division of responsibilities between our Board of Directors and our senior management team, keeping our Board of Directors at a manageable size whilst being able to involve some or all members of our senior management team in discussions with the Board of Directors if and when necessary.

In practice, all members of our senior management team are regularly involved in the discussions of our Board of Directors and its committees, in order to provide information and context to the various issues the Board of Directors needs to decide on. In addition to being present at meetings from time to time, our senior management and other senior leaders in the organization keep regular contact (face to face or via electronic means) with members of the Board of Directors and its committees.

Set out below is a summary of certain provisions of Dutch corporate law as of the date of this Annual Report, as well as a summary of relevant information concerning our Board of Directors and certain provisions of our articles of association (***Articles of Association***) and Board By-Laws (terms of reference) concerning our Board of Directors.

This summary does not purport to give a complete overview and should be read in conjunction with and is qualified in its entirety by reference to the relevant provisions of Dutch law as in force on the date of this Annual Report, the Articles of Association and Board By-Laws. The Articles of Association are available in the governing Dutch language and an unofficial English translation thereof, and the Board By-laws are available in English, on our website.

3.2.2 Statement of the Board of Directors

Responsibilities for the Financial Statements and Management Report

In accordance with Article 5:25c(2)(c) of the Dutch Financial Supervision Act (Wet toezicht financiële verslaggeving) (***DFSA***), the Board of Directors hereby certifies that, to the best of our knowledge, our consolidated financial statements as of December 31, 2022, prepared in accordance with International Financial Reporting Standards (***IFRS***) as adopted by the EU, and with the legal requirements applicable in the Netherlands, give a true and fair view of the assets, liabilities, financial position and profit or loss of the company and the undertakings included in the consolidation taken as a whole, and that the management report includes a fair review of the development and performance of the business and the position of argenx and the undertakings included in the consolidation taken as a whole, together with a description of the principal risks and uncertainties that they face.

Responsibility for this Annual Report

The Board of Directors declares that the information contained in this Annual Report, including our consolidated financial statements as of December 31, 2022 and the management report, is, to the best of its knowledge, in accordance with the facts and contains no omission likely to affect its import. The Board of Directors is responsible for the information given in this Annual Report.

In Control Statement

Our Board of Directors is responsible for the oversight of our risk management activities and has specifically designated the audit and compliance committee to assist our Board of Directors in this task and prepare recommendations in this respect to the Board of Directors. While our Board of Directors oversees our risk management, our senior management is responsible for day-to-day risk management processes. Our Board of Directors expects our senior management to consider risk and risk management in each business decision, to proactively develop and monitor risk management strategies and processes for day-to-day activities and to effectively implement risk management strategies adopted by the Board of Directors. We believe this division of responsibilities is the most effective approach for addressing the risks we face.

See section 3.5 "**Risk Appetite & Control**" for further information on our risk appetite and control.

3.2.3 Board of Directors

Responsibilities

Under Dutch law (Section 2:129 paragraph 1 of the Dutch Civil Code (***DCC***)), our Board of Directors is collectively responsible for our general affairs. Our Board of Directors, our executive director as well as our non-executive directors, define our strategy (as further set out in section 1.2 "**Strategy and Objectives**"). Our strategy is regularly discussed and monitored at our Board of Directors meetings.

Pursuant to our Articles of Association, our Board of Directors will divide its duties among its members, with our day-to-day management entrusted to the executive director(s). The non-executive directors are tasked with supervising our management and advising the executive director(s). In addition, both the executive director(s) and

the non-executive directors must perform the duties assigned to them pursuant to the Articles of Association. The division of tasks within our Board of Directors is determined (and amended, if necessary) by our Board of Directors. Our executive director(s) may not (i) serve as chairperson of our Board of Directors; (ii) determine the remuneration of an executive director or (iii) nominate directors for appointment.

Each director has a duty to properly perform the duties assigned to him or her and to act in our corporate interest. Under Dutch law, the corporate interest extends to the interests of all corporate stakeholders, such as shareholders, creditors, employees and other stakeholders.

Composition, Appointment and Dismissal

The Articles of Association provide that our Board of Directors will consist of our executive director(s) and non-executive directors. The number of executive directors must at all times be less than the number of non-executive directors. The number of directors, as well as the number of executive directors and non-executive directors, is determined by our Board of Directors, provided that the Board of Directors must consist of at least three members.

Our directors are appointed by the shareholders at a general meeting of our shareholders (***General Meeting***) for a period of four years as either executive directors or as non-executive directors. In accordance with best practice principle 2.2.1 of the DCGC, executive directors may be re-appointed for periods of not more than four years at a time. In accordance with best practice principle 2.2.2 of the DCGC, non-executive directors are appointed for a period of four years and may subsequently be re-appointed for another four-year period. Non-executive directors may subsequently be reappointed again for a period of two years, which appointment may be extended by at most two years. In the event of a reappointment after an eight-year period, reasons will be given in the report of the Board of Directors. The Board of Directors is required to make one or more proposals for each seat on our Board of Directors to be filled. A resolution to nominate a director by our Board of Directors (with support from the remuneration and nomination committee) may be adopted by a simple majority of the votes cast. A nomination for appointment of an executive director must state the candidate's age and the positions he or she holds, or has held, insofar as these are relevant for the performance of the duties of an executive director. The nomination must state the reasons for the nomination of the relevant person. A nomination for appointment of a non-executive director must state the candidate's age, his or her profession, the number of shares he or she holds and the employment positions he or she holds, or has held, insofar as these are relevant for the performance of the duties of a non-executive director. Furthermore, the names of the legal entities of which he or she is already a supervisory board member or a non-executive member of the board shall be indicated; if those include legal entities which belong to the same group, a reference to that group will be sufficient. The nomination must state the reasons for the nomination of the relevant person.

Our Board of Directors designates one executive director as CEO. In addition, the Board of Directors may grant other titles to executive directors. Our Board of Directors also designates a non-executive director as chairperson of the Board of Directors and a non-executive director as vice chairperson of the Board of Directors. The legal relationship between an executive member of the Board of Directors and argenx will not be considered as an employment agreement. Employment agreements between an executive

director and a Group company (other than argenx SE) are permitted. In the absence of an employment agreement, members of a board of directors generally do not enjoy the same protection as employees under Dutch labor law.

As a foreign private issuer, under the listing requirements and rules of Nasdaq, we are not required to have a majority independent directors on our Board of Directors, except that our audit and compliance committee is required to consist fully of independent directors. However, our Board of Directors has determined that, taking into account any applicable committee independence standards, all of our non-executive directors, including the members of our audit and compliance committee, are "independent directors" under Rule 10A-3 of the U.S. Securities Exchange Act of 1934, as amended (***Exchange Act***) and the applicable rules of Nasdaq and of the DCGC. In making such determination, our Board of Directors considered the relationships that each non-executive director has with us and all other facts and circumstances our Board of Directors deemed relevant in determining the director's independence, including the number of ordinary shares beneficially owned by the director and his or her affiliated entities (if any).

The DCGC requires that the composition of non-executive directors is such that the members are able to operate independently and critically vis-à-vis one another, the executive directors, and any particular interests involved. As of the date of this Annual Report, all non-executive directors meet the independence criteria contained in the DCGC. Therefore, in the opinion of the non-executive directors, the composition of our non-executive directors complies with the independence requirements of best practice provisions 2.1.7 to 2.1.9 of the DCGC. Our Board of Directors has consequently also determined that all members of our committees are independent under the applicable rules of the DCGC.

As of the date of this Annual Report (or in any period before), none of the members of our Board of Directors and senior management has or has had a family relationship with any other member of our Board of Directors or senior management.

Directors may be suspended or removed by the shareholders at a General Meeting at any time, with or without cause, by means of a resolution passed by a simple majority of the votes cast. Under Dutch law (Section 2:134 paragraph 1 of the DCC), executive directors may also be suspended by the board of directors. A suspension of an executive director by the board of directors may be discontinued by the shareholders at any time at a General Meeting.

Diversity

We value diversity among our colleagues as an integral component in building a sustainable growth platform and believe that a diverse workforce enhances our overall performance and success. We take pride in creating and sustaining a culture and environment where each of us can excel. We bring together people with diverse backgrounds experiences and functional expertise. By doing so, we broaden the scope of ideas and creativity essential to developing and delivering innovative therapies to patients. Acknowledging and benefiting from different perspectives promotes diversity of thought and empowers innovation. It also contributes to our commitment to improve lives of patients, wherefore we need teams with a healthy mix of contrasting perspectives and backgrounds that reflect the diverse communities we serve. We recognize that our people are our greatest strength. Fostering an inclusive work environment where

everyone feels safe and encouraged to contribute leads to better work outcomes and supports high levels of employee commitment and retention. We aspire to be a consciously global company. Our success is built on, and dependent on true collaboration in cross-functional and often cross-regional teams in which open communication is encouraged and safeguarded. Everyone has a voice and is encouraged to contribute to the benefit of our common goals, irrespective of race, ethnicity, age, gender or cultural background. Good ideas as well as real concerns are taken seriously, regardless of who brings them forward.

In 2022, we adopted our new diversity, equity and inclusion policy, which sets out the basis for our inclusion, equity and diversity management throughout our organization in a way that we believe best supports our business objectives and our people. We monitor and annually report on relevant diversity, equity and inclusion metrics, initiatives and developments in this Annual Report and in our 2021 environmental, social and corporate governance (***ESG***) reports, of which an updated version will be published in the second quarter of fiscal 2023.

Our policy is that we aim to balance our Board of Directors and senior management team in terms of gender, age, background, race, ethnicity, sexual orientation, experience and nationality as much as reasonably possible while still having our Board of Directors and senior management team composed of the best possible candidates overall. It has been and will remain our priority to have the best available specialists on our Board of Directors and in our senior management team, who make a balanced panel of directors and managers able to advise and guide argenx to further growth and success for all its stakeholders. This means we require a number of specialties and character traits to be present. We will actively seek to further improve diversity on our Board of Directors if and when proposing new appointments to our Board of Directors, whilst recognizing that, considering the specialist nature of our business, aspects other than diversity are relevant as well for the ultimate decision to select a board member.

We aim to foster an inclusive work environment in support of our strategic plan and priorities. We continue to raise the bar in this regard, and to commit to measures and goals designed to support our maturing company culture. We have set ourselves the goal of gender balance across all levels at argenx, including our Board of Directors.

Our plan of action to achieve our goal of gender balance includes a number of recruitment and development-related initiatives to promote balanced and diversified candidate pools as well as diversity amongst persons receiving promotion and development opportunities. We value our fair, inclusive recruitment process, which is standardized across the organization and focuses on pre-identified ‘what counts’ factors. The process involves a diverse group of colleagues from across the organization, who are provided with training to recognize existing biases. Recruitment decisions are based on a group evaluation of available candidates, to encourage different perspectives. Our onboarding program is designed to promote inclusion by building a strong social fabric across teams, functions and geographic locations. Once hired, employees are encouraged to participate in a personal development program aimed at building on their individual strengths to benefit the broader team and taking into account their individual career aspirations. We offer opportunities for promotion, training and career development solely based on job-related, appropriate criteria such as skills, competencies, experience, aptitude and enthusiasm and giving account to each individual’s experience, ambitions and capabilities.

We will continue to implement our diversity, equity and inclusion policy by seeking new ways to improve and support diversity, equity and inclusion at the Company. We from time to time report on specific initiatives taken with respect to our diversity, equity and inclusion policy in our annual ESG report, of which an updated version will be published in the second quarter of fiscal 2023.

In accordance with Dutch legislation as entered into force on January 1, 2022, we will report to the Sociaal-Economische Raad whether or not we have complied with our diversity goals, and if we have not, the reasons for this.

As of December 31, 2022, our Board of Directors consisted of 9 directors, including 1 executive director and 8 non-executive directors. Of the directors who chose to disclose their gender, the Board of Directors contained 5 male directors and 3 female directors (non-executive directors), translating into a 55.55% male / 33$^{1/3}$% female balance for our full Board of Directors (compared to 6 males and 2 females (75% / 25%) as of December 31, 2021) and a 62.5% male / 37.5% female balance for our non-executive directors (compared to 5 males and 2 females (71.4% / 28.6%) as of December 31, 2021). As of December 31, 2022 and December 31, 2021, we estimated that our Company leadership team consisted of 31 persons, comprised of a mix of 19 males and 12 females, (61% / 39% respectively). In making this calculation we define our leadership team as consisting of our senior management team and the (other) leaders of our largest functions and projects. Each of these positions is characterized by a high impact across the organization, leading a global and cross functional team and having a global reach. We estimate that as of December 31, 2022, 63% of our workforce were female and 37% were male (compared to 58% female and 42% male as of December 31, 2021).

Board Diversity Matrix (as of the Date of this Annual Report)

Country of Principal Executive Offices	The Netherlands			
Foreign Private Issuer in the U.S.	Yes			
Disclosure of gender identity prohibited by Dutch Law	No			
Total Number of Directors	9			
Gender: Number of Directors	Female: 3	Male: 5	Non-Binary: 0	Did Not Disclose Gender identity: 1

Demographic Background Categories	**Number of Directors in Each Demographic Category**
Underrepresented individual in home country jurisdiction	1
LGTBQ+	0
Did not disclose demographic background	8

Meetings and Decision-Making

Our Board By-Laws, that describe, inter alia, the procedure for holding meetings of the Board of Directors, for the decision-making by the Board of Directors and the Board of Directors' operating procedures.

In accordance with our Articles of Association, our Board of Directors meets at least once every three months to discuss the state of affairs within the Company and the expected developments.

Under our Board By-Laws, the members of our Board of Directors must endeavor, insofar as is possible, to ensure that resolutions are adopted unanimously. Where unanimity cannot be achieved and Dutch law, the Articles of Association or the Board By-Laws do not prescribe a larger majority, all resolutions of our Board of Directors must be adopted by a simple majority of the votes cast in a meeting at which at least a majority of the members of our Board of Directors then in office are present or represented. The Articles of Association provide that in case of a tie of votes, the chairperson does not have a casting vote and as such the proposal will be rejected in case of a tie.

Under the Board By-Laws, some specific matters require approval of the majority of the non-executive directors. These matters are set out in Schedule 1 of our Board By-Laws. Our Board By-Laws are available on our website.

Resolutions of the Board of Directors may also be adopted outside of a meeting in writing, provided that all directors in office (in respect of whom no conflict of interest exists as referred to in the Articles of Association) have consented in writing to this manner of decision-making. A director may issue a proxy for a specific Board of Directors meeting to another director in writing.

A director having a direct or indirect personal interest that conflicts with the interest of the Company and its affiliated enterprise has a conflict of interest. Each director shall inform all other directors of a conflict of interest without delay. A director shall not participate in the deliberations and decision-making process in relation to an item if he has a conflict of interest with respect thereto. In such case, the other directors shall resolve the item. In case because of this no resolution can be adopted by the executive directors, the non-executive directors will resolve on the matter. In case because of this no resolution can be adopted by the non-executive directors, the Board of Directors will resolve on the matter as if there were no conflict of interest.

The executive director(s) are required to be asked their vision on their own remuneration in accordance with best practice provision 3.2.2 but may not participate in the adoption of resolutions (including any deliberations in respect of such resolutions) relating to their remuneration.

Committees

In accordance with the DCGC, our non-executive directors can set up specialized committees to analyze specific issues and advise the non-executive directors on those issues and prepare resolutions with respect thereto.

The committees are advisory bodies only, and the decision-making remains within the collegial responsibility of the Board of Directors. The non-executive directors determine the terms of reference of each committee with respect to the organization, procedures, policies and activities of the committee.

Our non-executive directors have established and appointed:

- an audit and compliance committee; and
- a remuneration and nomination committee.

The composition and function of all these committees complies with all applicable requirements of Euronext Brussels, the DCGC, the Exchange Act, the exchange on which the ordinary shares and the ADSs are listed and U.S. Securities and Exchange Commission (***SEC***) rules and regulations.

Only non-executive directors qualify for membership of these committees. The audit and compliance committee and the remuneration and nomination committee may not be chaired by the chairperson of the Board of Directors or by a former executive director of the Company.

In addition to the aforementioned legally required subcommittees, our Board of Directors may also opt to incorporate informal committees consisting of non-executive directors and other internal and external persons in argenx, in order to facilitate discussions and act as a sounding board on specific projects, as well as on a more permanent basis. Our Board of Directors has incorporated a research and development committee and a commercial committee.

Audit and Compliance Committee

Our audit and compliance committee consists of four members: Steve Krognes (chairperson), effective February 27, 2023, Peter K. M. Verhaeghe, Anthony A. Rosenberg and James M. Daly. Mr. Lanthaler was chairperson until February 27, 2023. Our Board of Directors previously established that Mr. Lanthaler qualified and Mr. Krognes qualifies as an "audit committee financial expert" as defined under the Exchange Act and Article 39 paragraph 1 of Directive 2014/56/EU of the European Parliament and of the Council of 16 April 2014 amending Directive 2006/43/EC on statutory audits of annual accounts and consolidated accounts and that the composition of the audit and compliance committee meets the requirements under the Dutch Decree on Establishing Audit Committees.

Our audit and compliance committee assists our Board of Directors in overseeing the accuracy and integrity of our accounting and financial reporting processes and audits and reviews of our consolidated financial statements, the implementation and effectiveness of an internal control system and our compliance with legal and regulatory requirements, the independent auditors' qualifications and independence and the performance of the independent auditors. Our audit and compliance committee is also responsible for monitoring the status of, and compliance with, our global ethics and compliance program and meets with our head of ethics and compliance at least quarterly to discuss the status and overall effectiveness of the program as well as any issues or incidents that occurred and remedial actions needed (if applicable). The committee furthermore supervises the status of the Company's cyber security program and regularly (at least quarterly) discusses the status thereof with our senior management team.

Our audit and compliance committee is governed by a charter that complies with Nasdaq listing rules and the DCGC, that was last updated on February 28, 2022 and is publicly available on our website. It is responsible for, among other things, establishing methods and procedures for supervising, and where necessary requiring improvements of, our financial reporting, risk management, ethics and compliance and organization for the purpose of making appropriate recommendations to our Board of Directors in that regard.

Our audit and compliance committee meets as often as is required for its proper functioning, but at least four times a year and at least once a year meets separately with our independent auditor. See section 3.3.7 "**Report Research and Development Committee**" for an overview of the number of meetings and attendance rates.

Our audit and compliance committee reports regularly to our Board of Directors on the exercise of its functions. It informs our Board of Directors about all areas in which action or improvement is necessary in its opinion and produces recommendations concerning the necessary steps or resolutions that need to be taken. The audit review and the reporting on that review cover us and our subsidiaries as a whole. The members of the audit and compliance committee are entitled to receive all information which they need for the performance of their function, from our Board of Directors and employees. Every member of the audit and compliance committee shall exercise this right in consultation with the chairperson of the audit and compliance committee.

Remuneration and Nomination Committee

We have established a remuneration and nomination committee, which serves as both the remuneration committee and selection and appointment committee as prescribed by the DCGC. Our remuneration and nomination committee currently consists of three members: J. Donald deBethizy (chairperson), Peter K. M. Verhaeghe and Ana Cespedes.

Our remuneration and nomination committee is responsible for, among other things:

- regularly reviewing the remuneration policy and practices in light of all relevant circumstances and benchmarks, and recommending to the non-executive directors the remuneration of the individual executive directors;
- advising our Board of Directors in respect of the remuneration for the non-executive directors;
- preparing the remuneration report to be included in our annual report;
- drawing up selection criteria and appointment procedures for directors and making proposals for appointment and re-appointment of the directors;
- periodically assessing the size and composition of our Board of Directors and making a proposal for a composition profile of the non-executive directors;
- periodically assessing the diversity (including gender diversity) on our Board of Directors and leadership teams, and taking into account any gaps between our then current diversity metrics and the goals specified in our diversity, equity and inclusion policy when making recommendations to the Board of Directors;
- periodically assessing the functioning of individual directors and reporting on this to the non-executive directors; and
- supervising the policy of the executive directors on the selection criteria and appointment procedures for senior management.

The remuneration and nomination committee consists of at least three members. The remuneration and nomination committee meets as often as is required for its proper functioning, but at least once per year to evaluate its functioning. See section 3.3.8 "**Report Commercial Committee**" for an overview of the number of meetings and attendance rates.

Informal subcommittees

Research and development committee

The research and development committee consists of members of our Board of

Directors and other persons, which composition may vary from time to time. Currently, the research and development committee consists of two members, who are also members of our Board of Directors: J. Donald deBethizy and Pamela Klein. Non-director members of the research and development committee include David Lacey, Hans de Haard and Wim Parys. Ad-hoc participants to the committee meetings include a variety of employees and/or external advisors, depending on the needs of the committee and the topics under discussion.

The research and development committee is responsible for, among other things:

- monitoring and overseeing our research and development goals, strategies and measures;
- serving as a sounding board to our research and development management, general management and Board of Directors;
- performing strategic reviews of our key research and development programs;
- reporting to our Board of Directors on the outcome of the strategic reviews;
- reviewing our scientific publication and communications plan;
- evaluating and challenging the effectiveness and competitiveness of our research and development endeavors;
- reviewing and discussing emerging scientific trends and activities critical to the success of our research and development;
- reviewing our clinical and preclinical product pipeline; and
- engaging in attracting, retaining and developing our senior research and development personnel.

All members of the research and development committee shall have adequate industrial, academic and/or practical experience with the research and development of biopharmaceuticals.

One purpose of our research and development committee is to engage in discussion with our research and development personnel, and the committee's responsibilities to carry out this purpose include, among others: monitoring the research and development activities, performing strategic reviews of the key research and development programs and reviewing the scientific publication plan, all with the intent to support our innovation mission.

Our research and development committee meets as often as is required for its proper functioning, but typically meets at least once prior to each meeting of our Board of Directors and reports regularly to our Board of Directors on the outcome of its deliberations, including any recommendations to the Board of Directors or the senior management team. The chairperson of our research and development committee reports to our Board of Directors on the research and development committee's discussions and strategic advice after each meeting on all matters within its duties and responsibilities. See section 3.3.7 "**Report Research and Development Committee**" for an overview of the number of meetings and attendance rates.

Commercial Committee

Our commercial committee consists of members of our Board of Directors and other persons, which composition may vary from time to time. As of the date of this Annual Report, the commercial committee consists of three permanent members: James M. Daly (chairperson), Anthony A. Rosenberg and Camilla Sylvest.

The commercial committee is responsible for, among other things:

- reviewing the performance of our commercial activities;
- serving as a sounding board to our branded and unbranded strategic marketing plans, size and scope of our franchises, pre and post launch market access plan of action;
- reviewing and discussing global commercial and political trends affecting our industry and development; and
- reporting to our Board of Directors on the outcome of the strategic reviews.

The non-executive directors shall appoint and dismiss the members of the commercial committee. All members of the commercial committee shall have adequate industrial, academic and/or practical experience with the commercialization of (bio) pharmaceuticals.

Our commercial committee meets as often as is required for its proper functioning and in practice meets at least once per quarter. The commercial committee reports regularly to our Board of Directors on the outcome of its strategic reviews and any recommendations to the Board of Directors or senior management team. See section 3.3.8 "**Report Commercial Committee**" for an overview of the number of meetings and attendance rates.

3.2.4 Non-Executive Directors

Our Board of Directors as of December 31, 2022 comprised the following eight non-executive directors:

Peter K. M. Verhaeghe

Peter Verhaeghe has served as a member and chairperson of the board of arGEN-X B.V. since October 2008 and as non-executive director on our Board of Directors since July 2014. Mr. Verhaeghe is the managing partner of VVGB Advocaten-Avocats, a corporate finance law and tax law firm, a position he has held since July 1999. He is currently lead counsel to a number of Belgian, Dutch, French, U.S. and Swiss life sciences companies. Mr. Verhaeghe also serves on the board of directors of Participatiemaatschappij Vlaanderen NV since May 2018, as chairman of the board of Haretis SA (Luxembourg) since March 2011, and as member of the board of directors of miDiagnostics since April 2020. Mr. Verhaeghe also serves as the chairman of the LP & advisory committee of Bioqube Factory Fund I NV. Mr. Verhaeghe served as the president of the board of directors of Merisant France SAS, as a member of the management board of Merisant Company 2 sàrl and as a member of the board of directors of CzechPak Manufacturing s.r.o. He previously also served as director of Innogenetics NV (Belgium), Tibotec-Virco NV, Biocartis SA, and as the chairman of the board of directors of PharmaNeuroBoost NV and as liquidator in charge of KBC Private Equity Fund Biotech NV from April 2009 to December 2012. Mr. Verhaeghe holds a degree in law (J.D.) from the University of Leuven and an LL.M. degree from Harvard Law School. At the annual General Meeting held on May 10, 2022 (***2022 Annual Meeting***), he was reappointed for a new term of 2 years.

Dr. Werner Lanthaler (until February 27, 2023)

Dr. Werner Lanthaler has served as a member of our Board of Directors from July 2014 until February 27, 2023. Dr. Lanthaler is the CEO of Evotec SE, a global drug discovery and development organization, a position he has held since March 2009. He also serves on the supervisory board of AC Immune SA (Switzerland). Dr. Lanthaler previously served on the supervisory boards of Bioxell SpA and Pantec Biosolutions AG. Dr. Lanthaler holds a degree in psychology, a Ph. D. in business administration from Vienna University of Economics and Business and a Master's degree in public administration from Harvard University. The Board of Directors nominated Mr. Lanthaler for re-appointment for a term of an additional 2 years during our 2022 General Meeting. Such re-appointment beyond the first 8 years on our Board of Directors was deemed in the best interest of the Company, to allow for the successful selection, appointment and onboarding of Mr. Lanthaler's successor. Mr. Lanthaler resigned from our Board of Directors following our board meeting of February 28, 2023 upon appointment and onboarding of Mr. Krognes, who was appointed as a non-executive director of the Company and chairperson of the Company's audit and compliance committee.

Mr. Steve Krognes (effective February 27, 2023)

Mr. Krognes serves as a member of our Board of Directors and as a chairperson of our audit and compliance committee since February 27, 2023. Mr. Krognes also serves on the boards of directors of Guardant Health, Inc., Denali Therapeutics, Inc., and Gritstone bio, Inc. He previously served on the board of directors of RLS Global AB and Corvus Pharmaceuticals, Inc. Mr. Krognes was the chief financial officer of Denali Therapeutics, Inc., from 2015 until retiring from that position in April 2022. Steve joined Denali Therapeutics, Inc., as the founding chief financial officer, building and leading the finance team as well as supervising the IT and facilities functions. He led successful financings for Denali Therapeutics, Inc., including the initial public offering in 2017, and has contributed significantly to the company's strategy, growth and strong financial position. His extensive leadership experience in the biotech and pharmaceutical industry includes 12 years in total at Roche and Genentech, Inc., serving as chief financial officer of Genentech, Inc., for six years and global head of Roche's mergers & acquisition team for six years. He chaired the Genentech Access to Care Foundation and represented Genentech on the board and executive committee of the California Life Science Association. Before that, he worked as an investment banker at Goldman Sachs, as a management consultant at McKinsey & Company, and as a venture capitalist in Scandinavia. Mr. Krognes holds a master's in business administration (***MBA***) from Harvard Business School and a Bachelor of Science in economics from the Wharton School of the University of Pennsylvania.

Dr. J. Donald deBethizy

Dr. J. Donald deBethizy has served as a member of our Board of Directors since May 2015. Dr. deBethizy has 30 years of experience in research and development and financial, business and operating management and board work in the biotechnology and consumer products industry. He is the president of White City Consulting ApS an executive coaching company. He currently serves on the supervisory boards of Lophora ApS, Newron Pharmaceuticals SpA, Proterris, Inc. and a board advisor for NDA Regulatory Service AB. Previously, Dr. deBethizy served as president and CEO of Santaris Pharma A/S until October 2014, when the company was sold to Roche. From August 2000 to June 2012, Dr. deBethizy was co-founder and CEO of Targacept, Inc. (***Targacept***), a U.S. biotechnology company listed on Nasdaq. From May 2013 to November 2014, he served as executive chairman of Contera Pharma ApS until it was sold to Bukwang Pharma (Korea), and from July 2015 to November 2017, he served as chairman of Rigotec GmbH until it was sold to Merck, Inc. He previously served on the boards of Albumedix Ltd (Chair, company sold to Sartorius AG in September 2022), Saniona AB (Chair), Asceneuron SA, TME Pharma NV (Chair, TME NV and AG), Serendex Pharmaceuticals A/S, Enbiotix, Inc., Targacept, Ligocyte Pharmaceuticals until it was sold to Takeda Pharmaceutical Co Ltd and Biosource, Inc. Dr. deBethizy has held adjunct appointments at Wake Forest University Babcock School of Management, Wake Forest University School of Medicine and Duke University. Dr. deBethizy holds a B. Sc. in biology from the University of Maryland, and an M.Sc. and a Ph.D. in toxicology from Utah State University.

Dr. Pamela Klein

Dr. Pamela Klein has served as a member of our Board of Directors since April 2016. Dr. Klein is a principal and founder of PMK BioResearch, which offers strategic consulting in oncology drug development to corporate boards, management teams and the investment community, a position she has held since 2008. She currently serves as a member of the board of directors of several companies including F-Star Therapeutics, Inc., I-Mab and Patrys Ltd; as well as various scientific advisor boards. Previously, Dr. Klein served on the board of directors of Jiya Acquisition Corp. Dr. Klein also spent seven years at the National Cancer Institute as Research Director of the NCI-Navy Breast Center, after which she joined Genentech as Vice President, Development until 2001. She served as chief medical officer for Intellikine, Inc., which was acquired by Takeda American Holdings. Dr. Klein holds a Bachelor's degree in biology from California State University and an M.D. from Stritch School of Medicine, Loyola University Chicago and is trained in internal medicine and medical oncology.

Anthony A. Rosenberg

Anthony A. Rosenberg has served as a member of our Board of Directors since April 2017. He currently serves as CEO of TR Advisory Services GmbH, his own consultancy firm advising on business development, licensing and mergers and acquisitions. Mr. Rosenberg also currently serves on the boards of directors of SiO2 Material Science, Oculis SA (chairman) and Cullinan Oncology (chairman). Previously Mr. Rosenberg held the positions of Managing Director at MPM Capital, a venture capital firm (2015 until 2020); head of M&A and Licensing of Novartis International (2013 to 2015) and head of business development and licensing at Novartis Pharma (2005 to 2012). Mr. Rosenberg also previously served on the boards of directors at Radius Health, Inc., TriNetX, Inc., iOmx Therapeutics AG, and Clinical Ink. Msc. A.A. Rosenberg has a B.Sc. (Hons) from the University of Leicester and a M.Sc. Physiology from the University of London.

James M. Daly

James M. Daly has served as a member of our Board of Directors since May 2018. He joined GlaxoSmithKline in 1985 where he held various positions, including sr. vice president – respiratory division with with full responsibility for sales, marketing and medical affairs. He moved to Amgen in 2002 where he was sr. vice president for the North America commercial operations 2011. In 2012, he joined Incyte Corp, a publicly-traded company focused on oncology and inflammation, where he was chief commercial officer until June 2015. Mr. Daly currently serves as a director of Acadia Pharmaceuticals, Inc., Halozyme, Bellicum Pharmaceuticals, Inc. and Madrigal Pharmaceuticals, Inc., all Nasdaq-listed companies. Mr. Daly holds a Bachelor of Science and an MBA from the University at Buffalo, State University of New York. He was reappointed for a new 4-year term at the 2022 General Meeting.

Camilla Sylvest

Camilla Sylvest was appointed as non-executive director on September 8, 2022 and brings strong strategic and operational leadership in the scaling of global commercial pharmaceutical organizations with a specific focus on company culture and sustainability. Camilla Sylvest currently serves as the executive vice president, commercial strategy & corporate affairs of Novo Nordisk A/S. Ms. Sylvest also serves as the vice chair of the World Diabetes Foundation Board and as a member of the board of directors of Danish Crown A/S. Camilla Sylvest has more than 25 years of working experience within Novo Nordisk A/S and was based in Switzerland, Denmark, Germany, Malaysia and the PRC.

Over the years, Camilla Sylvest headed up affiliates of growing size and complexity in Europe within Novo Nordisk A/S and she was also corporate vice president business area Oceania and Southeast Asia and senior vice president and general manager Novo Nordisk region China. Camilla Sylvest holds a Master of Science in Economics from the University of Odense, Denmark and an executive MBA from the Scandinavian Management Institute in Copenhagen, Denmark.

Ana Cespedes

Ana Cespedes was appointed as non-executive director on December 12, 2022 and brings robust experience across a broad range of critical areas for commercialization and access, as well as for organizational effectiveness.

Ana Cespedes is the chief operating officer of the International AIDS Vaccine Initiative (***IAVI***), a global organization dedicated to developing accessible vaccines and antibodies for infectious diseases. Prior to joining IAVI, Ms. Cespedes held several roles at Merck KGaA, based in Boston, MA, most recently serving as senior vice president, global marketing & strategy. Ms. Cespedes founded and led the global market access and pricing function for the company and worked with stakeholders to communicate the clinical, economic, and societal value of innovative medicines. Prior to that, Ms. Cespedes led the first integrated corporate affairs group at Serono Iberia and Merck Spain, was managing director of the Spanish branch of the company's nonprofit organization, and worked as a senior consultant at Arthur Andersen.

Ms. Cespedes is a founding member of the National Congress of Corporate Affairs in Spain, the London School of Economics Market Access Academy, and the Cooperation for Oncology Data. She is also the founder of Living Mindfulness S.L.

Ms. Cespedes holds a B.S. and a Pharm.D. from the Complutense University of Madrid, and an MBA from IESE Business School.

The following table sets forth certain information with respect to the current non-executive members of our Board of Directors, including their ages, as of December 31, 2022.

Name	Age	Gender	Position	Nationality	Date of Initial Appointment	Date of last (re-) appointment	Term expiration
Peter K. M. Verhaeghe	64	M	Non-Executive Director (chairperson)	Belgium	October 15, 2008	May 10, 2022	2026
Werner Lanthaler [1)]	54	M	Non-Executive Director (vice-chairperson)	Austria	July 9, 2014	May 10, 2022	2024
J. Donald deBethizy	72	M	Non-Executive Director	U.S.	May 13, 2015	May 7 2019	2023
Pamela Klein	61	F	Non-Executive Director	U.S.	April 28, 2016	May 12, 2020	2024
Anthony A. Rosenberg	69	M	Non-Executive Director	UK	April 26, 2017	May 11, 2021	2025
James M. Daly	61	M	Non-Executive Director	U.S.	May 8, 2018	May 10, 2022	2026
Camilla Sylvest	50	F	Non-executive director	Denmark	September 8, 2022	September 8, 2022	2026
Ana Cespedes	49	F	Non-executive director	Spain	December 12, 2022	December 12, 2022	2026

[1)] Werner Lanthaler resigned effective February 27, 2023 and was succeeded by Steve Krognes effective February 27, 2023 whose term will expire at our 2027 annual General Meeting.

The address for our non-executive directors is our registered office, Laarderhoogtweg 25, 1101 EB Amsterdam, the Netherlands.

Steve Krognes was appointed at an extraordinary General Meeting on February 27, 2023. Peter K.M. Verhaeghe, and James M. Daly were re-appointed at the 2022 General Meeting.

The following table sets forth the companies and partnerships of which the current non-executive members of our Board of Directors have been a member of the administrative, management or supervisory bodies or partner at any time in the previous five years, indicating whether or not the individual is still a member of the administrative, management or supervisory bodies or partner, as of the date of this Annual Report, other than argenx or our subsidiaries:

Name	Current	Past
Peter K. M. Verhaeghe	VVGB Advocaten – Avocats	PharmaNeuroBoost NV
	Haretis SA	Biocartis SA
	Participatiemaatschappij Vlaanderen NV	Fujirebio Europe NV (formerly Innogenetics NV)
	miDiagnostics NV	Tibotec-Virco NV
	Bioqube Factory Fund I NV	Merisant France SAS
		Merisant Company 2 sàrl
		CzechPak Manufacturing s. r. o.
		Bever Zwerfsport BV
Werner Lanthaler [1)]	Evotec SE	Bioxell SpA
	AC Immune SA	Pantec Biosolutions AG
J. Donald deBethizy	White City Consulting ApS	Rigotec GmbH
	Newron Pharmaceuticals SpA	TME Pharma NV and AG
	Protteris, Inc.	Saniona AB
	Lophora ApS	Albumedix A/S
	Albumin Holdings ApS	Asceneuron SA
	Innovent LLC	
Pamela Klein	PMK BioResearch	Olema Oncology
	Patrys Limited	Jiya Acquisition Corp.
	I-Mab	
	F-Star Therapeutics, Inc.	

1) Werner Lanthaler resigned effective February 27, 2023 and was succeeded by Steve Krognes effective February 27, 2023 whose term will expire at our 2027 annual General Meeting.

Name	Current	Past
Anthony A. Rosenberg	Cullinan Oncology, Inc.	Radius Health, Inc.
	Oculis SA	TriNetX, Inc.
	TR Advisory Services GmbH	Clinical Ink, Inc.
		iOmx Therapeutics AG
		MPM Capital
		SiO2 Material Science
James M. Daly	Acadia Pharmaceuticals, Inc.	Chimerix, Inc.
	Halozyme Therapeutics, Inc.	
	Bellicum Pharmaceuticals, Inc.	
	Madrigal Pharmaceuticals	
	Coherus Biosciences	
Camilla Sylvest	Novo Nordisk	–
	World Diabetes Foundation	
	Crown A/S	
Ana Cespedes	Instituto ProPatients	Merck KGaA
		Merck Spain
		Serono Iberia
		Arthur Andersen
Steve Krognes	Denali Therapeutics, Inc.	R/S Global
	Guardant Health, Inc.	Corvus Pharmaceuticals, Inc.
	Gritstone bio, Inc.	

3.2.5 Senior Management

Our senior management team acts as our executive management. Of these people, only our CEO, Mr. Tim Van Hauwermeiren, is part of our Board of Directors as executive director. Our senior management team comprised of the following persons in 2022 and on the date of this Annual Report (appointment/retirement dates noted as relevant):

Tim Van Hauwermeiren

Tim Van Hauwermeiren co-founded our Company in 2008 and has served as our CEO since July 2008. He has served as a member of our Board of Directors since July 2014. Mr. Van Hauwermeiren has more than 20 years of general management and business development experience across the life sciences and consumer goods sectors. Mr. Van Hauwermeiren holds a Bachelor of Science and Master of Science in bioengineering from Ghent University (Belgium) and an executive MBA from The Vlerick School of Management. Tim Van Hauwermeiren serves on the board of directors of iTeos Therapeutics, Inc., and Aelin Therapeutics NV where he is chairman. At our 2022 General Meeting, he was reappointed as executive director to the Board of Directors for a new term of four years.

Keith Woods

Keith Woods has served as our chief operating officer from April 2018 to March 2023, at which time, he was succeeded by Karen Massey. Mr. Woods will transition to serve as an advisor to our Board of Directors. Mr. Woods has over 30 years of experience in the biopharmaceutical industry. He most recently served as senior vice president of North American operations for Alexion Pharmaceuticals, Inc. (***Alexion***), where he managed a team of several hundred people in the U.S. and Canada and was responsible for more than $1 billion in annual sales. Within Alexion, he previously served as vice president and managing director of Alexion UK, overseeing all aspects of Alexion's UK business, vice president of U.S. operations and executive director of sales, leading the launch of Soliris in atypical hemolytic uremic syndrome. Prior to joining Alexion, he held various positions of increasing responsibility within Roche, Amgen and Eisai Co., Ltd., over a span of 20 years. Keith Woods holds a Bachelor of Science in marketing from Florida State University.

Karen Massey (effective March 13, 2023)

Karen Massey has served as our chief operating officer since March 2023. Ms. Massey has over 20 years of experience in the pharmaceutical and biotechnology industry, including in commercial, product development, corporate strategy and innovation roles. Prior to joining argenx, Ms. Massey was with Genentech (Roche Group) for over nine years, where she most recently served as senior vice president of product development and global clinical operations and previously held various commercial leadership roles across marketing and business operations, including as the vice president of the multiple sclerosis and neuromyelitis optica business. Ms. Massey started her biopharmaceutical career in marketing at Pfizer, Inc., and returned there, after two years as a management consultant at Bain & Company, to take on leadership positions in corporate strategy, sales and as a commercial lead in Latin America. Ms. Massey holds a Bachelor of Economics from the University of Sydney and an MBA from the NYU Stern School of Business.

Karl Gubitz

Karl Gubitz has served as our chief financial officer since June 2021. Mr. Gubitz worked at Pfizer, Inc., for nearly 20 years, most recently as vice president of finance within the global oncology business. During his tenure at Pfizer, Inc., he successfully negotiated the commercialization model for tanezumab with Eli Lilly and Company in all non-U.S. markets as well as the Myovant Sciences Ltd. co-commercialization agreement for Orgovyx™.

Within Pfizer, Inc., Mr. Gubitz held country, regional, and global positions, and consistently delivered top-line growth. He managed teams of over 250 colleagues in financial leadership roles within the global internal medicine and global innovative products businesses. Prior to joining Pfizer, Inc., in 2003, Mr. Gubitz held various management roles at PricewaterhouseCoopers LLP.

He holds an MBA from Henley Management College in the UK, Bachelor's degree in computing from the University of South Africa, and Bachelor of commerce from the University of Pretoria.

Prof. Hans de Haard

Prof. Hans de Haard is a co-founder of argenx and has served as our chief scientific officer since July 2008. Prof. de Haard has been active in the antibody engineering field since 1989. He also serves as a Professor of immunology at University of Franche-Comté (France). Prof. de Haard holds a Master of Science in biochemistry from the Higher Professional Education for Laboratory Technicians (Oss, the Netherlands) and a Master of Science in chemistry from the Institute of Technology (Rotterdam, the Netherlands) and a Ph. D. in molecular immunology from Maastricht University. Prof. de Haard retired as chief scientific officer as of December 31, 2022 and was subsequently appointed as member of our research and development committee, in which capacity Prof. de Haard will remain involved with the Company as scientific advisor and as ambassador of our IIP.

Dr. Peter Ulrichts

Peter Ulrichts has served as our chief scientific officer since January 2023. In this role, he oversees the development of all clinical and pre-clinical compounds within our pipeline. Dr. Ulrichts previously served in various roles at the Company since he joined us in 2010; most recently, as our head of clinical science. As a research scientist, Dr. Ulrichts was involved in the development of various therapeutic antibodies for the treatment of cancer and autoimmune diseases. In 2013, he headed the development of our FcRn antagonist efgartigimod until the first-in-human study. He subsequently transitioned to become the lead scientist of our efgartigimod program. Dr. Ulrichts holds a Bachelor of Science in chemistry from Katholieke Universiteit Leuven, Belgium, as well as a Master's degree in Biotechnology and Ph.D. in Biomedical Sciences, both from the University of Ghent, Belgium.

Malini Moorthy

Malini Moorthy has served as our general counsel since February 2022. She has over 25 years of extensive global legal and compliance experience in the biopharmaceutical and medical device industries. She was most recently senior vice president and chief deputy general counsel, legal, compliance and government affairs at Medtronic plc where she played a pivotal role in shaping and driving enterprise and functional strategies. Before joining Medtronic plc, Ms. Moorthy spent four years at Bayer Corporation as the head of global litigation and investigations and ten years at Pfizer Inc., where she progressed to lead civil litigation globally. Ms. Moorthy began her career as a law firm associate, first with McCarthy Tétrault LLP and Genest Murray Desbrisay Lamek LLP in Toronto, Canada and then Salans LLP (now Dentons US LLP) in New York City. She holds a Bachelor of Arts in political science and economics from the University of North Carolina at Chapel Hill and a Bachelor of Laws from the Faculty of Law at Queen's University in Canada.

Luc Truyen

Luc Truyen has served as our chief medical officer since April 2022 and previously served as our head of research and development operations management from September 2021 to April 2022. Prior to this, Dr. Truyen was with Johnson & Johnson for over 20 years holding various leadership positions, primarily within neuroscience. In his most recent position prior to joining argenx, Dr. Truyen was global head of development and external affairs – neuroscience for neuroscience managing strategy and delivery of the early and late portfolio of assets for mood disorders and schizophrenia, and neurodegenerative and neuroinflammatory disorders. Besides Dr. Truyen's strong track record in clinical development resulting in several global innovative drug approvals, his broad-based experience also includes leading global clinical development operations for the whole Johnson & Johnson pharmaceutical group as well as serving as head of the research and development and chief medical officer of Janssen Alzheimer Immunotherapy Research & Development LLC, an internal spin-out from Johnson & Johnson. Dr. Truyen holds an M.D. and Ph.D. in Neurology from the University of Antwerp, Belgium.

Wim Parys (until March 31, 2022)

Wim Parys joined the Company as chief medical officer in 2019 and retired as on March 31, 2022. He had over 25 years of experience leading successful clinical programs in biopharma, including the development and regulatory submission of seven now-approved drugs. Prior to argenx, Mr. Parys was the research and development head of the newly established global public health group at Janssen (Johnson & Johnson) responsible for a portfolio including programs in human immunodeficiency virus (***HIV***) (developing first long-acting therapy), tuberculosis (***TB***), dengue fever and malaria. Before this, Mr. Parys was the head of development of the infectious disease therapeutic area of Janssen and Tibotec Pharmaceuticals Ltd. where he developed and launched innovative drugs for HIV (Prezista™, Intelence™ and Edurant™), Hepatitis C (Incivo™, Olysio™/Sovriad™), and TB (Sirturo™). Mr. Parys started his career within the Johnson & Johnson organization at the Janssen Research Foundation in Belgium where he led the research and development team developing galantamine (Reminyl™/Razadyne™) for Alzheimer's disease. Mr. Parys obtained his medical degree from the Katholieke Universiteit in Leuven, Belgium and worked in private practice for nine years prior to joining the industry. Following his retirement, Mr. Parys was appointed as member of our research and development committee, in which capacity Mr. Parys has agreed to continue to serve as medical advisor to the Company.

Arjen Lemmen

Arjen Lemmen joined argenx in 2016 and has served as our vice president of corporate development & strategy since 2019. He has successfully executed several transactions including a number of programs within the IIP.

Prior to joining the Company, Mr. Lemmen served as a corporate finance specialist at Kempen & Co NV focusing on mergers and acquisitions, equity capital markets and strategic advisory transactions in the European life sciences industry. He holds a Bachelor of Science in life science & technology from the University of Groningen and a Master of engineering management from Duke University.

Andria Wilk

Andria Wilk joined argenx as global head of quality in 2020. Ms. Wilk has more than 20 years of experience in quality assurance (***QA***) within the pharmaceutical industry. Most recently, Ms. Wilk served as senior director, head of medical, regulatory & clinical QA (***MRC QA***) at H Lundbeck A/S (***Lundbeck***), where she managed the global MRC QA group based in the EU, U.S. and Asia. In this role, she was responsible for the global audit programs and QA support for all clinical trial and post-marketing activities and related computerized systems. Prior to Lundbeck, she held various QA positions of increasing responsibility within AstraZeneca PLC, Takeda Global Research and Development Centre Europe and Astellas Pharma, Inc. Ms. Wilk holds a joint Bachelor of Science in pharmacology and biochemistry and is a member of Research Quality Association.

The following table sets forth certain information with respect to the members of our senior management, including their ages, as of December 31, 2022 and as of the date of this Annual Report:

Name	Age	Position	Nationality	Date of Initial Appointment
Tim Van Hauwermeiren	50	CEO and Executive Director	Belgium	July 15, 2008
Keith Woods [1)]	55	Chief Operating Officer	U.S.	April 5, 2018
Karen Massey [1)]	44	Chief Operating Officer	Australian	March 13, 2023
Karl Gubitz	53	Chief Financial Officer	South Africa	June 1, 2021
Prof. Hans de Haard [2)]	63	Chief Scientific Officer	The Netherlands	July 1, 2008
Peter Ulrichts [2)]	43	Chief Scientific Officer	Belgium	January 1, 2023
Malini Moorthy [3)]	53	General Counsel	Canada	February 14, 2022
Arjen Lemmen	38	Vice-President Corporate Development & Strategy	The Netherlands	May 1, 2016
Andria Wilk	50	Global Head of Quality	UK	January 13, 2020
Luc Truyen [4)]	58	Chief Medical Officer	Belgium	April 1, 2022

1) Keith Woods retired as COO effective March 13, 2023 and was succeeded by Karen Massey effective March 13, 2023.

2) Hans de Haard retired effective January 1, 2023 and was succeeded by Peter Ulrichts effective January 1, 2023.

3) Malini Moorthy was appointed as general counsel effective February 14, 2022.

4) Luc Truyen succeeded Wim Parys who retired as our chief medical officer effective April 1, 2022.

The address for our senior management is Industriepark-Zwijnaarde 7, 9052 Zwijnaarde (Ghent), Belgium.

The following table sets forth the companies and partnerships of which the members of our senior management (or persons who have been members of our senior management in 2022) have been a member of the administrative, management or supervisory bodies or partner at any time in the previous five years, indicating whether or not the individual is still a member of the administrative, management or supervisory bodies or partner, as of the date of this Annual Report, other than argenx or our subsidiaries:

Name	Current	Past
Tim Van Hauwermeiren	Iteos Therapeutics, Inc.	–
	Aelin Therapeutics NV	
Keith Woods [1)]	–	–
Karen Massey	–	Genentech, Inc.
Karl Gubitz	–	Pfizer, Inc.
Prof. Hans de Haard	–	–
Peter Ulrichts	–	–
Malini Moorthy [2)]	–	Pfizer, Inc.
		Bayer Corporation
		Medtronic plc
Arjen Lemmen	–	–
Andria Wilk	–	H Lundbeck A/S
Luc Truyen [3)]	–	Johnson & Johnson

1) Keith Woods retired as COO effective March 13, 2023 and was succeeded by Karen Massey effective March 13, 2023.

2) Malini Moorthy was appointed as our general counsel effective February 14, 2022.

3) Luc Truyen succeeded Wim Parys who retired as our chief medical officer effective April 1, 2022.

3.2.6 Confirmation of No Past Offenses

As of the date of this Annual Report and except as set out below, none of the members of our Board of Directors and senior management team for at least the previous five years:

- has been convicted of any fraudulent offenses;
- has been a senior manager or a member of the administrative, management or supervisory bodies of any company at the time of or preceding any bankruptcy, receivership, liquidation or of such company being put into administration;
- has been subject to any official public incrimination and/or sanction by any statutory or regulatory authority (including any designated professional body); or
- has ever been disqualified by a court from acting as a member of the administrative, management or supervisory bodies of any company or from acting in the management or conduct of affairs of any company.

3.2.7 Conflict-of-Interest Transactions

Directors must immediately report any (potential) direct or indirect personal interest in a matter that conflicts with the interests of the Company and the business connected with it to the chairperson of our Board of Directors and to the other directors. Directors must also provide all relevant information, including information concerning their spouse, registered partner or other partner, foster child and relatives by blood or marriage up to the second degree as defined under Dutch law (Section 1:3 paragraph 1 of the DCC).

The non-executive directors will decide, without the director concerned being present, whether there is a conflict of interest. Under Dutch requirements, a conflict of interest in relation to a director in any event exists if we intend to enter into a transaction with a legal entity (i) in which such director personally has a material financial interest, (ii) which has an executive director or a member of the management board who is related under family law to such director or (iii) in which such director has an executive or non-executive position. A director will not participate in any discussions and decision making if he or she has a conflict of interest in the matter being discussed. In case because of this no resolution can be adopted by the executive directors, the non-executive directors will resolve on the matter. All transactions in which there are conflicts of interest with directors will be agreed on terms that are customary in the sector concerned. Decisions to enter into transactions in which there are conflicts of interest with directors that are of material significance to us or to the relevant director require the approval of the non-executive directors. All transactions between us and legal or natural persons who hold at least one tenth of our shares will be agreed on terms that are customary in the sector in which we and our combined businesses are active. The non-executive directors are required to approve such transactions that are of a material significance to us or to such persons.

Dutch law provides that transactions with related parties are material and thereby require approval of the Board of Directors if they are (a) not entered into in the ordinary course of our business or (b) not concluded on normal market terms. The Board of Directors has established an internal procedure to periodically assess whether transactions are concluded in the ordinary course of business and on normal market terms. We must make material transactions must be made public by argenx at the time the transaction is entered into. Transactions with related parties are considered material if (i) information on the transaction qualifies as inside information under the (Regulation (EU) No. 596/2014) (***MAR***) and (ii) such transaction is entered into with one or more holders of shares in argenx representing at least 10% of issued share capital, or a member of our Board of Directors. Transactions that are individually non-material, but which are entered into with the same related party during the same fiscal year, must be evaluated in the aggregate to determine if they are material.

There are no arrangements or understandings in place with major shareholders, customers, suppliers or others pursuant to which any member of our Board of Directors or senior management team has been appointed. There are no conflicts of interests between argenx and any administrative, management and supervisory bodies and senior management, nor are there any potential conflicts of interests of the members of our Board of Directors and senior management between any duties to argenx and their private interests and or other duties.

3.2.8 Code of Business Conduct and Ethics

We adopted a Code of Business Conduct and Ethics (***Code of Conduct***), that is applicable to all of our employees and directors. The Code of Conduct is available on our **website**. The audit and compliance committee of our Board of Directors is responsible for overseeing the Code of Conduct and is required to approve any waivers of the Code of Conduct for employees and directors. We expect that any amendments to the Code of Conduct, and any waivers of its requirements, will be disclosed on our website.

3.3 Report of the Non-Executive Directors

3.3.1 Meetings

Our Board of Directors had five formal meetings in the course of 2022. The meetings were held in the months March, May, July, September and December, most of which were held (partially) via videoconferencing due to restrictions related to the COVID-19 pandemic. The committees of the Board of Directors also convened regularly (see also sections 3.3.5 "**Report Audit and Compliance Committee**" to 3.3.8 "**Report Commercial Committee**" below for the separate reports of the committees).

All Board of Director meetings and all formal committee meetings were also attended by Mr. Van Hauwermeiren, as executive director. In addition, several members of the senior management team were invited to discuss specific items included on the Board of Director and committee meetings' agendas.

3.3.2 Attendance Record Board of Director Meetings

In 2022, five Board of Directors meetings were held. The meeting attendance rate for our directors is set out in the table below.

Name	Number of meetings attended in 2022 since appointment	Attendance (in %)
Peter K. M. Verhaeghe (chairperson)	5	100
Tim Van Hauwermeiren	5	100
Werner Lanthaler	5	100
J. Donald deBethizy	5	100
Pamela Klein	5	100
Anthony A. Rosenberg	5	100
James M. Daly	5	100
Yvonne Greenstreet [1)]	–	–
Camilla Sylvest [2)]	2	100
Ana Cespedes [3)]	1	100

1) Yvonne Greenstreet resigned from our Board of Directors in March 2022.

2) Camilla Sylvest was appointed as member of our Board of Directors on September 8, 2022.

3) Ana Cespedes was appointed as member of our Board of Directors on December 12, 2022.

In 2022, all of the five Board of Directors meetings with solely the non-executive directors being present were held as closed sessions at the beginning or the end of other meetings. These meetings were attended by all non-executive directors appointed at such time, except one meeting held in March, which was not attended by Yvonne Greenstreet.

Name	Number of meetings attended in 2022 since appointment	Attendance (in %)
Peter K. M. Verhaeghe (chairperson)	5	100
Werner Lanthaler	5	100
J. Donald deBethizy	5	100
Pamela Klein	5	100
Anthony A. Rosenberg	5	100
James M. Daly	5	100
Yvonne Greenstreet [1)]	–	–
Camilla Sylvest [2)]	2	100
Ana Cespedes [3)]	1	100

1) Yvonne Greenstreet resigned from our Board of Directors in March 2022.

2) Camilla Sylvest was appointed as member of our Board of Directors on September 8, 2022.

3) Ana Cespedes was appointed as member of our Board of Directors on December 12, 2022.

3.3.3 Activities

The agenda for the Board of Directors included long-term value creation as well as the manner in which the senior management team implements our strategy, our culture to ensure proper monitoring by the non-executive directors, our financial position as well as the results of our subsidiaries, acquisitions, large investment proposals, yearly budget, director changes and the internal risk management and control system, diversity, equity and inclusion policy, adjustment of board fees and changes of office locations.

In 2022, specific attention was given to the statutory and governance topics including the long-term succession and contingency planning of the Board of Directors and senior management, leading to the appointment of Ms. Camilla Sylvest and Ms. Ana Cespedes as non-executive director to our Board of Directors, the re-appointment of Mr. Peter K.M. Verhaeghe, Mr. James Michael Daly and Mr. Werner Lanthaler as non-executive directors and the re-appointment of Mr. Tim Van Hauwermeiren as executive director. The Board of Directors furthermore discussed the long-term succession planning of the senior management team leading to the appointment of Ms. Malini Moorthy as our general counsel, Mr. Luc Truyen as our chief medical officer and Mr. Peter Ulrichts as our chief scientific officer. The Board of Directors discussed the impact of COVID-19 and related mitigating measures, business updates, review and approval of forecasts, the Company's preparation of and execution of commercial launches relating to VYVGART in the U.S., Japan and Europe, and product portfolios, business and corporate development, review and approval of consolidated financial statements, update research and developments, committee reports, financing of the Company and the approval of the proposed agenda's and other meeting documents for General Meetings. The Board of Directors discussed the appointment of Mr. Hans de Haard and Mr. Wim Parys as members of our research and development committee. The Board of Directors furthermore specifically discussed the input received from shareholders with respect to its remuneration policy and practices, its progress towards achieving the newly approved goals for gender diversity in the Board of Directors and the Company leadership team and the implementation and oversight over the Company's healthcare compliance program.

3.3.4 Board Evaluation

The Board of Directors evaluates its functioning and the functioning of its committees and of each individual director annually. The evaluation process is performed with the help of an external professional board evaluation consultant (in 2022 this was performed by Nasdaq Governance Solutions). The evaluation includes preparing specific questionnaires focusing on the skills and competences most relevant to us, and the most material board topics and challenges we face. The written questionnaire is then followed up by one-to-one interviews with each member of the Board of Directors, followed by a debrief to the entire Board of Directors both in writing (in form of a report) and in the form of a live discussion of the evaluation report aimed at distilling specific learnings and conclusions.

Based on the self-evaluation performed, the non-executive directors concluded that the Board of Directors and its committees had properly discharged their responsibilities during 2022. The Board of Directors identified certain strengths and weaknesses and adopted a plan for further board development and succession in 2023.

3.3.5 Report Audit and Compliance Committee

The audit and compliance committee reports regularly to our Board of Directors on the exercise of its functions. It informs our Board of Directors about all areas in which action or improvement is necessary in its opinion and produces recommendations concerning the necessary steps that need to be taken. The audit review and the reporting on that review cover argenx and its subsidiaries as a whole.

In 2022, the main points of discussion at the meetings were the key findings and risk areas of the 2022 gap analysis on compliance, the key findings of the 2022 gap analysis on ESG, the 2021 ESG report, the 2021 consolidated financial statements and press release, internal audit plan for 2022, internal and external auditors' 2021 audit reports, the interim consolidated financial statements and press releases, the external auditor's 2021 audit plan and external audit report for the year 2022, the interim financial statements, review of quarterly forecasts, updates on internal control activities, updates on corporate audit activities, updates on tax priorities, policy and audit, update on the impact of the Russia/Ukraine conflict on the risk reporting, and updates on cash, cash equivalents and financial assets, the Company's enterprise risk management system and dashboard, the company's corporate ethics and compliance program and the Company's data privacy program.

In 2022, seven audit and compliance committee meetings were held. The meeting attendance rate for our directors is set out in the table below.

Name	**Number of meetings attended in 2022 since appointment**	**Attendance** (in %)
Peter K. M. Verhaeghe	100 %	80
Werner Lanthaler (chairperson)	85.71 %	100
Anthony A. Rosenberg	100 %	100
James M. Daly	100 %	100

3.3.6 Report Remuneration and Nomination Committee

The remuneration and nomination committee assists the Board of Directors by, amongst other matters, regularly reviewing our remuneration policy, preparing remuneration proposals and periodically assessing the size and composition of the Board of Directors, as well as preparing the policy of the senior management team on the selection criteria and appointment procedures for senior management. During their deliberations in 2022, the main topics of discussion were the design and implementation of our diversity, equity and inclusion policy, the review and discussion of our social disclosures in our 2021 ESG report, the long-term succession and contingency planning for the Board of Directors and senior management, the achievements of senior management's 2022 targets and their remuneration, the outcome of our say-on-pay vote at our 2022 General

Meeting and the numerous investor interactions in relation thereto to ensure broad societal support for our remuneration practices and the strategy for our ESG reporting on social aspects in 2023 and beyond.

In 2022, four formal remuneration and nomination committee meetings were held. The meeting attendance rate for our directors is set out in the table below.

Name	Number of meetings attended in 2022 since appointment	Attendance (in %)
Peter K. M. Verhaeghe	4	100
Werner Lanthaler	4	100
J. Donald deBethizy (chairperson)	4	100
Yvonne Greenstreet [1)]	–	–

1) One meeting was held prior to Yvonne Greenstreet's resignation in 2022, which Mrs. Greenstreet was unable to attend.

3.3.7 Report Research and Development Committee

The research and development committee functions as a sounding board to our research and development management, general management and the Board of Directors, and monitors our research and development goals, strategies and measures. In 2022, the committee held five formal meetings, in which it focused mainly on the vision and strategy on science, the Company's research and development pipeline including its preclinical and clinical stage product-candidates, potential future indications for its commercial stage products and developments in relation to our IIP.

The meeting attendance rate for our directors is set out in the table below.

Name	Number of meetings attended in 2022 since appointment	Attendance %
J. Donald deBethizy	4	80
Pamela Klein	5	100
David Lacey	5	100
Wim Parys [1)]	3	100

1) Wim Parys was appointed as non-director member of the research and development committee as of May 3, 2022.

3.3.8 Report Commercial Committee

The commercial committee functions as a sounding board on branded and unbranded strategic marketing plans for the Board of Directors. In 2022, the committee held five formal meetings, in which it focused mainly on our preparation and subsequent execution of our launch of VYVGART in gMG in the U.S., Japan, Europe, the Middle East and Africa as well as the preparation for potential future launches, subject to obtaining further approvals.

The meeting attendance rate for our directors is set out in the table below.

Name	Number of meetings attended in 2022 since appointment	Attendance %
Anthony A. Rosenberg	5	100
James M. Daly (chairperson)	5	100
Camilla Sylvest [1)]	2	100

[1)] Camilla Sylvest was appointed as a member of the commercial committee as of September 8, 2022.

3.4 Remuneration Report and Compensation Statement

3.4.1 Introduction

We are pleased to present our 2022 remuneration report and compensation statement. At our 2021 General Meeting, we received just over 51% approval for our 2021 remuneration report and compensation statement. Recognizing that there is room for improvement, we have since had over 30 bilateral engagement meetings with shareholders and shareholder representatives (jointly representing an estimated 50% or more of our share capital) to obtain their feedback and understand any concerns with our remuneration policy and practices. We believe that shareholder engagement is a fundamental element in the decision-making process and therefore we actively seek feedback on an ongoing basis. We have carefully considered the feedback received and have reviewed our remuneration practices in the key markets where we compete for talent. We also compared our practices to our most recent reference group data (as of September 2022). The results of these efforts have led to a number of key changes to our remuneration practices and a higher level of detail in this remuneration report compared to prior years. We are committed to continually reviewing and improving our remuneration and remuneration reporting practices.

Before going into detail on the key changes we have made, we want to highlight the fact that as a dual listed, global biotech company, we face some unique challenges in establishing an effective and appropriate performance-based remuneration programme.

In particular, it is challenging to balance adherence to local market (Dutch) remuneration best practices and those of the countries in which we are listed (Belgium and the U.S.) as these requirements are different and sometimes in conflict. Adding to this challenge, we are simultaneously striving to ensure a remuneration structure that is competitive in the global markets for talent in which we compete, in particular in the U.S. This is especially true with respect to the design of our long-term incentive program in the form of equity compensation, which was a recurring topic in most of the investor engagements we had in the 12 month period leading up to this Annual Report. To be succesful in our global mission, we need to effectively compete for top talent across a number of regions which have differing and at times conflicting remuneration practices. To be able to effectively compete for talent, we collect benchmark data on the composition and size of remuneration packages offered by our reference companies in these key jurisdictions, including both EU and U.S. companies in our reference group (as further detailed in section 3.4.4 below), and to a large extent align our remuneration practices with those of our peers. We aim to take a balanced approach by adopting practices that help attract top talent while taking account of the best practices in our home jurisdiction (the Netherlands) and those of the countries in which our shares are listed (Belgium and the U.S.).

3.4.2 Changes to our remuneration practices in response to shareholder dissent

The feedback we collected showed differing views on the various remuneration practices and components including on our equity incentive practices and other methods of linking pay and performance. In particular:

1. We grant stock options to non-executive directors which is a form of performance-based incentives and as such not in line with Dutch remuneration best practices;

2. We grant stock options and RSUs to our executives which are linked to Company (share price) performance but are not linked to individual performance targets;

3. Some shareholders were of the view that we did not sufficiently disclose the method of setting award levels under our equity plan;

4. The RSUs we grant vest in equal portions of 25% over a four-year period, and underlying shares may be sold on vesting. This is not in line with Dutch remuneration best practices (requiring a five-year holding period for shares). Additionaly, we did not impose holding requirement for executives;

5. We did not disclose in detail the short-term performance targets and their achievements and corresponding pay-outs for our CEO and other key executives;

6. Certain proxy voting agencies held that we did not sufficiently address shareholder concerns raised in relation to our 2020 annual report (76% majority approved).

To address shareholder feedback, we want to take the opportunity to further explain our rationale for the abovementioned remuneration practices, and report on any changes to our remuneration practices (implemented or expected) in relation thereto.

1. We grant stock options to our non-executive directors which is a form of performance-based incentives and is as such not in line with Dutch remuneration best practices.

With regard to non-executive directors participating in our Equity Incentive Plan specifically: the DCGC recommends, as best practice, not to grant equity incentives to non-executive directors; in contrast, the Belgian Corporate Governance Code requires that at least part of the compensation of non-executive directors be paid in the form of equity. Moreover, granting equity to non-executive directors is common practice among the companies in our U.S. reference group (100% of these companies granted equity in 2021, 94% of which also offered stock options) and to a lesser but still significant extent, our 2022 EU reference group (56% grant equity, 33% of which also offered stock options). Considering the anticipated need to attract a number of new, highly qualified directors to our Board of Directors, our remuneration and nomination committee recommended our Board of Directors continue to align the remuneration practices for non-executive directors with those of our global reference group. We note that this practice continues to be fully aligned with our shareholder-approved remuneration policy. In 2022, based on the benchmarking exercise performed, we reduced the total number of equity instruments to be granted to non-executive directors, to re-align the projected value with the 50th percentile of our reference group.

In addition to stock options being a common remuneration component in the markets where we compete for talent, they have the advantage of aligning the interests of our non-executive directors with those of our shareholders. The use of stock options rewards a focus on long-term value creation over short-term successes, as the value of a stock option depends on the company's value increasing in the time between the grant and exercise of the stock option. To further solidify this effect, we have implemented a three-year cliff vesting on stock options for non-executive directors and post-termination holding requirements, to ensure equity incentive instruments are held as long term investments in the Company.

Some shareholders hold that alignment of interests between the non-executive directors and the shareholders should be avoided, as it could impact our directors' independence. We note that our Board of Directors (with the exception of our CEO) qualifies as independent under Dutch, Belgian and U.S. independence rules. To address this concern further, we have updated our Equity Performance Plan such that equity incentives granted to directors and vested will not be forfeited if directors leave our Board of Directors, unless they are discharged by the shareholders, thereby ensuring that directors are not disincentivized from resigning from the Board of Directors if they are unable to reconcile their views with management team's or the other directors'. Directors who are discharged by shareholders, however, will lose their unvested equity. Finally, we have implemented post-termination holding requirements for non-executive directors which continue to apply for 24 months after a director leaves the Board of Directors.

2. We grant stock options and RSUs to our executives which are linked to company (share price) performance but are not linked to individual performance targets. Some shareholders disagree with the use of stock options altogether.

Stock options are by nature performance-linked equity instruments. When we grant options, the exercise price is set at the market value of the shares at the grant date. The stock options vest over an extended time period (three years) and are bound to further holding requirements or exercise restrictions for our directors and senior management team, in line with our equity holding guidelines (see section **3.4.2**, paragraph 4 below). In addition, our executives who are Belgian tax residents (including our CEO) may not exercise stock options in the first three years after they are granted. As a result, only successful long-term value creation will lead to an actual value attribution to stock options, thereby directly aligning shareholder interests with the interests of individual key persons. Multi-year vesting periods ensure that decision making in favor of long-term value creation is prioritized over short-term successes. The post-termination holding requirements further amplify this effect.

A vast majority of our reference group companies continue to use stock options as an important compensation element. Moving away from stock options may harm our competitive position in the key jurisdictions where we operate and compete for talent, which we believe would not support long-term value creation.

Some shareholders have questioned the overall award levels or overall value generated in the form of stock options. We note that the number of stock options and RSUs we grant, is based on an expected value of such grant at the time the award level is set, and which is aligned with the peer group percentile targets explained in section **3.4.4** below. Any value creation beyond the projected value at grant corresponds with real value generated for our stakeholders, including shareholders, patients and employees, by delivering on our key company goals and building our Company's long-term success and value. We believe that award value realized should not be viewed in isolation, but should be viewed in light of the overall shareholder return realized. For illustration purposes, we provide shareholder return realized in the 5-year period for argenx shareholders versus European and U.S. biotech peers, as well as the Bel20 as reference for other large cap Belgian listed companies.

Period: 5 years
(comparing closing prices on January 1, 2018 and December 31, 2022)

argenx stock price evaluation	+545%
NASDAQ Biotech index	+22.45%
Next Biotech	+23.55%
Bel20	-6.99%

We have so far not linked the vesting or exercisability of stock options to individual performance targets. However, continued engagement with the Company is a requirement for vesting equity. Persons who have not performed adequately do not receive full recurring equity grants but may receive a reduced grant or no grant at all. As a result, granted and vested stock options are linked to Company performance but are no longer linked to individual performance, receiving and vesting a grant of stock options requires continued high performance of the individual.

3. We are evaluating our options to address shareholder feedback with respect to linking equity awards to performance. Some shareholders were of the view that we did not sufficiently disclose the method of setting award levels under our equity plan;

We have included a more detailed explanation on how we set award levels under the Equity Incentive Plan in section **3.4.4** of this Annual Report.

4. The RSUs we grant, vest in equal portions of 25% over a 4 year period, and underlying shares may be sold upon vesting. This is not in line with Dutch remuneration best practices (requiring a 5 year holding period for shares). Additionally, we did not impose a holding requirement for executives;

In addition to the participation of non-executive directors in our Equity Incentive Plan, we also reviewed our reference group's practices with respect to equity vesting and exercisability requirements. The DCGC recommends that any shares granted to executive directors are held for at least five years. However, 100% of our U.S. peers granted annual equity which vested after one year. Instead of a five- year lockup, our U.S. reference group companies typically implemented holding requirements which prescribe a continued holding of company stock at a certain multiple of an individual's base salary, but they did not implement extended lock-up periods. In order not to risk the competitiveness of our plan and to ensure it is in line with market practice, we continue to allow RSUs to vest over four-years (25% each anniversary of the grant date). However, to ensure that company equity is held as a long term investment by our non-executive directors and our senior management team, we have implemented holding requirements for the duration of their engagement with the Company and a period of 24 months thereafter, as further detailed below:

Holding requirements

Following feedback from our shareholders on our 2021 remuneration report, our Board of Directors introduced equity holding guidelines for our Board of Directors and senior management team. The guidelines became effective in February 2022. Under these guidelines, the following minimum shareholding requirements apply for the following persons:

- Non-executive directors: 1-year cash compensation
- Executive directors: 3-year base cash compensation
- Senior management members: 1-year base cash compensation

The holding requirements must be built up over a period of no more than five years, and the shares beneficially held under such holding requirement may not be disposed of for the duration of such director or senior management member's service period with the Company and a period of 24 months thereafter. The holding requirements do not apply to directors or executives who had already retired or announced their retirement prior to implementation of the policy on 3 March 2023.

5. We did not disclose in detail the short term performance targets and their achievement and corresponding pay out for our CEO and other key executives.

We now disclose (retrospectively) the full set of short term performance targets for our CEO, CFO and COO, which we understand to be market practice for companies of our size and in our industry.

6. Certain proxy voting agencies held that we did not sufficiently address shareholder concerns raised in relation to our 2021 report (76% majority approved).

We have attempted to collect as much feedback as we could by reaching out to a large number of stakeholders. We have summarized the key findings of those engagements in this section and provided detailed explanations and (where appropriate) remediating actions accordingly.

3.4.3 Remuneration Policy

Our remuneration policy rewards contributions to achieving Company objectives and generating stakeholder value. We aim to provide competitive remuneration packages that align with market practices in the key markets where we compete for talent. We conduct regular reviews (at least once every three years) of director and senior management members' total remuneration compared to our reference companies. Our remuneration policy and total compensation aligns or slightly exceeds the market median for fixed compensation, benefits, and short-term variable compensation. The long-term incentive component consists of equity grants, is the size of which is positioned between the 50th and the 75th percentile of our global reference group. Our remuneration policy 2021 is available on our **website**. Our remuneration policy was adopted at the 2021 General Meeting with a 76% majority vote.

3.4.4 Reference Group and Setting Reward Levels

As explained in section 3.4.1 above, we face challenges in setting remuneration levels and structures which are competitive in the key markets where we compete for talent, due to the global nature of our operations. As a result, a key aspect of how we set our remuneration levels is how we define our reference group for benchmarking purposes, which is explained in detail in this section 3.4.4.

This section describes how our Board of Directors sets the level of cash compensation and the award levels under our equity plan. With the help of an independent outside advisory firm, we conduct periodic reviews of compensation levels for senior management and the Board of Directors by comparing against our reference group compensation levels. The Company reviews the benchmark at least once every three years (the last review was conducted in September 2022). The outcome of these benchmarking activities is subsequently reviewed and discussed by our remuneration and nomination committee, which then prepares recommendations to the Board of Directors for the adjustment of our remuneration package composition, size and corresponding terms and conditions.

We use a combined reference group composed of U.S.- and European-based biopharmaceutical companies, as we consider Europe and the U.S. key markets for talent in which we compete. Japanese biopharmaceutical companies were not included in the reference group as we did not identify any Japanese company that meets the relevant combination of criteria defined by our remuneration and nomination committee (shared below).

The companies included in the reference group take into account our global ambitions and include relevant industry peers based on a combination of key criteria as reflected in the below overview.

As the industry in which we operate is highly dynamic, marked by uncertainty, mergers, acquisitions, setbacks and successes we aim to maintain a reference group that is comprised out of at least 24 companies, meeting a combination of the defined key criteria. We deem this necessary to ensure that the reference group is representative of the industry's current landscape in which we compete for talent and includes relevant companies with similar characteristics. As we grow and our industry evolves, companies may enter or exit the market, or their business models may shift, making it necessary to reassess the reference group for accurate comparisons. Therefore, regular updates to the reference group and the criteria used is essential to ensure accurate benchmarking and informed decision-making, and to ensure long-term stability and relevance of the benchmarking outcomes.

Key Peer Company Selection Criteria for most recent benchmark (September 2022)

Element	Historical 2021 Peer Company Selection Criteria	Current 2022 Peer Company Selection Criteria
Sector	• Biotechnology and pharmaceutical industries	• No change
Stage of Development	• Primarily phase 3 with some NDA/ recently market-stage companies	• Market-stage companies
Market Capitalization	• $5 billion to $50 billion based on our 30-day average market value of approximately $16 billion as of July 16, 2021	• 1/3x – 3x our 30-day average market value as of May 20, 2022 • $5 billion to $50 billion (no change)
Headcount	• 200 to 2,000 employees based on our projected FYE21 headcount at that time (650 employees)	• 1/3x – 3x the midpoint of our projected FYE 22 and FYE 23 headcount • 300 to 2,500 employees
Revenue	• N/A – not a criterion last year	• Less than $1 billion in revenues
Years Public (Secondary)	• Preference towards companies that went public in the last ten years	• No change

Current Reference Companies

US Peers	EU Peers
Acadia Pharmaceuticals, Inc.	Galapagos NV
Alnylam Pharmaceuticals, Inc.	UCB SA
Amicus Therapeutics, Inc.	ALK-Abelló A/S
BeiGene Ltd	Ascendis Pharma A/S
Biohaven Pharmaceutical Holding Co Ltd	Genmab A/S
BioMarin Pharmaceutical, Inc.	BioNTech SE
Blueprint Medicines Corp	Evotec SE
Denali Therapeutics, Inc.	Incyte Corporation
Intellia Therapeutics, Inc.	Horizon Therapeutics PLC
Intra-Cellular Therapies, Inc.	Recordati S.p.A.
Ionis Pharmaceuticals, Inc.	uniQure NV
Mirati Therapeutics, Inc.	Swedish Orphan Biovitrum AB
Neurocrine Biosciences, Inc.	CRISPR Therapeutics AG
Sarepta Therapeutics, Inc.	Idorsia Ltd.
Seagen, Inc.	Vifor Pharma AG
	Abcam PLC
	Hikma Pharmaceuticals PLC

Our Board of Directors sets award levels based on the outcome of our benchmarking exercise. Our remuneration policy, contains the following guidance in this respect:

	Non-executives	**Senior management team** (including our CEO)
Cash-based compensation	50th percentile of the companies in our global reference group	50th percentile of U.S. companies in our reference group for U.S.-based executives, and at or around the 75th percentile of EU companies in our reference group for EU-based executives
Equity-based compensation	50th percentile of the U.S. companies in our reference group	50th to 75th percentile of the U.S. companies in our reference group

3.4.5 Remuneration Components of our Senior Management Team Compensation

Pursuant to our shareholder-approved remuneration policy, the remuneration of our executive director(s) consists of the following components:

- fixed-base compensation;
- short-term variable compensation, based on the achievement of pre-determined targets;

- severance arrangements;
- long-term variable compensation, in the form of stock options and RSUs; and
- pension and fringe benefits.

We note that while our remuneration policy by law applies only to members of our Board of Directors, we apply its principles to all our employees. In the rest of this chapter 3.4, we have limited our reporting to members of our Board of Directors and our senior management team unless explicitly mentioned otherwise.

Fixed-Base Compensation

We grant our senior management team members a fixed base (cash) compensation determined on the basis of our benchmarking exercise explained in section **3.4.2** above. The final determination of a senior management member's fixed-base pay is made considering the benchmark, the individual's skills, experience and performance, the remuneration practices and conditions across the wider organization and our interactions with key stakeholders to secure broad public support for our remuneration practices and the feedback from the individual on their own remuneration levels. The target fixed cash compensation levels are set in accordance with our remuneration policy (as detailed in section **3.4.4**) but we note that the actual base cash remuneration for our executive director is below the targeted percentiles, taking into account the feedback from our executive director on proposals of the remuneration and nomination committee to increase the base pay to align more closely with the targeted percentile of the benchmark.

Short-Term Variable Compensation based on the Achievement of Pre-Determined Targets

The objective of our short-term annual incentive compensation is to ensure that our senior management team is incentivized to achieve pre-defined performance targets in the shorter term. Variable cash incentives are granted for achieving predetermined specific performance targets. Our senior management team is eligible for an annual short-term variable incentive of their annual base compensation. The short-term target percentage is equal to up to 60% of the fixed-base compensation for our CEO, between 40–50% for our C-level employees (benchmarked per role) and up to 35% for vice president level members of our senior management team. The short-term incentive opportunity is capped at 200% of the target percentages, in line with the principles applied for the broader employee base at the Company. We have not established pay-out caps per individual target, but apply the pay-out cap of 200% of the total variable pay opportunity (i.e. in case of our CEO, the maximum variable pay cap of 200% represents 120% of base cash remuneration).

Long-term variable compensation, in the form of stock options and RSUs

Stock options and RSUs may be awarded every year, in accordance with our Equity Incentive Plan, whereby the stock options vest over a three-year period and the RSUs vest over a four-year period. Stock options may not be exercised by our Belgian tax resident employees (including our CEO) until the fourth calendar year following the year of the grant. RSUs vest 25% of the total grant at each anniversary of the grant date. Shares obtained through the vesting of RSUs and through the exercise of stock options, are subject to our equity holding requirements further explained in section **3.4.2**.

Severance Arrangements

Our CEO has a severance arrangement in place of 18 months if he is discharged for reasons other than for cause.

Pension and Fringe Benefits

Pension and fringe benefits are awarded based on local market practices. For Belgium tax resident employees (including our CEO) this includes a defined contribution pension scheme operated by a third-party pension insurance organization, a company car (as from a certain paygrade level) and a hospitalization plan. We note that the pension arrangements offered to our Belgian based executives including our CEO mirror those offered to other Belgian based employees.

Performance of Scenario Analyses

In accordance with the DCGC, when determining the remuneration package of our executive director(s), scenario analyses are performed annually and taken into account in setting the level of the base remuneration to be paid as well as the variable remuneration and the corresponding targets.

3.4.6 Executive Remuneration paid in 2022

Compensation of our CEO

The following table sets forth information regarding compensation we paid to Mr. Van Hauwermeiren for services performed during the fiscal year ended December 31, 2022.

Compensation (in $)	**Financial year ended December 31, 2022**
Base salary	638,901
Short-term Incentive	766,689
Option awards [1)]	4,174,684
RSUs [2)]	2,159,689
Employer social security contribution stock options [3)]	–
Non-Equity Incentive Plan compensation	–
Pension contributions	23,384
Social security costs	–
Other [4)]	14,958
Total	**7,778,305**

1) Amount shown represents the expenses with respect to the option awards granted in 2022 to Mr. Van Hauwermeiren measured using the Black Scholes formula. For a description of the assumptions used in valuing these awards, see **note 13** to our financial statements included elsewhere in this Annual Report. These amounts do not reflect the actual economic value realized by Mr. Van Hauwermeiren.

2) Amounts shown represent the expenses with respect to the RSUs awards granted in 2022, measured using the Black Scholes formula. For a description of the assumptions used in valuing these awards, see **note 13** to our consolidated financial statements in section 6 "**Consolidated Financial Statements**".

3) We incur employer social security costs with respect to the options granted to members of our senior management. The amount of employer social security costs depends on the actual economic value realized and therefore varies based on the price of our ordinary shares. At each reporting date, we make a calculation of the exposure.

4) Consists of $11,615 attributable to the lease of a company car, $182 in employer-paid medical insurance premiums and $3,161 of allowance.

Increase in base salary for our CEO

Our CEO base salary increased by 10% from fiscal year 2021 to fiscal year 2022. The 10% increase was deemed appropriate by our remuneration & nomination committee to more closely align our CEO base pay to that of the reference group, and considering the continued high performance of the CEO and the Company through its rapid growth over the past years. We note that our CEO's base pay continues to be below the reference group 50th percentile. The aforementioned 10% includes inflation correction and merit increase.

Variable vs Fixed Compensation Determination for CEO

The mix between fixed and variable cash based remuneration components (excluding equity compensation) for our executive director for the last three years is set out below:

(in $) [1]	2022	2021	2020
Fixed	677,243	621,071	599,230
Variable	766,682	523,799	456,362
Total	**1,443,925**	**1,144,870**	**1,055,592**

[1] Using a fixed exchange rate of 1.05 USD / 1 EUR, taking into account that our CEO's salary is paid in EUR but our functional and reporting currency is in USD.

The ratio between fixed and variable cash payments to our CEO for the fiscal year ended December 31, 2022 equals $677,243 / $766,682 or 46.9% / 53.1%, respectively.

Short term incentives

Name	Type	Company strategy	Measure	Assesment of performance	Achievement	Overall achieve-ment (in %)	Overall pay-out (in %)
Tim Van Hauwermeiren CEO	Building the Business	Commercial launch performance	Outperform VYVGART launch forecast	Four quarterly beat & raise events. Internal launch forecast significantly exceeded, while reinforcing our science-based, patient-focused and transparent foundation and reputation	Overachieved	200	200
		Financing	Raise >$500 million to finance business plan	$805 million raised despite unfavorable market conditions	Overachieved		
	Building the Organization	Pipeline development (co-creation)	Live the cultural pillar of co-creation, including modelling exemplary collaboration with external experts in our IIP	Personally engaged in our IIP work for undisclosed antibody targets; successfully coached next-gen scientists and guided seamless transition of the chief scientist officer role	Achieved		
		Commercial launch performance (empowerment)	Ensure Company-wide alignment behind business plan to support key priorities and empower our people	Spent more than five months on the road with newly installed commercial organization in support of our launch priorities. Personally welcomed all new hires and reinforced key priorities across the company	Achieved		
Keith Woods COO	Building the Business	Commercial launch performance	Outperform VYVGART launch forecast	Four quarterly beat & raise events. Internal launch forecast significantly exceeded, while reinforcing our science-based, patient-focused and transparent foundation and reputation	Overachieved	200	200
		Commercial expansion	Deliver successful Japan launch, EMA approval for VYVGART in gMG in Q3, sales in Germany in Q4, Canada regulatory submission in Q3	Significantly exceeded internal target. Marketing approval in Germany ahead of schedule	Overachieved		
	Building the Organization	Commercial performance (co-creation)	Live the cultural pillar of co-creation leveraging collaboration between local teams globally	New operating model for cross-regional collaboration between local commercial organizations implemented and fully operational, contributing to above expectation launches, cross-regional sharing of learnings on ongoing basis and commercial and scientific teams aligned on patient-focused objectives	Achieved		
		Succession planning & development	High quality personal development plans in place for all direct reports. Identify excellent successor with broad buy-in across the entire commercial organization in accordance with long-term succession plan	High quality personal development plans in place. Selection of successor progressed significantly (and completed as of the date of this Annual Report) per succession plan.	Achieved		

Name	Type	Company strategy	Measure	Assesment of performance	Achievement	Overall achieve-ment (in %)	Overall pay-out (in %)
Karl Gubitz CFO	Building the Business	Financing	Raise >$500 million to finance the business plan	$805 million raised despite unfavorable market conditions	Overachieved	125	125
		Commercial performance, transparency, stakeholder relations	Ensure internal and external alignment of expectations around financial launch performance	Expectations on commercial launch performance evolved in line with launch dynamic, while reinforcing science-based, patient-focused and transparent foundation and reputation.	Achieved		
	Building the Organization	Financial performance, Excellence	Drive expense discipline and capital allocation focused on innovation. Establish procurement, management reporting	Procurement and management reporting established; internal efficiency gain measured as significantly cost-saving. Significantly improved forecasting and budgeting processes.	Achieved		
		Financial performance, Innovation	Improve our enterprise-wide processes and tools, including usability and user-friendliness	Achieved, including in relation to finance related tools (enterprise resource planning system simplification) as measured through internal survey results.	Achieved		

Remuneration of other members of our senior management

The following table sets forth information regarding aggregate compensation we paid to members of our senior management team (excluding our CEO Mr. Van Hauwermeiren) during the fiscal year ended December 31, 2022. We note that these numbers also include compensation paid to persons who were part of our senior management for part of 2022 (i.e., Mr. Wim Parys, Ms. Malini Moorthy and Mr. Luc Truyen).

(in $)	**Compensation**
Base salary	3,560,204
Short-term incentive	2,310,530
Option awards [1)]	14,218,284
RSUs [2)]	7,434,327
Employer social security contribution stock options [3)]	1,100,665
Termination benefits	–
Pension contributions	81,030
Social security costs	1,014,821
Other [4)]	356,581
Total	**30,076,443**

1) Amounts shown represent the expenses with respect to the option awards granted in 2022 to Mr. Karl Gubitz, Mr. Keith Woods, Mr. Luc Truyen, Mr. Arjen Lemmen. Ms. Malini Moorthy and Ms. Andria Wilk measured using the Black Scholes formula. For a description of the assumptions used in valuing these awards, see **note 13** to our consolidated financial statements incorporated elsewhere in this Annual Report. These amounts do not reflect the actual economic value realized by these members of our senior management.

2) Amounts shown represent the expenses with respect to the RSUs awards granted in 2022, measured using the Black Scholes formula. For a description of the assumptions used in valuing these awards, see **note 13** to our consolidated financial statements in section 6 "**Consolidated Financial Statements**".

3) The Company incurs employer social security costs with respect to the option awards granted to the members of our senior management. The amount of employer social security costs depends on the actual economic value realized and therefore varies based on the price of our ordinary shares. At each reporting date, the Company makes a calculation of the exposure.

4) Consists of $35,536 attributable to the leases of company cars, $232,517 in car, housing and other allowances and $88,529 in employer-paid medical insurance premiums.

Option Awards to our Senior Management in 2022

The following table sets forth information regarding option awards granted to our senior management during the fiscal year ended December 31, 2022:

Name	Stock options	Expiration date	Exercise price (in $)	Exercise price (in EUR)
Tim Van Hauwermeiren [1]	25,000	23/12/2032	383.55	359.6
Keith Woods [2]	16,000	23/12/2032	383.55	359.6
Karl Gubitz	16,000	01/07/2032	381.31	357.5
Prof. Hans de Haard [3]	–	–	–	–
Malini Moorthy	24,000	01/04/2032	301.31	282.5
Luc Truyen [1]	16,000	23/12/2032	383.55	359.6
Wim Parys [4]	–	–	–	–
Arjen Lemmen	16,000	23/12/2032	383.55	359.6
Andria Wilk [1]	4,600	23/12/2032	383.55	359.6

1) On December 23, 2022, the Company granted options for which Belgian tax resident beneficiaries have a 60-day period to choose between a contractual term of five or ten years.

2) Keith Woods retired as COO effective March 13, 2023 and was succeeded by Karen Massey effective March 13, 2023.

3) Prof. de Haard retired effective December 31, 2022 and, therefore, was not granted any equity in 2022 and was succeeded by Peter Ulrichts effective January 1, 2023.

4) Mr. Parys retired effective March 30, 2022 and, therefore, was not granted any equity in 2022 and was succeeded by Mr. Truyen effective April 1, 2022.

The following table sets forth information regarding RSUs granted to our senior management during the fiscal year ended December 31, 2022:

Name	# of RSUs	Vesting End Date [2]
Tim Van Hauwermeiren	5,700	23/12/2026
Keith Woods	3,600	23/12/2026
Karl Gubitz	3,600	01/07/2026
Prof. Hans de Haard	–	–
Malini Moorthy	5,400	01/04/2026
Wim Parys [1]	–	–
Arjen Lemmen	3,600	23/12/2026
Luc Truyen [1]	3,600	23/12/2026
Andria Wilk	1,000	23/12/2026

1) Mr. Parys retired effective March 30, 2022 and, therefore, was not granted any equity incentives in 2021 and was succeeded by Luc Truyen effective April 1, 2022.

2) RSUs vest equally over a period of four years with 1/4th of the total grant vesting at each anniversary of the date of grant. RSUs do not have an expiry date.

The table below shows (i) the stock options held as of January 1, 2022, (ii) the stock options granted to our senior management which vested during the year ended December 31, 2022, (iii) the number of stock options exercised and vested during the year, (iv) the respective exercise price of such stock options and (v) the stock options held as of December 31, 2022. Each stock option was granted pursuant to our Equity Incentive Plan:

Remuneration in Stock Options CEO and Senior Management

								Information regarding the reported financial year							
								Opening balance	During the Year			Closing balance			
Name of Directors, Position	Specification of plan	Performance period	Award date	Vesting date [1]	End of retention period	Exercise period	Exercise price of stock option (in €)	Stock options held at the beginning of the year	Stock options awarded	Stock options exercised	Stock options vested during the year	Stock options subject to a performance condition	Stock options awarded and unvested	Stock options held at the end of the year	Stock options subject to a retention period
Tim van Hauwermeiren, chief executive officer	Equity Incentive Plan	14/12/2017–01/12/2020	14/12/2017	Please refer to footnote.	31/12/2020	01/01/2021–14/12/2027	21.17	80,000	–	(7,500)	–	–	–	72,500	–
		21/12/2018–01/12/2021	21/12/2018		31/12/2021	01/01/2022–21/12/2028	86.32	80,000	–	–	–	–	–	80,000	–
		20/12/2019–01/12/2022	20/12/2019		31/12/2022	01/01/2023–20/12/2029	135.75	80,000	–	–	26,667	–	–	80,000	–
		21/12/2020–01/12/2023	21/12/2020		31/12/2023	01/01/2024–21/12/2030	247.60	50,000	–	–	16,667	16,667	16,667	50,000	50,000
		24/12/2021–01/12/2024	24/12/2021		31/12/2024	01/01/2025–24/12/2031	309.20	25,000	–	–	8,333	16,667	16,667	25,000	25,000
		23/12/2022–01/12/2025	23/12/2022		31/12/2025	01/01/2026–23/12/2032	359.60	–	25,000	–	–	25,000	25,000	25,000	25,000
Total								**315,000**	**25,000**	**(7,500)**	**51,667**	**58,334**	**58,334**	**332,500**	**100,000**
Keith Woods, chief operations officer	Equity Incentive Plan	21/12/2018–01/12/2021	21/12/2018	Please refer to footnote.	N/A	21/12/2019–21/12/2028	86.32	25,000	–	(25,000)	–	–	–	–	N/A
		20/12/2019–01/12/2022	20/12/2019		N/A	20/12/2020–20/12/2029	135.75	50,000	–	(15,000)	16,700	–	–	35,000	N/A
		21/12/2020–01/12/2023	21/12/2020		N/A	21/12/2021–21/12/2030	247.60	50,000	–	–	16,668	16,667	16,667	50,000	N/A
		24/12/2021–01/12/2024	24/12/2021		N/A	24/12/2022–24/12/2031	309.20	16,000	–	–	5,333	10,667	10,667	16,000	N/A
		23/12/2022–01/12/2025	23/12/2022		N/A	23/12/2023–23/12/2032	359.60	–	16,000	–	–	16,000	16,000	16,000	N/A
Total								**141,000**	**16,000**	**(40,000)**	**38,701**	**43,334**	**43,334**	**117,000**	

[1] 1/3 of the option vests on the first anniversary of the Award Date and the remaining 2/3rd vest during the following two years in equal parts of 1/24th, each time upon the 1st day of each month.

								Information regarding the reported financial year							
								Opening balance	During the Year			Closing balance			
Name of Directors, Position	Specification of plan	Performance period	Award date	Vesting date[1]	End of retention period	Exercise period	Exercise price of stock option (in €)	Stock options held at the beginning of the year	Stock options awarded	Stock options exercised	Stock options vested during the year	Stock options subject to a performance condition	Stock options awarded and unvested	Stock options held at the end of the year	Stock options subject to a retention period
Karl Gubitz, chief financial officer	Equity Incentive Plan	01/07/2021–01/07/2024	01/07/2021	Please refer to footnote.	N/A	01/07/2022–01/07/2031	255.10	24,000	–	–	11,333	12,667	12,667	24,000	N/A
		01/07/2022–01/07/2025	01/07/2022		N/A	01/07/2023–01/07/2032	357.50	–	16,000	–	–	16,000	16,000	16,000	N/A
Total								**24,000**	**16,000**	**–**	**11,333**	**28,667**	**28,667**	**40,000**	
Prof. Hans de Haard, chief scientific officer	Equity Incentive Plan	29/06/2012–29/06/2015	29/06/2012	Please refer to footnote.	31/12/2017	01/01/2018–18/12/2024	2.44	108,996	–	(108,996)	–	–	–	–	–
		30/09/2014–30/09/2017	30/09/2014		31/12/2018	01/01/2019–15/12/2025	2.44	35,826	–	(35,826)	–	–	–	–	–
		18/12/2014–01/12/2017	18/12/2014		31/12/2017	01/01/2018–18/12/2024	7.17	109,000	–	–	–	–	–	109,000	–
		15/12/2015–01/12/2018	15/12/2015		31/12/2018	01/01/2019–15/12/2025	9.47	28,200	–	–	–	–	–	28,200	–
		25/05/2016–01/05/2019	25/05/2016		31/12/2019	01/01/2020–25/05/2026	11.47	28,200	–	–	–	–	–	28,200	–
		13/12/2016–01/12/2019	13/12/2016		31/12/2019	01/01/2020–13/12/2026	14.13	28,200	–	–	–	–	–	28,200	–
		26/06/2017–01/06/2020	26/06/2017		31/12/2020	01/01/2021–26/06/2027	18.41	14,353	–	–	–	–	–	14,353	–
		14/12/2017–01/12/2020	14/12/2017		31/12/2020	01/01/2021–14/12/2027	21.17	43,200	–	–	–	–	–	43,200	–
		21/12/2018–01/12/2021	21/12/2018		31/12/2021	01/01/2022–21/12/2028	86.32	50,000	–	–	–	–	–	50,000	–
		20/12/2019–01/12/2022	20/12/2019		31/12/2022	01/01/2023–20/12/2029	135.75	50,000	–	–	16,666	–	–	50,000	–
		21/12/2020–01/12/2023	21/12/2020		31/12/2023	01/01/2024–21/12/2030	247.60	50,000	–	–	33,334	–	–	50,000	50,000
		24/12/2021–01/12/2024	24/12/2021		31/12/2024	01/01/2025–24/12/2031	309.20	16,000	–	–	16,000	–	–	16,000	16,000
Total								**561,975**		**(144,822)**	**66,000**			**417,153**	**66,000**

[1] 1/3 of the option vests on the first anniversary of the Award Date and the remaining 2/3rd vest during the following two years in equal parts of 1/24th, each time upon the 1st day of each month.

								Information regarding the reported financial year							
								Opening balance	During the Year			Closing balance			
Name of Directors, Position	**Specification of plan**	**Performance period**	**Award date**	**Vesting date** [1]	**End of retention period**	**Exercise period**	**Exercise price of stock option** (in €)	**Stock options held at the beginning of the year**	**Stock options awarded**	**Stock options exercised**	**Stock options vested during the year**	**Stock options subject to a performance condition**	**Stock options awarded and unvested**	**Stock options held at the end of the year**	**Stock options subject to a retention period**
Luc Truyen, chief medical officer	Equity Incentive Plan	01/10/2021–01/10/2024	01/10/2021	Please refer to footnote.	31/12/2024	01/01/2025–01/10/2026	259.50	24,000	–	–	9,333	14,667	14,667	24,000	24,000
		23/12/2022–01/12/2025	23/12/2022		31/12/2025	01/01/2026–23/12/2032	359.60	–	16,000	–	–	16,000	16,000	16,000	16,000
Total								**24,000**	**16,000**		**9,333**	**30,667**	**30,667**	**40,000**	**40,000**
Wim Parys, chief medical officer	Equity Incentive Plan	21/12/2018–01/12/2021	21/12/2018	Please refer to footnote.	31/12/2021	01/01/2022–21/12/2028	86.32	125,000	–	(85,000)	–	–	–	40,000	–
		20/12/2019–01/12/2022	20/12/2019		31/12/2022	01/01/2023–20/12/2029	135.75	50,000	–	–	16,667	–	–	50,000	–
		21/12/2020–01/12/2023	21/12/2020		31/12/2023	01/01/2024–21/12/2030	247.60	50,000	–	–	16,666	16,667	16,667	50,000	50,000
Total								**225,000**		**(85,000)**	**33,333**	**16,667**	**16,667**	**140,000**	**50,000**

[1] 1/3 of the option vests on the first anniversary of the Award Date and the remaining 2/3rd vest during the following two years in equal parts of 1/24th, each time upon the 1st day of each month.

								Information regarding the reported financial year							
								Opening balance	During the Year			Closing balance			
Name of Directors, Position	Specification of plan	Performance period	Award date	Vesting date [1]	End of retention period	Exercise period	Exercise price of stock option (in €)	Stock options held at the beginning of the year	Stock options awarded	Stock options exercised	Stock options vested during the year	Stock options subject to a performance condition	Stock options awarded and unvested	Stock options held at the end of the year	Stock options subject to a retention period
Arjen Lemmen, vice president of corporate development & strategy	Equity Incentive Plan	26/06/2017–01/06/2020	26/06/2017	Please refer to footnote.	31/12/2020	01/01/2021–26/06/2027	18.41	4,306	–	(4,306)	–	–	–	–	–
		14/12/2017–01/12/2020	14/12/2017		31/12/2020	01/01/2021–14/12/2027	21.17	6,328	–	(6,328)	–	–	–	–	–
		28/06/2018–01/06/2021	28/06/2018		31/12/2021	01/01/2022–21/12/2028	80.82	3,195	–	(2,500)	–	–	–	695	–
		21/12/2018–01/12/2021	21/12/2018		31/12/2021	01/01/2022–21/12/2028	86.32	15,952	–	–	–	–	–	15,952	–
		20/12/2019–01/12/2022	20/12/2019		31/12/2022	01/01/2023–20/12/2029	135.75	50,000	–	–	12,518	–	–	50,000	–
		21/12/2020–01/12/2023	21/12/2020		31/12/2023	01/01/2024–21/12/2030	247.60	50,000	–	–	16,666	16,667	16,667	50,000	50,000
		24/12/2021–01/12/2024	24/12/2021		31/12/2024	01/01/2025–24/12/2031	309.20	16,000	–	–	5,333	10,667	10,667	16,000	16,000
		23/12/2022–01/12/2025	23/12/2022		N/A	23/12/2023–23/12/2032	359.60	–	16,000	–	–	16,000	16,000	16,000	–
Total								**145,781**	**16,000**	**(13,134)**	**34,517**	**43,334**	**43,334**	**148,647**	**66,000**
Andria Wilk, Global Head of Quality	Equity Incentive Plan	20/12/2019–01/12/2022	20/12/2019	Please refer to footnote.	31/12/2022	01/01/2023–20/12/2029	135.75	9,400	–	–	2,354	–	–	9,400	–
		21/12/2020–01/12/2023	21/12/2020		31/12/2023	01/01/2024–21/12/2030	247.60	9,900	–	–	2,663	2,662	2,662	9,900	9,900
		24/12/2021–01/12/2024	24/12/2021		31/12/2024	01/01/2025–24/12/2031	309.20	4,446	–	–	2,935	756	756	4,446	4,446
		23/12/2022–01/12/2025	23/12/2022		31/12/2025	01/01/2026–23/12/2032	359.60	–	4,600	–	–	4,600	4,600	4,600	4,600
Total								**23,746**	**4,600**	**–**	**7,952**	**8,018**	**8,018**	**28,346**	**18,946**
Malini Moorthy, general counsel	Equity Incentive Plan	01/04/2022–01/04/2025	01/04/2022	Please refer to footnote.	N/A	01/04/2023–01/04/2035	282.50	–	24,000	–	–	24,000	24,000	24,000	N/A
Total								**–**	**24,000**	**–**	**–**	**24,000**	**24,000**	**24,000**	

[1] 1/3 of the option vests on the first anniversary of the Award Date and the remaining 2/3rd vest during the following two years in equal parts of 1/24th, each time upon the 1st day of each month.

The table below shows (i) the RSUs held as of January 1, 2022, (ii) the RSUs granted to our senior management which vested during the year ended December 31, 2022 and (iii) the number of RSUs held as of December 31, 2022. Each RSU was granted pursuant to the Equity Incentive Plan:

Remuneration in Restricted Stock Units (RSU's) CEO and Senior Management

						Information regarding the reported financial year						
	The main conditions of RSU plan					Opening balance	During the Year		Closing balance			
Name of Directors, Position	Specification of plan	Performance period	Award date	Vesting date [1]	End of retention period	RSU's held at the beginning of the year	RSU's awarded	RSU's vested	RSU's subject to a performance condition	RSU's awarded and unvested	RSU's held at the closing of the year	RSU's subject to a retention period
Tim van Hauwermeiren, chief executive officer	Equity Incentive Plan	24/12/2021–24/12/2025	24/12/2021	Please refer to footnote.	N/A	5,700	–	(1,425)	4,275	4,275	4,275	N/A
		23/12/2022–23/12/2026	23/12/2022		N/A	–	5,700	–	5,700	5,700	5,700	N/A
Total						**5,700**	**5,700**	**(1,425)**			**9,975**	
Luc Truyen, chief medical officer	Equity Incentive Plan	01/10/2021–01/10/2025	01/10/2021	Please refer to footnote.	N/A	5,400	–	(1,350)	4,050	4,050	4,050	N/A
		23/12/2022–23/12/2026	23/12/2022		N/A	–	3,600	–	3,600	3,600	3,600	N/A
Total						**5,400**	**3,600**	**(1,350)**			**7,650**	
Keith Woods, chief operations officer	Equity Incentive Plan	24/12/2021–24/12/2025	24/12/2021	Please refer to footnote.	N/A	3,600	–	(900)	2,700	2,700	2,700	N/A
		23/12/2022–23/12/2026	23/12/2022		N/A	–	3,600	–	3,600	3,600	3,600	N/A
Total						**3,600**	**3,600**	**(900)**			**6,300**	
Karl Gubitz, chief financial officer	Equity Incentive Plan	01/07/2021–01/07/2025	01/07/2021	Please refer to footnote.	N/A	5,400	–	(1,350)	4,050	4,050	4,050	N/A
		01/07/2022–01/07/2026	01/07/2022		N/A	–	3,600	–	3,600	3,600	3,600	N/A
Total						**5,400**	**3,600**	**(1,350)**			**7,650**	

[1] Options vest over a period of four years with 1/4th of the total grant vesting at each anniversary of the date of grant.

	The main conditions of RSU plan					Information regarding the reported financial year						
						Opening balance	During the Year		Closing balance			
Name of Directors, Position	**Specification of plan**	**Performance period**	**Award date**	**Vesting date [1)]**	**End of retention period**	**RSU's held at the beginning of the year**	**RSU's awarded**	**RSU's vested**	**RSU's subject to a performance condition**	**RSU's awarded and unvested**	**RSU's held at the closing of the year**	**RSU's subject to a retention period**
Prof. Hans de Haard, chief scientific officer	Equity Incentive Plan	24/12/2021–31/12/2022	24/12/2021	Please refer to footnote.	N/A	3,600	–	(3,600)	–	–	–	N/A
Total						**3,600**	**–**	**(3,600)**			**–**	
Malini Moorthy, general counsel	Equity Incentive Plan	01/04/2022–01/04/2026	01/04/2022	Please refer to footnote.	N/A	–	5,400	–	5,400	5,400	5,400	N/A
Total						**–**	**5,400**	**–**			**5,400**	
Wim Parys	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	–	N/A
Total						**–**	**–**	**–**			**–**	
Arjen Lemmen, vice president of corporate development & strategy	Equity Incentive Plan	24/12/2021–24/12/2025	24/12/2021	Please refer to footnote.	N/A	3,600	–	(900)	2,700	2,700	2,700	N/A
		23/12/2022–23/12/2026	23/12/2022		N/A	–	3,600	–	3,600	3,600	3,600	N/A
Total						**3,600**	**3,600**	**(900)**			**6,300**	
Andria Wilk, global head of quality	Equity Incentive Plan	24/12/2021–24/12/2025	24/12/2021	Please refer to footnote.	N/A	988	–	(247)	741	741	741	N/A
		23/12/2022–23/12/2026	23/12/2022		N/A	–	1,000	–	1,000	1,000	1,000	N/A
Total						**988**	**1,000**	**(247)**			**1,741**	

[1)] Options vest over a period of four years with 1/4th of the total grant vesting at each anniversary of the date of grant.

Arrangements with Respect to Leaver Equity

With respect to Mr. Wim Parys, the Board of Directors approved that his equity awards will continue to vest until the end of the month in which he last performs services as an advisor to the research and development committee of the Board of Directors. With respect to Prof. Hans de Haard, the Board of Directors determined his long-term equity incentives vested in full on December 31, 2022, consistent with the terms of his employment contract and in recognition of his significant contributions made as a founder of argenx and his ever-lasting impact on our current and future value creation including as a future member of the research and development committee, ambassador of our IIP and mentor to talent, all as set out in a service agreement entered into between us and Prof. de Haard, and for which no remuneration shall be paid.

3.4.7 Remuneration of Non-Executive Directors

The remuneration of the individual members of the Board of Directors is determined by the Board of Directors, at the recommendation of our remuneration and nomination committee, within the limits of the remuneration policy adopted by the shareholders at a General Meeting. The description below reflects the remuneration policy approved at our 2022 General Meeting.

Pursuant to the remuneration policy, the remuneration of the non-executive directors consists of the following fixed and variable components:

- a fixed fee;
- if applicable, a fee for chairing the audit and compliance committee, the research and development committee, the remuneration and nomination committee or the commercial committee;
- a fixed fee for board committee membership; and
- a long-term variable incentive in the form of stock options and RSUs.

Fixed Fee

The Board of Directors has set the annual base remuneration, the annual remuneration for members of the audit and compliance committee, the research and development committee, the remuneration and nomination committee and the commercial committee and, in each case, the additional remuneration for the respective chairperson as follows:

Relevant Body	**Position**	**Fees** (in $)	**Fees** (in €)
Board of Directors	Chairperson	79,024	75,000
	Member	47,414	45,000
Audit and compliance committee/ Research and development committee	Chairperson	15,805	15,000
	Member	7,902	7,500
Remuneration and nomination committee	Chairperson	10,537	10,000
	Member	5,268	5,000
Commercial committee	Chairperson	10,537	10,000
	Member	5,268	5,000
Research and development committee	Chairperson	15,805	15,000
	Member	7,902	7,500

In 2022, the non-executive director cash remuneration was increased by €10,000 to re-align with the benchmark. These fees had not been increased to re-aligned the benchmark since our Euronext initial public offering in 2014.

Long-Term Incentive Plan

Non-executive directors receive stock options and/or RSUs from time to time, ensuring an overall fair and competitive remuneration that is in line with the remuneration practices of our reference companies. The conditions of our Equity Incentive Plan apply to our non-executive directors, as set forth in section 3.4.7 "**Remuneration of Non-Executive Directors**".

The following table sets forth the information regarding the compensation earned by our non-executive directors during the fiscal year ended December 31, 2022:

Name	Fees earned or paid in cash (in $)	Option awards (in $) [1)]	RSU awards (in $) [2)]	Total (in $)
Peter K.M. Verhaeghe	92,194	456,407	**230,130**	**778,731**
Werner Lanthaler	68,487	–	–	**68,487**
Pamela Klein	55,317	444,481	230,130	**729,927**
J. Donald deBethizy	65,853	444,481	230,130	**740,464**
Anthony A. Rosenberg	60,585	444,481	230,130	**735,195**
James M. Daly	65,853	444,481	230,130	**740,464**
Yvonne Greenstreet	7,044	–	–	**7,044**
Camilla Sylvest	17,561	741,510	353,738	**1,112,808**
Ana Cespedes	4,390	666,721	345,194	**1,016,306**

2) These amounts do not reflect the actual economic value realized by the non-executive directors. Amounts shown represent the expenses with respect to the stock option awards granted in 2022 to the non-executive directors measured using the Black Scholes formula. For a description of the assumptions used in valuing these awards, see **note 13** to our consolidated financial statements in section 6 "**Consolidated Financial Statements**".

3) These amounts do not reflect the actual economic value realized by the non-executive directors. Amounts shown represent the expenses with respect to the RSUs awards granted in 2022 to the non-executive directors measured using the Black Scholes formula. For a description of the assumptions used in valuing these awards, see **note 13** to our consolidated financial statements in section 6 "**Consolidated Financial Statements**".

The table below shows (i) the stock options held at January 1, 2022, (ii) the stock options granted to the non-executive directors which have vested during the year ended December 31, 2022, (iii) the number of stock options exercised and vested during the year, (iv) the respective exercise price of such stock options and (v) the stock options held as of December 31, 2022:

Remuneration in Stock Options Non-Executive Directors

								Information regarding the reported financial year							
								Opening balance	During the Year			Closing balance			
Name of Directors, Position	Specification of plan	Performance period	Award date	Vesting date [1)]	End of retention period	Exercise period	Exercise price of stock option (in €)	Stock options held at the beginning of the year	Stock options awarded	Stock options exercised	Stock options vested during the year	Stock options subject to a performance condition	Stock options awarded and unvested	Stock options held at the end of the year	Stock options subject to a retention period
Peter Verhaeghe	Equity Incentive Plan	29/06/2012–29/06/2015	29/06/2012	Please refer to footnote.	N/A	01/01/2016–29/06/2022	2.44	8,741	–	(8,741)	–	–	–	–	N/A
		30/09/2014–30/09/2017	30/09/2014		N/A	30/09/2015–30/09/2024	2.44	2,885	–	–	–	–	–	2,885	N/A
		30/09/2014–30/09/2017	30/09/2014		N/A	30/09/2015–30/09/2024	3.95	1,969	–	–	–	–	–	1,969	N/A
		18/12/2014–18/12/2017	18/12/2014		N/A	18/12/2015–18/12/2024	7.17	5,000	–	–	–	–	–	5,000	N/A
		16/06/2016–18/06/2019	18/06/2016		N/A	18/06/2017–18/06/2026	11.38	10,000	–	–	–	–	–	10,000	N/A
		21/12/2018–21/12/2021	21/12/2018		N/A	21/12/2019–21/12/2028	86.32	10,000	–	–	–	–	–	10,000	N/A
		20/12/2019–20/12/2022	20/12/2019		N/A	20/12/2020–20/12/2029	135.75	10,000	–	–	3,333	–	–	10,000	N/A
		21/12/2020–21/12/2023	21/12/2020		N/A	21/12/2021–21/12/2030	247.60	10,000	–	–	3,334	3,333	3,333	10,000	N/A
		24/12/2021–24/12/2024	24/12/2021	Upon third anniversary of the grant	24/12/2024	24/12/2024–24/12/2031	309.20	2,700	–	–	–	2,700	2,700	2,700	2,700
		23/12/2022–23/12/2025	23/12/2022		23/12/2025	23/12/2025–23/12/2032	359.60	–	2,700	–	–	2,700	2,700	2,700	2,700
Total								**61,295**	**2,700**	**(8,741)**	**6,667**	**8,733**	**8,733**	**55,254**	**5,400**
Yvonne Greenstreet	Equity Incentive Plan	01/07/2021–03/03/2022	01/07/2021	Upon third anniversary of the grant	01/07/2022	01/07/2022–01/07/2031	255.10	1,350	–	–	1,350	–	–	1,350	N/A
Total								**1,350**	**–**	**–**	**1,350**	**–**	**–**	**1,350**	**–**

[4)] 1/3rd upon the first anniversary of the option's date of grant and for the remaining 2/3rd during the following two years in equal parts of 1/24th, each time upon the 1st day of each next month.

								Information regarding the reported financial year							
								Opening balance	During the Year			Closing balance			
Name of Directors, Position	Specification of plan	Performance period	Award date	Vesting date [1)]	End of retention period	Exercise period	Exercise price of stock option (in €)	Stock options held at the beginning of the year	Stock options awarded	Stock options exercised	Stock options vested during the year	Stock options subject to a performance condition	Stock options awarded and unvested	Stock options held at the end of the year	Stock options subject to a retention period
Werner Lanthaler	Equity Incentive Plan	21/12/2018–21/12/2021	21/12/2018	Please refer to footnote.	N/A	21/12/2019–21/12/2028	86.32	10,000	–	–	–	–	–	10,000	–
		20/12/2019–20/12/2022	20/12/2019		N/A	20/12/2020–20/12/2029	135.75	5,580	–	–	3,333	–	–	5,580	–
		21/12/2020–21/12/2023	21/12/2020		N/A	21/12/2021–21/12/2030	247.60	10,000	–	–	3,334	3,333	3,333	10,000	N/A
		24/12/2021–24/12/2024	24/12/2021	Upon third anniversary of the grant	24/12/2024	24/12/2024–24/12/2031	309.20	2,700	–	–	–	2,700	2,700	2,700	2,700
Total								**28,280**	**–**	**–**	**6,667**	**6,033**	**6,033**	**28,280**	**2,700**
J. Donald deBethizy	Equity Incentive Plan	16/06/2016–18/06/2019	18/06/2016	Please refer to footnote.	N/A	18/06/2017–18/06/2026	11.38	10,000	–	–	–	–	–	10,000	N/A
		21/12/2018–21/12/2021	21/12/2018		N/A	21/12/2019–21/12/2028	86.32	10,000	–	–	–	–	–	10,000	N/A
		20/12/2019–20/12/2022	20/12/2019		N/A	20/12/2020–20/12/2029	135.75	10,000	–	–	3,333	–	–	10,000	N/A
		21/12/2020–21/12/2023	21/12/2020		N/A	21/12/2021–21/12/2030	247.60	10,000	–	–	3,334	3,333	3,333	10,000	N/A
		24/12/2021–24/12/2024	24/12/2021	Upon third anniversary of the grant	24/12/2024	24/12/2024–24/12/2031	309.20	2,700	–	–	–	2,700	2,700	2,700	2,700
		23/12/2022–23/12/2025	23/12/2022		23/12/2025	23/12/2025–23/12/2032	359.60	–	2,700	–	–	2,700	2,700	2,700	2,700
Total								**42,700**	**2,700**		**6,667**	**8,733**	**8,733**	**45,400**	**5,400**

5) 1/3rd upon the first anniversary of the option's date of grant and for the remaining 2/3rd during the following two years in equal parts of 1/24th, each time upon the 1st day of each next month.

								Information regarding the reported financial year							
								Opening balance	During the Year			Closing balance			
Name of Directors, Position	Specification of plan	Performance period	Award date	Vesting date [1)]	End of retention period	Exercise period	Exercise price of stock option (in €)	Stock options held at the beginning of the year	Stock options awarded	Stock options exercised	Stock options vested during the year	Stock options subject to a performance condition	Stock options awarded and unvested	Stock options held at the end of the year	Stock options subject to a retention period
Pamela Klein	Equity Incentive Plan	18/06/2015–18/06/2016	18/06/2015	Please refer to footnote.	N/A	18/06/2016–18/06/2025	11.44	2,500	–	(2,500)	–	–	–	–	N/A
		18/06/2016–18/06/2017	18/06/2016		N/A	18/06/2017–18/06/2026	11.38	10,000	–	(10,000)	–	–	–	–	N/A
		21/12/2018–21/12/2021	21/12/2018		N/A	21/12/2019–21/12/2028	86.32	10,000	–	–	–	–	–	10,000	N/A
		20/12/2019–20/12/2022	20/12/2019		N/A	20/12/2020–20/12/2029	135.75	10,000	–	–	3,333	–	–	10,000	N/A
		21/12/2020–21/12/2023	21/12/2020		N/A	21/12/2021–21/12/2030	247.60	10,000	–	–	3,334	3,333	3,333	10,000	N/A
		24/12/2021–24/12/2024	24/12/2021	Upon third anniversary of the grant	24/12/2024	24/12/2024–24/12/2031	309.20	2,700	–	–	–	2,700	2,700	2,700	2,700
		23/12/2022–23/12/2025	23/12/2022		23/12/2025	23/12/2025–23/12/2032	359.60	–	2,700	–	–	2,700	2,700	2,700	2,700
Total								**45,200**	**2,700**	**(12,500)**	**6,667**	**8,733**	**8,733**	**35,400**	**5,400**
Anthony A. Rosenberg	Equity Incentive Plan	13/12/2016–13/12/2019	13/12/2016	Please refer to footnote.	N/A	18/06/2017–18/06/2026	14.13	15,000	–	–	–	–	–	15,000	N/A
		21/12/2018–21/12/2021	21/12/2018		N/A	21/12/2019–21/12/2028	86.32	10,000	–	–	–	–	–	10,000	N/A
		20/12/2019–20/12/2022	20/12/2019		N/A	20/12/2020–20/12/2029	135.75	8,840	–	–	3,333	–	–	8,840	N/A
		21/12/2020–21/12/2023	21/12/2020		N/A	21/12/2021–21/12/2030	247.60	10,000	–	(4,160)	3,334	3,333	3,333	5,840	N/A
		24/12/2021–24/12/2024	24/12/2021	Upon third anniversary of the grant	24/12/2024	24/12/2024–24/12/2031	309.20	2,700	–	–	–	2,700	2,700	2,700	2,700
		23/12/2022–23/12/2025	23/12/2022		23/12/2025	23/12/2025–23/12/2032	359.60	–	2,700	–	–	2,700	2,700	2,700	2,700
Total								**46,540**	**2,700**	**(4,160)**	**6,667**	**8,733**	**8,733**	**45,080**	**5,400**

[6)] 1/3rd upon the first anniversary of the option's date of grant and for the remaining 2/3rd during the following two years in equal parts of 1/24th, each time upon the 1st day of each next month.

								Information regarding the reported financial year							
								Opening balance	During the Year			Closing balance			
Name of Directors, Position	Specification of plan	Performance period	Award date	Vesting date [1)]	End of retention period	Exercise period	Exercise price of stock option (in €)	Stock options held at the beginning of the year	Stock options awarded	Stock options exercised	Stock options vested during the year	Stock options subject to a performance condition	Stock options awarded and unvested	Stock options held at the end of the year	Stock options subject to a retention period
James M. Daly	Equity Incentive Plan	28/06/2018–28/06/2021	28/06/2018	Please refer to footnote.	N/A	28/06/2019–28/06/2028	80.82	5,000	–	(5,000)	–	–	–	–	N/A
		21/12/2018–21/12/2021	21/12/2018		N/A	21/12/2019–21/12/2028	86.32	10,000	–	(10,000)	–	–	–	–	N/A
		20/12/2019–20/12/2022	20/12/2019		N/A	20/12/2020–20/12/2029	135.75	10,000	–	–	3,333	–	–	10,000	N/A
		21/12/2020–21/12/2023	21/12/2020		N/A	21/12/2021–21/12/2030	247.60	10,000	–	–	3,334	3,333	3,333	10,000	N/A
		24/12/2021–24/12/2024	24/12/2021	Upon third anniversary of the grant	24/12/2024	24/12/2024–24/12/2031	309.20	2,700	–	–	–	2,700	2,700	2,700	2,700
		23/12/2022–23/12/2025	23/12/2022		23/12/2025	23/12/2025–23/12/2032	359.60	–	2,700	–	–	2,700	2,700	2,700	2,700
Total								**37,700**	**2,700**	**(15,00)**	**6,667**	**8,733**	**8,733**	**25,400**	**5,400**
Camilla Sylvest	Equity Incentive Plan	03/10/2022–03/10/2025	03/10/2022	Upon third anniversary of the grant	03/10/2025	03/10/2025–03/10/2032	368.50	–	4,050	–	–	4,050	4,050	4,050	4,050
Total								**–**	**4,050**	**–**	**–**	**4,050**	**4,050**	**4,050**	**4,050**
Ana Cespedes	Equity Incentive Plan	23/12/2022–23/12/2025	23/12/2022	Upon third anniversary of the grant	23/12/2025	23/12/2025–23/12/2032	359.60	–	4,050	–	–	4,050	4,050	4,050	4,050
Total								**–**	**4,050**	**–**	**–**	**4,050**	**4,050**	**4,050**	**4,050**

7) 1/3rd upon the first anniversary of the option's date of grant and for the remaining 2/3rd during the following two years in equal parts of 1/24th, each time upon the 1st day of each next month.

The table below shows (i) the RSUs held at January 1, 2022, (ii) the RSUs granted to the non-executive directors which have vested during the year ended December 31, 2022 and (iii) the number of RSUs held at December 31, 2022:

Remuneration in restricted stock units (RSU's) non-executive directors

	The main conditions of RSU plan					Information regarding the reported financial year						
						Opening balance	During the Year		Closing balance			
Name of Directors, Position	**Specification of plan**	**Performance period**	**Award date**	**Vesting date [1)]**	**End of retention period**	**RSU's held at the beginning of the year**	**RSU's awarded**	**RSU's vested**	**RSU's subject to a performance condition**	**RSU's awarded and unvested**	**RSU's held at the closing of the year**	**RSU's subject to a retention period**
Peter Verhaeghe	Equity Incentive Plan	24/12/2021–24/12/2025	24/12/2021	Please refer to footnote.	N/A	600	–	(150)	450	450	450	N/A
		23/12/2022–23/12/2026	23/12/2022		N/A	–	600	–	600	600	600	N/A
Total						**600**	**600**	**(150)**	**1,050**	**1,050**	**1,050**	
Yvonne Greenstreet	Equity Incentive Plan	01/07/2021–03/03/2022	01/07/2021	Please refer to footnote.	N/A	225	–	(225)	–	–	–	N/A
Total						**225**	**–**	**(225)**	**–**	**–**	**–**	
Werner Lanthaler	Equity Incentive Plan	24/12/2021–24/12/2025	24/12/2021	Please refer to footnote.	N/A	600	–	(150)	450	450	450	N/A
Total						**600**	**–**	**(150)**	**450**	**450**	**450**	
J. Donald deBethizy	Equity Incentive Plan	24/12/2021–24/12/2025	24/12/2021	Please refer to footnote.	N/A	600	–	(150)	450	450	450	N/A
		23/12/2022–23/12/2026	23/12/2022		N/A	–	600	–	600	600	600	N/A
Total						**600**	**600**	**(150)**	**1,050**	**1,050**	**1,050**	

[1)] Vesting date: vest over a period of 4 years with 1/4th of the total grant vesting at each anniversary of the date of grant.

	The main conditions of RSU plan					Information regarding the reported financial year						
						Opening balance	During the Year		Closing balance			
Name of Directors, Position	**Specification of plan**	**Performance period**	**Award date**	**Vesting date [1)]**	**End of retention period**	**RSU's held at the beginning of the year**	**RSU's awarded**	**RSU's vested**	**RSU's subject to a performance condition**	**RSU's awarded and unvested**	**RSU's held at the closing of the year**	**RSU's subject to a retention period**
Pamela Klein	Equity Incentive Plan	24/12/2021–24/12/2025	24/12/2021	Please refer to footnote.	N/A	600	–	(150)	450	450	450	N/A
		23/12/2022–23/12/2026	23/12/2022		N/A	–	600	–	600	600	600	N/A
Total						**600**	**600**	**(150)**	**1,050**	**1,050**	**1,050**	
Anthony A. Rosenberg	Equity Incentive Plan	24/12/2021–24/12/2025	24/12/2021	Please refer to footnote.	N/A	600	–	(150)	450	450	450	N/A
		23/12/2022–23/12/2026	23/12/2022		N/A	–	600	–	600	600	600	N/A
Total						**600**	**600**	**(150)**	**1,050**	**1,050**	**1,050**	
James M. Daly	Equity Incentive Plan	24/12/2021–24/12/2025	24/12/2021	Please refer to footnote.	N/A	600	–	(150)	450	450	450	N/A
		23/12/2022–23/12/2026	23/12/2022		N/A	–	600	–	600	600	600	N/A
Total						**600**	**600**	**(150)**	**1,050**	**1,050**	**1,050**	
Camilla Sylvest	Equity Incentive Plan	03/10/2022–03/10/2026	03/10/2022	Please refer to footnote.	N/A	–	900	–	900	900	900	N/A
Total						**–**	**900**	**–**	**900**	**900**	**900**	
Ana Cespedes	Equity Incentive Plan	23/12/2022–23/12/2026	23/12/2022	Please refer to footnote.	N/A	–	900	–	900	900	900	N/A
Total						**–**	**900**	**–**	**900**	**900**	**900**	

[1)] Vesting date: vest over a period of 4 years with 1/4[th] of the total grant vesting at each anniversary of the date of grant.

3.4.8 Pay Ratios Within the Company

Our total expense for the non-equity remuneration paid to our CEO (and only executive director) for the year ended December 31, 2022, equaled $1,443,925.

The table below shows the evolution over the past five years of CEO compensation, the performance of our stock price and the median remuneration on a full-time equivalent basis (annualized for the employees who joined or left us during the year) of our employees, other than the executive director:

	Financial year ended December 31,				
(in thousands of $, unless otherwise indicated)	**2018**	**2019**	**2020**	**2021**	**2022**
Base salary of our CEO (EUR) [1)]	500,000	525,000	525,000	551,250	606,368
Base salary of our CEO (USD)	526,825	553,167	553,167	580,825	638,901
Non-equity remuneration of our CEO (base salary, short-term cash incentive, pension contributions and other compensation elements) [2)]	996,215	1,001,891	1,144,301	1,285,136	1,443,925
Non-equity median salary paid to our employees	110,196	121,603	163,062	157,349	153,193
Ratio employee/CEO	11%	12%	14%	12%	11%
Average compensation paid to non-executive director	59,891	60,372	57,925	54,484	48,587
Number of employees at end of year	105	188	336	650	843
Share price at end of year Euronext EUR	85.20	143.60	242	315.30	348.3
Share price at end of year Euronext USD	97.55	161.32	296.96	357.11	371.50

1) Shown in USD, using a fixed exchange rate of 1.05 USD / 1 EUR, taking into account that our CEO's salary is paid in EUR but our functional and reporting currency is in USD.

2) In our prior years remuneration reports, the cash value of benefits like medical insurance and car allowances was not included. For transparency, we have included these numbers in prior year and current year numbers. No significant increase of these contributions was granted between the prior financial years and 2022.

The decrease in the remuneration ratio between members of our CEO and other employees between 2021 and 2022 is primarily caused by our CEO receiving a short-term incentive payout equal to 200% of the target for 2022, in comparison to 150% payout related to 2021.

The comparison of non-equity compensation above is made between the compensation paid to our single executive director, and the median compensation paid to our employees. We have opted to compare non-equity salaries, because whereas the number of options granted is linked to the overall size of remuneration packages granted, the value of equity components depends on the evolution of our share price, volatility and the risk-free rate, which is unknown at granting and as such the forward-looking valuation methods for options normally do not provide an accurate representation of actual economic value granted.

Due to the global spread of our employees over multiple continents, we deem it relevant to also include the above comparison separately to our U.S. employees, EU employees and Japanese employees. Due to the overall higher compensation level in our business segment in the U.S. and Japan compared to the EU, there is a significant difference in the pay ratio when the CEO's compensation is compared to the median compensation of all our employees (the majority of which are EU citizens), as set out above, or compared to employees in the U.S. and Japan. The following information is provided for reference purposes:

Ratio of non-equity compensation of the median employee compared to the CEO for the fiscal year ended December 31, 2022	
All employees	11%
European employees	7%
U.S. employees	15%
Japanese employees	7%
Canadian employees	16%

Share-based payment ratios are as follows:

	Financial year ended December 31,				
	2018	**2019**	**2020**	**2021**	**2022**
Stock options granted to our CEO	80,000	80,000	50,000	25,000 [1)]	25,000 [1)]
Median stock options granted to our employees	2,500	2,800	2,900	981	900
Ratio employee/CEO	3.13%	3.50%	5.80%	3.9%	3.6%
Average number of stock options granted to non-executive directors	12,143	10,000	10,000	2,869	3,086
Median stock options granted to our employees	2,500	2,800	2,900	981	900
Ratio non-executive directors/ employee	20.59%	28%	29%	34.20%	29.17%

1) The Board of Directors had offered Tim Van Hauwermeiren long-term equity equal to 130% of target, resulting in 41,600 stock options and 9,360 RSUs but at the request of Tim Van Hauwermeiren, the Board of Directors agreed to reduce the grant for 2022 to 25,000 stock options and 5,700 RSUs, and to distribute the difference (of 16,600 stock options and 3,660 RSUs) to certain top-performing lower-level employees of the Company identified by Tim Van Hauwermeiren.

Total employment costs (excluding any stock options) we paid in fiscal year 2022 was split between regions as follows:

Total remuneration paid in the fiscal year ended December 31, 2022 (in millions of $)	
EU	57.5
U.S.	80.9
Japan	8.3
Canada	1.2

3.4.9 Long-Term Incentives Granted to Key Persons – Equity Incentive Plan

Our Equity Incentive Plan providing for the granting of a mix of stock options and RSUs was approved by our Board of Directors on March 15, 2021, as subsequently amended on December 15, 2021. The aim of our Equity Incentive Plan is to encourage our senior management, directors, all other key employees, and key outside consultants and advisors to acquire an economic and beneficial ownership interest in our growth and performance, to increase their incentive to contribute to our value and to attract and retain key individuals.

Our Board of Directors has also established an equity incentive allocation scheme that contains (i) the dates on which stock options and RSUs are granted each year, which shall be the same date each year (other than for new hires) and (ii) the number of stock options and RSUs granted to each person or to each group of persons, which shall be based on objective criteria only.

Stock options granted pursuant to the Equity Incentive Plan shall vest with respect to one third of the shares upon the first anniversary of the date of grant, with the remaining two thirds vesting in twenty-four equal monthly instalments with the stock options fully vesting upon the third anniversary of the date of grant, subject, in each case, to the optionee's continued status as a service provider. Stock options are exercisable when vested, and in any case not after the stock option expiration date included in each individual stock option grant, which is 10 years or in the case of Belgian tax resident employees, at their election either five years or ten years from the date of grant.

Each stock option shall be granted with an exercise price equal to the fair market value upon the date of grant and shall have a term equal to five or ten years from the date of grant. Optionees may prefer to elect the five-year period as this may limit their personal tax obligations in respect of the option in respect to the jurisdiction where options are taxed at grant, compared to a ten-year option. Stock options granted to Belgian tax resident beneficiaries (including our CEO) are not exercisable prior to the fourth year following the year of the grant. Stock options granted to non-executive directors vest at once on the third anniversary of the date of grant.

RSUs granted under the Equity Incentive Plan shall vest over a period of four years with respect to one fourth of the shares upon each anniversary of the date of grant. At the time of vesting, the holder of such RSUs receives our shares for free equal to the number equal of RSUs vested minus a certain number of shares required to cover employee taxes payable by us on behalf of the holder of RSUs, if applicable.

100% of any unvested equity incentives shall vest in the event of a (i) sale, merger, consolidation, tender offer or similar acquisition of shares or other transaction or series of related transactions as a result of which a change in control occurs, (ii) sale or other disposition of all or substantially all of our assets or (iii) our dissolution and/or liquidation.

Our Board of Directors, upon approval of a majority of the non-executive directors, may amend or terminate the Equity Incentive Plan or may amend the terms of this Equity Incentive Plan, also for any outstanding stock options or RSUs, provided that we will compensate any affected optionee for any direct negative impact of such amendment.

Other Arrangements

In fiscal year 2022, no severance payments were granted to our senior management and non-executive directors.

In fiscal year 2022, no variable remuneration was clawed back and no variable remuneration was adjusted (retroactively).

In fiscal year 2022, no remuneration was granted and allocated by subsidiaries or other companies whose financials we consolidate, other than the regular remuneration payments made by the entities with whom our management members have their employment contracts.

In fiscal year 2022, no (personal) loans were granted to our senior management and non-executive directors and no guarantees or the like have been granted in favor of any of the senior management and the non-executive directors.

Deviations

In 2022, we did not deviate from the decision-making process for the implementation of the 2021 remuneration policy for our senior management and non-executive directors and no temporary deviations took place from the 2021 Remuneration Policies.

3.5 Risk Appetite & Control

Before reading this section, please carefully review the following cautionary statement:

In this section we will make the required disclosures regarding our risk appetite and mitigating actions. We fully take the risk mitigation actions and risk management described in this section into account while preparing the description of the main risks and uncertainties we face, as set out in section 2 "**Risk Factors**". Any mitigating language used in this section does not have any impact on the risks and uncertainties we face or their potential adverse effects as they are described in section 2 "**Risk Factors**".

Section 2 "**Risk Factors**" describes the main risks and uncertainties we face already fully having taken into account our risk management and the risk mitigating actions described herein.

3.5.1 Introduction

This section 3.5 provides a general description of our willingness to mitigate the risks and uncertainties we face (also called our 'risk appetite'), and to give a description of the mitigating actions we have taken with regard to our most relevant risks.

3.5.2 General Description of our Risk Appetite

Our risk appetite serves as a guideline to determine the measures we may take in mitigating some of the risks and uncertainties we face. Our risk appetite is aligned with our strategy and priorities. The business we operate in is inherently high-risk. In general, we are willing, and in our view required, to take significant risks to be able to operate successfully in our line of business. Some of the risks and uncertainties we face are entirely outside of our control whereas others may be influenced or mitigated.

The process of developing, implementing and improving risk management procedures remains an ongoing effort. In accordance with guideline 400.110c of the Dutch Counsel for annual reporting (Raad voor de Jaarverslaggeving), this risk management section provides an overview of the risk mitigating actions taken or planned to be taken by us. The mentioning of these mitigating actions may not in any way be viewed as an implied or express guarantee that such mitigation will in practice be effective in limiting the risk exposure and/or the potential damage to us from any such risk materializing.

3.5.3 Controlling Actions We Take with Regard to our most Relevant Risks and Uncertainties

The following is a description of the main risks and uncertainties we face (being the first risk of each category of risk factors set out in section 2 "**Risk Factors**") and a description of the measures we took to control them. A description of the expected impact upon materialization of these risks is included for each risk in section 2 "**Risk Factors**".

Risk factor	Measures taken to control these risks
We have incurred significant losses since our inception and expect to incur losses for the foreseeable future. We may never achieve or sustain profitability.	We have adopted a business model and strategic portfolio management approach to spread risks over wholly-owned programs as well as partnered programs, and to manage risks within our own proprietary product candidates pipeline. We continue to conduct research and development, preclinical testing, clinical trials and regulatory compliance activities as well as the continued commercialization of VYVGART and other products candidates, for current and future indications, and we intend to continue our efforts to expand our sales, marketing and distribution infrastructure.
We will face significant challenges in successfully commercializing our products and additional product candidates after they are launched.	We plan to focus on the successful development and commercialization of the products and product candidates after they are launched. We aim to expand our sales and marketing organization, enter into collaboration arrangements with third parties, outsource certain functions to third parties, or use some combination of each. We have already built, and continue to expand, our sales forces in certain of the VYVGART Approved Countries and plan to further develop our sales and marketing capabilities to promote our products, and product candidates, including new indications, if and when marketing approval has been obtained in other relevant jurisdictions.
We are subject to healthcare laws, regulation and enforcement. Our failure to comply with these laws could harm our results of operations and financial conditions.	We are continuing to build and refine an internal program to ensure compliance with the different healthcare, compliance and reporting laws and regulations in multiple jurisdictions.
Failure to successfully identify, select and develop efgartigimod in other indications, additional products or product candidates could impair our ability to grow.	We remain committed to using technology and contracting with parties that are able to achieve the level of sophistication we need to accurately and reliably identify, select and develop efgartigimod in other indications, additional products or product candidates. We expect our spending to continue to increase as we expand our global commercial infrastructure and drug inventory for VYVGART™ for the treatment of gMG, the progress of our clinical-stage pipeline, including ongoing clinical trials for five indications of efgartigimod.

Risk factor	Measures taken to control these risks
We rely, and expect to continue to rely, on third parties to conduct some of our research activities and clinical trials and for parts of the development and commercialization of our existing and future research programs, products and product candidates. If our relationships with such third parties are not successful, our business may be adversely affected.	We endeavor to meet our contractual obligations and any relevant milestone achievements under our collaboration contracts, maintain a rich pipeline of possible collaboration partners as well as foster good relationships with existing and potential future collaboration partners in order to limit reliance on a limited number of collaboration partners. Furthermore, third-party contractor selection and management is subject to our quality management system. Customary contractual agreements are put in place in an effort to protect us from under-performance. We are typically spreading operational risks over various service providers. Project management belongs to our core internal competences.
Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, or insider trading violations, which could significantly harm our business.	We have adopted a Code of Conduct, that is applicable to all of our employees and directors, which addresses the key risks related to potential breaches of ethical standards. All employees have accepted and are trained (and retrained annually) on our Code of Conduct. We expect all newcomers to accept, and commit to, the contents of the Code of Conduct. To increase compliance and ensure our colleagues know where to go with questions on the Code of Conduct and its application, we have established the argenx COMPASS Helpline, where our employees can raise any concerns they may have regarding potential violations of our policy confidentially or anonymously (to the extent allowed by law).
Failure to adequately enforce or protect our intellectual property rights in products, product candidates and platform technologies could adversely affect our ability to develop and market our products and product candidates.	We strive to protect the proprietary technologies that we believe are important to our business, including pursuing and maintaining patent protection intended to cover the platform technologies incorporated into, or used to produce, our product candidates, the compositions of matter of our product candidates and their methods of use, as well as other inventions that are important to our business. In addition to patent protection, we also rely on 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 future growth and ability to compete depends on retaining our key personnel and recruiting additional qualified personnel.	We offer competitive remuneration packages and share-based incentives in the form of the Equity Incentive Plan. We perform periodic benchmark analyses with an external service provider to ensure the competitiveness of the compensation offered to our key personnel in comparison to other (reference group) companies. We pay close attention to creating an environment that supports the further development of the talents of our key people.

3.5.4 Material Impact of Risk Materialization in 2022

During the period between January 1, 2022 and December 31, 2022, we did not identify any material impact as a result of materialization of previously identified risks and uncertainties.

3.5.5 Financial Risks and Controls

In running our business, we seek to implement a sustainable policy regarding internal control and risk management. Our Board of Directors has delegated an active role to our audit and compliance committee in the design, implementation and monitoring of an internal risk management and control system to manage the significant risks to which we are exposed.

Our financial reporting is structured within a tight framework of budgeting, reporting and forecasting. A distinction is made between reports for internal and external use. External reporting at group level consists of an annual report (in the form of this Annual Report), including financial statements audited by the independent auditor, as well semi-annual reporting and quarterly updates, containing summarized financial information. The external reports are based on the internal financial reporting.

Internal financial reporting consists of extensive consolidated monthly reports in which current developments are compared to the monthly (cumulative) budgets and previous forecasts. In addition, each quarter we reiterate or update our forecast for the annual results, including the cash flow position at the end of the fiscal year. The quarterly budgets are part of the annual group budget, which is prepared every year by our senior management and approved by our Board of Directors. Our specialized finance and administration department are primarily responsible for evaluating the draft internal and external reporting, before these are finally approved by our Board of Directors.

Our Board of Directors discusses the financial results of the group at all formal board meetings, which meetings are minuted.

Our internal controls over financial reporting are a subset of internal controls and include policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of our financial statements in accordance with IFRS as issued by the International Accounting Standards Board and as adopted by the EU, and that receipts and expenditures are being made only by authorized persons; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Since we have securities registered with the SEC and are a large accelerated filer within the meaning of Rule 12b-2 of the Exchange Act, we need to assess the effectiveness of our internal controls over financial reporting and provide a report on the results of our assessment. Our Board of Directors reviewed its internal controls over financial reporting based on criteria established in the Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission and engaged an external advisor to help assess the effectiveness of its controls.

3.5.6 Recent or Current Developments in our System of Risk Management

In 2022, we further increased our attention to pro-active risk management by making the evaluation of our core risks and uncertainties a standing discussion topic for our Board of Directors.

4 General Description of the Company and its Share Capital

4 General Description of the Company and its Share Capital

4.1 Legal Information on the Company

4.1.1 General

We were incorporated on April 25, 2008 in the Netherlands and under Dutch law. Our commercial name is 'argenx' and since April 26, 2017, our corporate name is 'argenx SE'. We are a Dutch European public company (*Societas Europaea* or SE) registered with the trade register of the Dutch Chamber of Commerce under number 24435214. Our corporate seat is in Rotterdam, the Netherlands, and our registered office is at Laarderhoogtweg 25, 1101 EB Amsterdam, the Netherlands. Our telephone number is +31 (0) 10 70 38 441. Our website address is **http://www.argenx.com**.

Our European legal entity identifier number (***LEI***) is 7245009C5FZE6G9ODQ71. Our ordinary shares are listed on Euronext Brussels under ISIN NL0010832176 under the symbol "ARGX". The ADSs are listed on Nasdaq, under the symbol "ARGX".

4.1.2 Statutory/Corporate Objective

Pursuant to Article 3 of our Articles of Association, our corporate objectives are: (a) to exploit, including all activities relating to research, development, production, marketing and commercial exploitation; biological, chemical or other products, processes and technologies in the life sciences sector in general, and more specifically in the diagnostic, pharmaceutical, medical, cosmetic, chemical and agricultural sector; (b) to design and develop instruments which may be used in medical diagnosis and affiliated areas; (c) the worldwide distribution of, sale of and rendering services relating to our products and subsidiaries directly to customers as well as through third parties; (d) to incorporate, to participate in any way whatsoever, to manage, to supervise, to operate and to promote enterprises, businesses and companies; (e) to render advice and services to businesses and companies with which we form a group and to third parties; (f) to finance businesses and companies; (g) to borrow, to lend and to raise funds, including the issue of bonds, promissory notes or other securities or evidence of indebtedness as well as to enter into agreements in connection with the aforementioned; (h) to render guarantees, to bind us and to pledge our assets for obligations of the companies and enterprises with which we form a group and on behalf of third parties; (i) to obtain, alienate, manage and exploit registered property and items of property in general; (j) to trade in currencies, securities and items of property in general; (k) to develop and trade

in patents, trademarks, licenses, know-how and other industrial property rights; and (l) to perform any and all activities of industrial, financial or commercial nature, as well as everything pertaining the foregoing, relating thereto or conductive thereto, all in the widest sense of the word.

4.2 Share Capital

4.2.1 Authorized and Issued Share Capital

Under Dutch Law, a company's authorized share capital sets out the maximum amount and number of shares that it may issue without amending its articles of association. Our Articles of Association provide for an authorized share capital in the amount of €9.0 million divided into 90 million shares, each with a nominal value of €0.10. All issued and outstanding shares have been fully paid up and the shares are held in dematerialized form.

As of December 31, 2022 our issued and paid up share capital amounted to €5,539,585.60, represented by 55,395,856 ordinary shares with a nominal value of €0.10, each representing an identical fraction of our share capital. As of December 31, 2022, neither we nor any of our subsidiaries held any of our own shares.

4.2.2 Stock Options and Restricted Stock Units

In addition to the shares already outstanding, we have granted stock options which upon exercise will lead to an increase in the number of our outstanding shares. A total of 5,511,767 stock options (where each stock option entitles the holder to subscribe for one new ordinary share) were outstanding and granted as of December 31, 2022. Upon exercise of these 5,511,767 stock options, a total amount of $1,130 million in stock option exercise price we will receive, increasing our share capital and share premium by the same amount.

Further, we have granted RSUs which upon vesting will lead to an increase in the number of our outstanding shares. A total of 385,280 RSUs (where the holder receives an equal number of new ordinary shares, minus a certain number of shares required to cover certain costs, if applicable) were outstanding and granted as of December 31, 2022.

Apart from the stock options and RSUs granted under our Equity Incentive Plan, we do not currently have other stock options, RSUs, options to purchase securities, convertible securities or other rights to subscribe for or purchase securities outstanding. For stock option information through December 31, 2022, see note 13 "**Share-Based Payments**" in our consolidated financial statements in section 6 "**Consolidated Financial Statements**".

4.2.3 New shares created during 2022

As a result of the exercise of stock options and vesting of RSUs under our Equity Incentive Plan, 1,044,207 new shares were created in 2022.

On March 23, 2022, we offered 2,333,334 of our ordinary shares through a global offering which consisted of (i) a public offering of 1,433,701 ADSs in the U.S. and certain other countries outside the EEA at a price of $300 per ADS, before underwriting discounts and commissions and offering expenses and (ii) a concurrent private placement of 899,633 ordinary shares in the EEA and the UK at an offering price of €273.10 per share, before underwriting discounts and commissions and offering expenses. On March 29, 2022, the underwriters of the offering exercised their over-allotment option to purchase 350,000 additional ADSs in full. As a result, we received $804.1 million of gross proceeds from this offering, decreased by $44.2 million of underwriter discounts and commissions, and offering expenses, of which $44.0 million has been deducted from equity. The total net cash proceeds from the offering amounted to $761.0 million.

The following table shows the developments in our share capital for the fiscal year ending December 31, 2022:

Number of shares outstanding on December 31, 2020	**47,571,283**
Number of shares outstanding on December 31, 2021	**51,668,315**
Exercise of stock options in 2022	1,024,626
Vesting of RSUs	19,581
Global public offering in Euronext and Nasdaq on March 23, 2022	2,333,334
Over-allotment option exercised by underwriters on March 29, 2022	350,000
Number of shares outstanding on December 31, 2022	**55,395,856**
Issuance of shares in January 2023 relating to exercise of stock options and vesting of RSU in December 2022	15,076
Exercise of stock options in January 2023	159,385
Exercise of stock options in February 2023	217
Number of shares outstanding on February 15, 2023	**55,570,534**

4.2.4 American Depository Shares

In connection with our initial public offering on Nasdaq, the Bank of New York Mellon, as depositary, registered and delivered ADSs. Each ADS represents one share (or a right to receive one share) deposited with ING Bank N.V., as custodian for the depositary in the Netherlands. Each ADS also represents any other securities, cash or other property which may be held by the depositary. The depositary's office at which the ADSs are administered is located at 101 Barclay Street, New York, New York 10286. The Bank of New York Mellon's principal executive office is located at 225 Liberty Street, New York, New York 10286.

An ADS holder will not be treated as one of our shareholders and does not have shareholder rights. Dutch law governs shareholder rights. The depositary will be the holder of

the shares underlying the ADSs. A registered holder of ADSs has ADS holder rights. A deposit agreement among us, the depositary, ADS holders and all other persons indirectly or beneficially holding ADSs sets out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs.

The depositary has agreed to pay or distribute to ADS holders the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, upon payment or deduction of its fees and expenses. ADS holders will receive these distributions in proportion to the number of shares their ADSs represent. An ADS holder may surrender his ADSs at the depositary's office. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver the shares and any other deposited securities underlying the ADSs to the ADS holder or a person the ADS holder designates at the office of the custodian. Or, at an ADS holder's request, risk and expense, the depositary will deliver the deposited securities at its office, if feasible.

The depositary may charge the ADS holder a fee and its expenses for instructing the custodian regarding delivery of deposited securities. ADS holders may instruct the depositary how to vote the number of deposited shares their ADSs represent. If we request the depositary to solicit the ADS holders' voting instructions (and we are not required to do so), the depositary will notify them of a General Meeting and send or make voting materials available to them. Those materials will describe the matters to be voted on and explain how ADS holders may instruct the depositary how to vote. For instructions to be valid, they must reach the depositary by a date set by the depositary. The depositary will try, as far as practical, subject to Dutch law and the provisions of our Articles of Association or similar documents, to vote or to have its agents vote the shares or other deposited securities as instructed by ADS holders. If we do not request the depositary to solicit the ADS holders' voting instructions, an ADS holder can still send voting instructions, and, in that case, the depositary may try to vote as he instructs, but it is not required to do so. In any event, the depositary will not exercise any discretion in voting deposited securities and it will only vote or attempt to vote as instructed or as described in the following sentence. If we asked the depositary to solicit an ADS holder's instructions at least 45 days before the meeting date but the depositary does not receive voting instructions from an ADS holder by the specified date, it will consider such ADS holder to have authorized and directed it to give a discretionary proxy to a person designated by us to vote the number of deposited securities represented by its ADSs. The depositary will give a discretionary proxy in those circum¬stances to vote on all questions to be voted upon unless we notify the depositary that:

- we do not wish to receive a discretionary proxy;
- there is substantial shareholder opposition to the particular question; or
- the particular question would have an adverse impact on our shareholders.

We are required to notify the depositary if one of the conditions specified above exists. In order to give an ADS holder a reasonable opportunity to instruct the depositary as to the exercise of voting rights relating to our shares, if we request the depositary to act, we agree to give the depositary notice of any meeting and details concerning the matters to be voted upon at least 30 days in advance of the meeting date.

4.2.5 Issue of Shares

The Articles of Association provide that shares may be issued or rights to subscribe for our shares may be granted pursuant to a resolution of the shareholders at a General Meeting, or alternatively, by our Board of Directors if so designated by the shareholders at a General Meeting. A resolution of the shareholders at a General Meeting to issue shares, to grant rights to subscribe for shares or to designate our Board of Directors as the corporate body authorized to do so can only take place at the proposal of our Board of Directors with the consent of the majority of the non-executive directors. Shares may be issued or rights to subscribe for shares may be granted by resolution of our Board of Directors, if and insofar as our Board of Directors is designated to do so by the shareholders at a General Meeting. Designation by resolution of the shareholders at a General Meeting cannot be withdrawn unless determined otherwise at the time of de-signation. The scope and duration of our Board of Directors' authority to issue shares or grant rights to subscribe for shares (such as granting stock options or issuing convertible bonds) is determined by a resolution of the shareholders at a General Meeting and relates, at the most, to all unissued shares in our authorized capital at the relevant time. The duration of this authority may not exceed a period of five years. Designation of our Board of Directors as the body authorized to issue shares or grant rights to subscribe for shares may be extended by a resolution of the shareholders at a General Meeting for a period not exceeding five years in each case. The number of shares that may be issued is determined at the time of designation. No shareholders' resolution or Board of Directors' resolution is required to issue shares pursuant to the exercise of a previously granted right to subscribe for shares. A resolution of our Board of Directors to issue shares and to grant rights to subscribe for shares can only be taken with the consent of the majority of the non-executive directors.

The 2022 General Meeting designated our Board of Directors as the corporate body competent to issue additional shares and grant rights to subscribe for shares up to a maximum of 10% of the outstanding capital at the date of the 2022 General Meeting, and to limit or exclude pre-emptive rights of shareholders for such shares with the prior consent of the majority of the non-executive directors for a period of 18 months.

4.2.6 Pre-Emption Rights

Dutch law (Section 2:96a of the DCC) and the Articles of Association give shareholders pre-emptive rights to subscribe on a pro rata basis for any issue of new shares or, upon a grant of rights, to subscribe for shares. Holders of shares have no pre-emptive rights upon 1) the issue of shares against a payment in kind (being a contribution other than in cash); (2) the issue of shares to our employees or the employees of a member of our group; and (3) the issue of shares to persons exercising a previously granted right to subscribe for shares.

A shareholder may exercise pre-emptive rights during a period of at least two weeks from the date of the announcement of the issue of shares. Pursuant to the Articles of Association, the shareholders at a General Meeting may restrict or exclude the pre-emptive rights of shareholders. A resolution of the shareholders at a General Meeting to restrict or exclude the pre-emptive rights or to designate our Board of Directors as our corporate body authorized to do so, may only be adopted on the proposal of our Board

of Directors with the consent of the majority of the non-executive directors. A resolution of the shareholders at a General Meeting to exclude or restrict pre-emptive rights, or to authorize our Board of Directors to exclude or restrict pre-emptive rights, requires a majority of at least two-thirds of the votes cast, if less than 50% of our issued and outstanding share capital is present or represented at a General Meeting.

With respect to an issuance of shares pursuant to a resolution of our Board of Directors, the pre-emptive rights of shareholders may be restricted or excluded by resolution of our Board of Directors if and insofar as our Board of Directors is designated to do so by the shareholders at a General Meeting. A resolution of our Board of Directors to restrict or exclude pre-emptive rights can only be taken with the consent of the majority of the non-executive directors.

The designation of our Board of Directors as the body competent to restrict or exclude the pre-emptive rights may be extended by a resolution of the shareholders at a General Meeting for a period not exceeding five years in each case. Designation by resolution of the shareholders at the General Meeting cannot be withdrawn unless determined otherwise at the time of designation.

See also sections 4.2.5 "**Issue of Shares**" and 4.2.6 "**Pre-Emption Rights**" with respect to the current right of the Board of Directors to limit or exclude pre-emptive rights.

4.2.7 Acquisition of Shares in our Capital

We may not subscribe for our own shares on issue. We may acquire fully paid-up shares at any time for no consideration or, if:

- our shareholders' equity less the payment required to make the acquisition, does not fall below the sum of called-up and paid-in share capital and any statutory reserves;
- we and our subsidiaries would thereafter not hold shares or hold a pledge over shares with an aggregate nominal value exceeding 50% of our issued share capital; and
- our Board of Directors has been authorized thereto by the shareholders at a General Meeting.

As part of the authorization, the shareholders at a General Meeting must specify the number of shares that may be repurchased, the manner in which the shares may be acquired and the price range within which the shares may be acquired. An authorization by the shareholders at a General Meeting to our Board of Directors for the repurchase of shares can be granted for a maximum period of 18 months. No authorization of the shareholders at a General Meeting is required if ordinary shares are acquired by us with the intention of transferring such ordinary shares to our employees under the Equity Incentive Plan. A resolution of our Board of Directors to repurchase shares can only be taken with the consent of the majority of the non-executive directors.

Shares held by us in our own share capital do not carry a right to any distribution. Furthermore, no voting rights may be exercised for any of the shares held by us or our subsidiaries unless such shares are subject to the right of usufruct or to a pledge in favor of a person other than us or our subsidiaries and the voting rights were vested in the pledgee or usufructuary before we or our subsidiaries acquired such shares. Neither we

nor our subsidiaries may exercise voting rights in respect of shares for which we or our subsidiaries have a right of usufruct or a pledge.

4.2.8 Reduction of Share Capital

The shareholders at a General Meeting may, upon a proposal by our Board of Directors with the consent of the majority of the non-executive directors, resolve to reduce the issued share capital by cancelling shares or by amending the Articles of Association to reduce the nominal value of the shares. Only shares held by us or shares for which we hold the depositary receipts may be cancelled. A resolution of the shareholders at a General Meeting to reduce the number of shares must designate the shares to which the resolution applies and must lay down rules for the implementation of the resolution. A resolution to reduce the issued share capital requires a majority of at least two-thirds of the votes cast, if less than 50% of our issued and outstanding share capital is present or represented at a General Meeting.

4.3 Share Classes and Principal Shareholders

As of February 15, 2023 our issued share capital amounted to €5,557,053.40 and was represented by 55,570,534 ordinary shares. There is only one class of shares (ordinary shares, including ordinary shares represented by ADSs), and there are no special rights attached to any of the ordinary shares, nor special shareholder rights, including voting rights, for any of our shareholders. Each shareholder has one vote.

Any substantial holding and gross short positions in issuing institutions and shares with special controlling rights have to be notified. An issuing institution is a public limited company (*naamloze vennootschap*) incorporated under Dutch law whose (depositary receipts for) shares are admitted to trading on a regulated market in the Netherlands or in another EU Member State or an EEA Member State, or a legal entity incorporated under the law of a state that is not an EU Member State and whose (depositary receipts for) shares are admitted to trading on a regulated market in the Netherlands.

Holders are required to report as soon as their substantial holding or short position equals or exceeds 3% of the issued capital. Subsequently, holders should notify the Dutch Authority for the Financial Markets (Stichting Autoriteit Financiële Markten) (***AFM***) again when their substantial holding or short position consequently reaches, exceeds or falls below a threshold. This can be caused by the acquisition or disposal of shares by the shareholder or because the issued capital of the issuing institution is increased or decreased. Pursuant to chapter 5.3 of the DFSA, relevant thresholds are: 3%, 5%, 10%, 15%, 20%, 25%, 30%, 40%, 50%, 60%, 75% and 95%.

The duty to notify applies to legal entities as well as natural persons.

As of February 15, 2023, the following major shareholdings fall under the mandatory notice provisions of chapter 5.3 of the DFSA on the basis of information provided by the shareholders and/or the public register of all notifications made available pursuant to the DFSA at the AFM's website (see also section 4.2 "**Share Capital**"). No shareholdings above 3% were reported to the Company directly.

Name of beneficial owner	Number of shares	Capital interest	Number of voting rights	Voting rights
T. Rowe Price Group, Inc. [1]	5,505,351 [2]	9.95%	5,426,030 [3]	9.81%
FMR LLC [1]	5,532,361.06 [4]	10.00%	5,527,972.06 [4]	9.99%
Artisan Investments GP LLC [1]	2,674,146 [5]	4.89%	2,674,146 [5]	4.89%
The Vanguard Group [1]	1,978,464	4.16%	–	–
BlackRock, Inc. [1]	2,792,002 [6]	5.04%	3,319,096 [7]	5.99%
Baillie Gifford & Co. [1]	–	–	2,966,216	6.24%
Wellington Management Group LLP [1]	–	–	2,276,361 [9]	4.81%

1) Based on the number of shares reported in, and at the time of, the most recent transparency notification filed with the AFM.

2) Consisting of 7,110 ordinary shares and 5,498,241 ADSs. T. Rowe Price Group, Inc. has reported holding 3,959,686 ADSs in its Schedule 13G/A filed with the SEC on February 14, 2023.

3) Consisting of voting rights on 7,110 ordinary shares and 5,418,920 ADSs.

4) FMR LLC has reported holding 5,532,356 ordinary shares in its Schedule 13G/A filed with the SEC on February 9, 2023.

5) Consisting of 46,766 ordinary shares and 2,627,380, according to the AFM filing, depository receipts and the respective number of voting rights. Artisan Investments GP LLC reported holding 2,615,415 ordinary shares in its Schedule 13G/A filed with the SEC on February 10, 2023.

6) Consisting of 2,045,011 ordinary shares, 1,291 contracts for difference, and 745,700, according to the AFM filing, depository receipts.

7) Consisting of voting rights on 2,497,994 ordinary shares, 1,775 contracts for difference and 819,327, according to the AFM filing, depository receipts.

8) Consisting of voting rights on 1,545,652 ordinary shares, 729,479 ADSs and 1,230 equity swaps.

The total number of stock options and RSUs outstanding as of February 15, 2023 amounts to 5,352,165 stock options and 385,280 RSUs.

As of the date of this Annual Report, we are not directly or indirectly owned or controlled by any shareholder, whether individually or acting in concert. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

As of the date of this Annual Report, as far as we are aware, there are no direct or indirect relationships between us and any of our significant shareholders.

4.4 General Meeting and Voting Rights

The Articles of Association provide that at least one annual General Meeting shall be held within six months after the close of each fiscal year. Other General Meetings will be held whenever our Board of Directors deems such to be necessary. Shareholders representing alone or in aggregate at least one-tenth of our issued and outstanding share capital may, pursuant to the DCC, request that a General Meeting be convened. Within three months of it becoming apparent to our Board of Directors that our equity has decreased to an amount equal to or lower than one-half of the paid-in and called-up capital, a General Meeting would be held to discuss any requisite measures.

We will give notice of any General Meeting by publication on our website and furthermore, to the extent required, in another manner in accordance with the applicable stock exchange regulations. The notice convening any General Meeting must include, among other items, an agenda indicating the place and date of the meeting, the items for discussion and voting, the proceedings for registration including the registration date, as well as any proposals for the agenda. Pursuant to Dutch law, shareholders holding at least 3% of our issued and outstanding share capital have a right to request our Board of Directors to include items on the agenda of the General Meeting. Our Board of Directors must agree to these requests, provided that (i) the request was made in writing and motivated, and (ii) the request was received by the Chair of our Board of Directors at least sixty days prior to the date of a General Meeting.

Our Board of Directors must give notice of a General Meeting, by at least such number of days prior to the day of the meeting as required by Dutch law, which is currently forty-two days.

Shareholders (as well as other persons with voting rights or meeting rights) may attend a General Meeting, to address the General Meeting and, in so far as they have such right, to exercise voting rights pro rata to its shareholding, either in person or by proxy. Shareholders may exercise these rights, if they are the holders of shares on the registration date which is currently the 28th day before the day of a General Meeting, and they or their proxy have notified our Board of Directors of their intention to attend a General Meeting in writing at the address and by the date specified in the notice of said meeting.

Each shareholder may cast one vote for each ordinary share held.

Members of our Board of Directors may attend a General Meeting in which they have an advisory role. The voting rights attached to shares are suspended as long as such shares are held by us.

General Meetings resolutions are taken by an absolute majority, except where Dutch law or our Articles of Association provide for a qualified majority or unanimity.

Three General Meetings were held in 2022. The 2022 General Meeting was held on May 10, 2022. In this meeting our annual report and annual accounts for the fiscal year 2021 were approved, Mr. Van Hauwermeiren was reappointed as an executive director to the Board of Directors for a term of four years, each of Peter Verhaeghe and Werner

Lanthaler were reappointed as non-executive directors to the Board of Directors for terms of two years, James Daly was reappointed as a non-executive director to the Board of Directors for a term of four years, and the Board of Directors was authorized to issue shares and grant rights to subscribe for shares in our share capital for up to 10% of the outstanding share capital at the date of the meeting and for a period of 18 months from the meeting, proposed amendments to our Articles of Association were approved and the appointment of Deloitte Accountants B.V. as the Company's auditor for the 2022 fiscal year.

On September 8, 2022, an extraordinary General Meeting was held, to appoint Camilla Sylvest as a non-executive director to the Board of Directors for a term of four years.

On December 12, 2022, an extraordinary General Meeting was held, to appoint Ana Cespedes as non-executive director to the Board of Directors for a term of approximately four years ending on the day of the annual General Meeting to be held in 2026.

4.5 Anti-Takeover Provisions

Various protective measures are possible and permissible within the boundaries set by Dutch law and Dutch case law. We have not implemented specific measures with the aim of deterring takeover attempts. However, we have adopted several provisions that may have the effect of making a takeover of argenx more difficult or less attractive, including requirements that certain matters, including an amendment of our Articles of Association, may only be brought to our shareholders for a vote upon a proposal by our Board of Directors. No takeover bid has been instigated by third parties in respect of our equity during the current or previous financial year and the current fiscal year.

4.6 Amendments of Articles of Association

The shareholders at a General Meeting may amend the Articles of Association, at the proposal of our Board of Directors, with the consent of the majority of the non-executive directors.

Changing the rights of any of the shareholders will require the Articles of Association to be amended.

The 2022 General Meeting approved the amendment of our Articles of Association to align with current Dutch law and practice. The Articles of Association were amended pursuant to the notarial deed of partial amendment of the Articles of Association, executed on May 10, 2022. The full text of the Articles of Association and an unofficial English translation thereof are available on our **website**.

4.7 Transparency Directive

We are a European public company with limited liability (*Societas Europaea* or SE) incorporated and existing under the laws of the Netherlands. The Netherlands is our EU home member state (*lidstaat van herkomst*) for the purposes of Directive 2004/109/EC (as amended by Directive 2013/50/EU), or the Transparency Directive, as a consequence of which we are subject to the DFSA in respect to certain ongoing transparency and disclosure obligations. In addition, as long as our shares are listed on Euronext Brussels and the ADSs on Nasdaq, we are required to disclose any regulated information which has been disclosed pursuant to the DFSA as well as in accordance with the Belgian Law of May 2, 2007, the Belgian Royal Decree of November 14, 2007 as well as Nasdaq listing rules. We must publish our annual accounts within four months after the end of each financial year and our half-yearly figures within two months after the end of the first six months of each financial year. Within five calendar days after adoption of our annual accounts, we must file our adopted annual accounts with the AFM. Pursuant to the DFSA, we will be required, among other things, to make public without delay any change in the rights attaching to our shares or any rights to subscribe our shares.

4.8 Dutch Financial Reporting Supervision Act

DFSA applies to financial years starting from 1 January 2006. On the basis of the DFSA, the AFM supervises the application of financial reporting standards by, among others, companies whose corporate seat is in the Netherlands and whose securities are listed on a Dutch Regulated Market or foreign stock exchange. Pursuant to the DFSA, the AFM has an independent right to (i) request an explanation from us regarding its application of the applicable financial reporting standards and (ii) recommend to us the making available of further explanations. If we do not comply with such a request or recommendation, the AFM may request that the Dutch Enterprise Chamber of the Amsterdam Court of Appeal (Ondernemingskamer van het Gerechtshof te Amsterdam) (***Enterprise Chamber***) order us to (i) make available further explanations as recommended by the AFM, (ii) provide an explanation of the way we have applied the applicable financial reporting standards to its financial reports or (iii) prepare our financial reports in accordance with the Enterprise Chamber's instructions.

This Annual Report also concerns the annual financial reporting within the meaning of 5:25c(2) DFSA.

4.9 Dividends and Other Distributions

Our Board of Directors has declared a series of interim distributions on account of the Company's freely distributable reserves for such amounts as was required to pay up the aggregate nominal value of all such shares that were issued to holders of vested RSUs, all in accordance with our Equity Incentive Plan. In accordance with Dutch law, our Board of Directors prepared and filed an interim simplified balance sheet demonstrating that there were sufficient freely distributable reserves for such interim distributions. Such interim simplified balance sheet was filed with the Dutch trade register. The aggregate amount of these interim distributions amounted to approximately €3,000 ($3,500) in 2022.

Other than these interim distributions, we have not paid or declared any cash dividends on our ordinary shares, and we do not anticipate paying any cash dividends in the foreseeable future. All of our outstanding shares have the same dividend rights. We intend to retain all available funds and any future earnings to fund the development and expansion of our business.

Even if future operations lead to significant levels of distributable profits, we currently intend that any earnings will be re¬invested in our business and that cash dividends will not be paid until we have an established revenue stream to support continuing cash dividends. In addition, payment of any future dividends to shareholders would be subject to shareholder approval at a General Meeting, upon proposal of our Board of Directors, which proposal would be subject to the approval of the majority of the non-executive directors after taking into account various factors including our business prospects, cash requirements, financial performance and new product development.

Under Dutch law, a Dutch European public company with limited liability (Societas Europaea or SE) may only pay dividends if the shareholders' equity (eigen vermogen) exceeds the sum of the paid-up and called-up share capital plus the reserves required to be maintained by Dutch law or our Articles of Association. Subject to such restrictions, any future determination to pay dividends would be at the discretion of the shareholders at our General Meeting.

Our Articles of Association, as available on our website, contain the provision on the distribution of profits in article 20 (Profits, distributions and losses).

4.10 Financial Calendar 2023

May 2, 2023	Annual General Meeting in Amsterdam, the Netherlands
May 4, 2023	First quarter 2023 financial results
July 27, 2023	Half year and second quarter 2023 financial results
October 27, 2023	Third quarter 2023 financial results

5 Operating and Financial Review

5 Operating and Financial Review

5.1 Overview

Since our inception in 2008, we have focused most of our financial resources and efforts towards developing our SIMPLE AntibodyTM Platform and antibody engineering technologies, identifying potential product candidates, establishing process, development and manufacturing capabilities for our product candidates and advancing multiple discovery programs into the clinic. In 2022, we executed on our global launch of VYVGART our first-in-class neonatal FcRn blocker, which is now approved in the U.S, Japan and Europe, the successful commercialization of which generated a global product net sales of $400.7 million. On our research and development, we continue towards advancing a deep pipeline of both clinical- and preclinical-stage product candidates for the treatment of severe autoimmune diseases, hematological disorders and cancer. Leveraging our technology suite and clinical expertise, we have advanced several candidates into late-stage clinical development and we currently have multiple programs in the discovery stage. Through December 31, 2022, we have raised aggregate gross proceeds of $4,318.5 million, including total net cash proceeds of $761.0 million from our U.S. public offering on Nasdaq in March 2022.

As of December 31, 2022 and December 31, 2021, we had cash, cash equivalents and current financial assets of $2,192.5 million and $2,336.7 million, respectively.

Our balance sheet shows our total assets accumulate to $3,134.3 million for the year ended December 31, 2022, compared to $2,850.3 million for the year ended December 31, 2021 and $2,279.4 million for the year ended December 31, 2020. The main reason for the material change in balance sheet total are the various equity financing rounds, completed over the period covered by the financial statements.

Since our inception, we have incurred significant operating losses. For the years ended December 31, 2022 and 2021, we incurred total comprehensive losses of $730.3 million and $450.6 million, respectively. As of December 31, 2022, we had accumulated losses of $2,109.8 million.

Although we have generated revenue of $400.7 million from global product net sales of VYVGART in fiscal year 2022, we can provide no assurances that we will be able to achieve or remain profitable based on sales in that indication alone or that we will be able to receive regulatory approval of and commercialize VYVGART in other indications or in other countries. On December 17, 2021, the FDA approved efgartigimod, which is marketed as VYVGART™ (efgartigimod alfa-fcab), for the treatment of gMG in adult patients who are AChR-AB+. On January 20, 2022, the PMDA approved VYVGART™ (efgartigimod alfa) for the treatment of adult patients with gMG who do not have sufficient response to steroids or non-steroidal ISTs. On August 11, 2022, the EU Commission granted marketing authorization for VYVGART™ (efgartigimod alfa-fcab) as an add-on to standard therapy for the treatment of adult patients with gMG who are AChR-AB+. These are the only approved products we currently have.

We expect our expenses to continue to increase as we expand our global commercial infrastructure and drug product inventory for VYVGART™ for the treatment of gMG, the advancement of our clinical-stage pipeline, including ongoing registrational clinical trials across five indications of efgartigimod, and continued investment in our IIP. We anticipate that our expenses will increase substantially if and as we:

Research and Development Activities:

- execute the Phase 2/3 clinical trials of efgartigimod in ITP, CIDP, PF and in PV;
- execute the Phase 2/3 clinical trials of efgartigimod in BP and Myositis and launch Phase 2/3 clinical trials in other indications;
- continue the research and development of our other clinical- and preclinical-stage product candidates and discovery stage programs; and
- seek regulatory approvals for any product candidates, including new indications, that successfully complete clinical trials.

Pre-Commercial and Commercial Activities

- further build-out our sales, marketing and distribution infrastructure and scale-up manufacturing capabilities for the continued commercialization of VYVGART™ for which we obtained regulatory approval from the FDA, PMDA and EU Commission and any product candidate, including new indications, for which we may obtain approval; and
- expand our global reach enabling us to commercialize any product candidates, including new indications, for which we may obtain regulatory approval.

Other Activities

- seek to enhance our technology platform and discover and develop additional product candidates;
- maintain, expand and protect our intellectual property portfolio, including litigation costs associated with defending against alleged patent infringement claims;
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts; and
- experience any delays or encounter any issues, including failed studies, ambiguous clinical trial results, safety issues or other regulatory challenges.

We expect that the costs of development and commercialization might also significantly increase due to current and future collaborations with research and development partners as well as commercial partners.

Information pertaining to the year ended December 31, 2021 was included in our annual report on Form 20-F for the year ended December 31, 2021 under section 5, "**Operating and Financial Review**", which was filed with the SEC on March 21, 2022.

5.2 Basis of Presentation

5.2.1 Foreign Currency Transactions

Functional and Presentation Currency

Items included in the consolidated financial statements of each of our entities are valued using the currency of their economic environment in which the entity operates. As of January 1, 2021, and for all periods thereafter, the consolidated financial statements are presented in USD, which is the Company's presentation currency.

Change in Functional and Presentation Currency as of January 1, 2021

As of January 1, 2021, the Company changed its functional and presentation currency from EUR to USD. The change in functional currency was made to reflect that USD has become the predominant currency for the Company, representing a significant part of the Company's cash flows and financing. The change has been implemented with prospective effect.

The change in presentation currency, effective January 1, 2021, from EUR to USD is retroactively applied to comparative figures according to IAS 8 and IAS 21, as if USD had always been the presentation currency of the consolidated financial statements. The change was made to better reflect the economic footprint of the Company's business going forward. The Company believes that the presentation currency change will give investors and other stakeholders a clearer understanding of the Company's performance over time.

5.2.2 Revenue from Sale of Product

Revenue from the sale of goods is recognized at an amount that reflects the consideration that we expect to be entitled to receive in exchange for transferring goods to a customer, at the time when the customer obtains control of the goods rendered. This means when the customer has the ability to direct the use of the asset. The consideration that is committed in a contract with a customer can include fixed amounts, variable amounts, or both. The amount of the consideration may vary due to discounts, rebates, returns, chargebacks or other similar items. Contingent consideration is included in the transaction price when it is highly probable that the amount of revenue recognized is not subject to future significant reversals.

Our product net sales consist of sales of VYVGART in U.S., Japan and Europe. Product net sales are recognized once we satisfy the performance obligation at a point in time under the revenue recognition criteria in accordance with IFRS 15 "Revenue from Contracts with Customers".

Revenue arising from the commercial sale of VYVGART is presented in the consolidated financial statements of profit or loss under note 15 "**Product Net Sales**". In accordance with IFRS 15 "Revenue from Contracts with Customers", such revenue is recognized when the product is physically transferred, in accordance with the delivery and acceptance terms agreed with the customer. Payment of the transaction price is payable at the point the customer obtains the legal title to the goods.

5.2.3 Revenue from Collaborations and License Agreements

Revenues to date have consisted principally of milestones, license fees, non-refundable upfront fees and research and development service fees in connection with collaboration and license agreements.

We recognize revenue when the customer obtains control of promised goods or services, in an amount that reflects the consideration that we expect to receive in exchange for those goods and services. In order to determine revenue recognition for agreements that we determine to be in the scope of IFRS 15, the following five steps are performed:

1. Identify the Contracts

In our current collaboration and license agreements, we are mainly licensing our intellectual property and/or providing research and development products/services, which might include a cost-sharing mechanism and/or in the future, selling our products to collaborative partner entities. Revenue is generated through these arrangements via upfront payments, milestone payments based on clinical and regulatory criteria, research and development service fees and future sales-based milestones and sales-based royalties. In some cases, the collaboration and license agreements also include an equity subscription component. If this is the case, we analyze if the criteria to combine contracts, as set out by IFRS 15, are met.

2. Identify Performance Obligations

Depending on the type of contract, there can be one or more distinct performance obligations under IFRS 15. This is based on an assessment of whether the promises in an agreement are capable of being distinct and are distinct from the other promises to transfer goods and/or services in the context of the contract.

For our material ongoing collaboration and license agreement (i.e., the Zai Lab Agreement), we assessed that there is more than one distinct performance obligation, being the transfer of a license and supply of clinical and commercial product.

This is because we consider the performance obligation is distinct in the context of the contract as the license has stand-alone value without our further involvement in the research and development collaboration and that there is no interdependence between the license and the clinical and commercial supply to be provided.

For other material collaboration and license agreements, we assessed that there is one single performance obligation in our collaboration and license agreements, being the transfer of a license combined with performance of research and development services.

3. Determine the Transaction Price

Our material ongoing collaboration and license agreements include non-refundable upfront payments or license fees, milestone payments, the receipt of which is dependent upon the achievement of certain clinical, regulatory or commercial milestones, royalties on sales and research and development service fees.

3.1 Non-Refundable Upfront Payments or License Fees

If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenue from non-refundable upfront fees allocated to this license at the point in time the license is transferred to the customer and the customer has the right to use the license.

For all our material ongoing collaboration and license agreements, we consider the performance obligations related to the transfer of the license as distinct from the other promises to transfer goods and/or services; we use judgement to assess the nature of the performance obligation to determine whether the performance obligation is satisfied over time or at a point in time. If over time, revenue is then recognized based on a pattern that best reflects the transfer of control of the service to the customer.

3.2 Milestone Payments Other than Sales-Based Milestones

A milestone payment, being a variable consideration, is only included in the transaction price to the extent it is highly probable that a significant reversal in the amount of cumulative revenue recognition will not occur when the uncertainty associated with the variable consideration is subsequently resolved. We estimate the amount to be included in the transaction price upon achievement of the milestone event. The transaction price is then allocated to each performance obligation on a stand-alone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each reporting period, we re-evaluate the probability of achievement of such milestones and any related constraint, and, if necessary, adjusts the estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue and earnings in the period of adjustment.

3.3 Research and Development Service Fees

Our material ongoing collaboration and license agreements may include reimbursement or cost sharing for research and development services. Research and development services are performed and satisfied over time given that the customer simultaneously receives and consumes the benefits provided by us. Such costs reimbursements received are recognized in revenues when costs are incurred and agreed by the parties.

3.4 Sales-Based Milestone Payments and Royalties

Our material ongoing collaboration and license agreements include sales-based royalties, including commercial milestone payments based on the level of sales, and the license has been deemed to be the predominant item to which the royalties and commercial milestone payments relate. Related revenue is recognized as the subsequent underlying sales occur.

4. Allocate the Transaction Price

In principle, an entity shall allocate the transaction price to each performance obligation identified in the contract on a relative stand-alone selling price basis. As our material ongoing collaboration and license agreement (i.e., the Zai Lab Agreement) contains more than one performance obligation, we allocate the transaction price to all performance obligations identified.

5. Recognize Revenue

Revenue is recognized when the customer obtains control of the goods and/or services as provided in the collaboration and license agreements. The control can be transferred over time or at a point in time – which results in the recognition of revenue over time or at a point in time, respectively.

As our ongoing collaboration and license agreement (i.e., the Zai Lab Agreement) contains more than one performance obligation, we recognized revenue at the point in time of the transfer of license and we recognize revenue over time for supply of clinical and commercial products as the customer simultaneously receives the benefits provided by our performance, satisfied over time.

Other ongoing collaboration and license agreements only contain one single performance obligation which is, as the customer simultaneously receive the benefits provided by our performance, satisfied over time, we recognize revenue over time.

The recognition of revenue over time is based on a pattern that best reflects the satisfaction of the related performance obligation, applying the input method. The input method estimates the satisfaction of the performance obligation as the percentage of total collaboration costs that are completed each period compared to the total estimated collaboration costs.

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

5.2.4 Other Operating Income

As a company that carries extensive research and development activities, we benefit from various grants, research and development incentives and payroll tax rebates from certain governmental agencies. These grants and research and development incentives generally aim to partly reimburse approved expenditures incurred in our research and development efforts. The primary grants, research and development incentives and payroll tax rebates are as follows:

Government Grants

We have received several grants from agencies of the Flemish government to support various research programs focused on technological innovation in Flanders. These grants require us to maintain a presence in the Flemish region for a number of years and invest according to pre agreed budgets.

Research and Development Incentives

Companies in Belgium can benefit from tax savings on amounts spent on research and development by applying a one time or periodic tax deduction on research and development expenditures for the acquisition or development of patents. This tax credit is a reduction of the corporate income taxes for Belgian statutory purposes and is transferrable to the next four accounting periods. These tax credits are paid to us in cash after five years to the extent they have not been offset against corporate taxes due.

Payroll Tax Rebates

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

Changes in Fair Value on Non-Current Financial Assets

In March 2019, we entered into a license agreement with AgomAb for the use of hepatocyte growth factor-mimetic SIMPLE Antibodies™, developed under our IIP. In exchange for granting this license, we received a profit share in AgomAb.

In June 2022, AgomAb secured €38.4 million as a result of the extension of Series B. We used the post-money valuation of this Series B financing round and the number of outstanding shares in determining the fair value of the profit-sharing instrument, which results in a change in fair value of non-current financial assets of $4.3 million recorded through profit or loss. The fair value of non-current financial assets is updated at the end of each reporting period.

5.2.5 Research and Development Expenses

Research and development expenses consist principally of:

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

We incur various external expenses under our collaboration and license agreements for material and services consumed in the discovery and development of our partnered product candidates. Under our agreement with AbbVie, our own research and development expenses were not reimbursed. Under our agreement with Zai Lab, we are responsible for certain costs relating to future clinical trials involving efgartigimod conducted partially by Zai Lab.

Our research and development expenses may vary substantially from period to period based on the timing of our research and development activities, including the timing of the initiation of clinical trials, production of product batches and enrolment of patients in clinical trials. Research and development expenses are expected to increase as we advance the clinical development of efgartigimod and ARGX-117 and further advance the research and development of our other early-stage pipeline candidates. The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing and estimated costs of the efforts that will be necessary to complete the development of, or the period, if any, in which material net cash inflows may commence from, any of our product candidates. This is due to numerous risks and uncertainties associated with developing drugs, as fully described in section 2 "**Risk Factors**" and including the uncertainty of:

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

5.2.6 Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of:

- personnel expenses relating to salaries and related costs for personnel, including share-based compensation, of our employees in executive, finance, business development, marketing, commercial and support functions;
- professional fees for business development, marketing, IT, audit, commercial, legal services and investor relations costs;
- Board of directors expenses consisting of directors' fees, travel expenses and share-based compensation for non-executive board members;
- costs associated with commercial launch of VYVGART™ for the treatment of gMG and marketing and promotional activities and continued investment in supply chain;
- allocated facilities costs; and
- other selling, general and administrative expenses, including leasing costs, office expenses, travel costs.

We expect our general and administrative expenses to increase as we continue to support our growth. Such costs include increases in our finance and legal personnel, additional IT-related expenses, and expenses and costs associated with compliance with the regulations governing public companies. We expect our selling and marketing expenses to increase due to marketing and promotional activities with respect to the

ongoing commercial launch of VYVGART™ and preparation of commercial launch of our other product candidates.

5.2.7 Financial Income (Expense)

Financial income mainly reflects interest earned on our cash and cash equivalents and current financial assets and net gains on our cash and cash equivalents and current financial assets held at fair value through profit or loss. Financial expense corresponds mainly to net losses on cash and cash equivalents and current financial assets held at fair value through profit or loss and other financial expenses.

5.2.8 Exchange Gains (Losses)

Our exchange gains (losses) relate to (i) our transactions denominated in foreign currencies, mainly in euro, Swiss francs, British pounds and Japanese yens which generate exchange gains or losses and (ii) the translation at the reporting date of assets and liabilities denominated in foreign currencies into USD, which is our functional and presentation currency since January 1, 2021 and therefore the presentation currency throughout this Annual Report unless otherwise specified. For more information on currency exchange fluctuations on our business, please see note 26 "**Financial Risk Management**". We have no derivative financial instruments to hedge interest rate and foreign currency risk.

5.2.9 Income Tax Expense

We have a history of losses. We expect to continue to incur losses as we continue to invest in our clinical and pre-clinical development programs and our discovery platform, and as we incur costs for the commercial launch of VYVGART, following the regulatory approval by the FDA, the PMDA and the EU Commission. Consequently, we do not have any deferred tax asset regarding certain tax losses on our consolidated statements of financial position.

We incur current income tax expense on the profit generated in various subsidiaries in view of the transfer price agreements set up between argenx BV and these subsidiaries.

5.3 Capitalization and Indebtedness

The table below sets forth our capitalization as of December 31, 2022 on an actual basis:

(in thousands of $)	**As of December 31, 2022** (audited)
Total current debt (including current portion of non-current debt)	–
Guaranteed	–
Secured	–
Unguaranteed/unsecured	–
Total non-current debt (excluding current portion of non-current debt)	–
Guaranteed	–
Secured	–
Unguaranteed/unsecured	–
Shareholder equity	**2,813,699**
Share capital	6,639
Share premium	4,309,887
Legal reserve(s) [1)]	129,280
Retained earnings	(2,109,791)
Other reserves	477,691
Total	**2,813,699**

1) Legal reserves are the amount of translation differences.

The table below sets forth our indebtedness as of December 31, 2022 on an actual basis:

(in thousands of $)	**As of December 31, 2022** (audited)
A. Cash	77,477
B. Cash equivalents [1)]	723,263
C. Other current financial assets [2)]	1,391,808
D. Liquidity (A)+(B)+(C)	2,192,548
E. Current financial debt (including debt instruments, but excluding current portion of non-current financial debt)	–
F. Current portion of non-current financial debt [3)]	3,417
G. Current financial indebtedness (E + F)	3,417
H. Net current financial indebtedness (G – D)	(2,189,131)
I. Non-current financial debt (excluding current portion and debt instruments) [3)]	9,009
J. Debt instruments	–
K. Non-current trade and other payables	–
L. Non-current financial indebtedness (I)+(J)+(K)	9,009
M. Total financial indebtedness (H)+(L)	(2,180,122)

1) See note 11 "**Cash and Cash Equivalents**" to our consolidated financial statements in section 6 "**Consolidated Financial Statements**".

2) See note 10 "**Financial Assets – Current**" to our consolidated financial statements in section 6 "**Consolidated Financial Statements**".

3) Please note that financial debt balances as presented in the table above do not include any indirect or contingent indebtedness. For more information on the Company's indirect and contingent indebtedness, please see note 29 "**Commitments**" to our consolidated financial statements in section 6 "**Consolidated Financial Statements**".

As of December 31, 2022, current financial debt (as disclosed in item E. in the table above) included current liabilities related to short-term leases in the amount of $3.4 million and non-current financial debt (as disclosed in item I. in the table above) included non-current liabilities related to long-term leases in the amount of $9.0 million.

More information is included in our consolidated financial statements and related notes included in section 6 "**Consolidated Financial Statements**".

5.4 Critical Accounting Estimates and Judgments

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

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

5.4.1 Critical Estimates in Applying Accounting Policies

Gross to Net Adjustments

Our product gross sales are subject to various deductions, which are primarily composed of rebates to government agencies, distributors, health insurance companies and managed healthcare organizations. These deductions represent estimates of the related obligations, requiring the use of judgment when estimating the effect of these sales deductions on product gross sales for a reporting period. These adjustments are deducted from product gross sales to arrive at product net sales. The significant components of variable consideration under revenue recognition policy summarizes the nature of these deductions and how the deduction is estimated. After recording these, product net sales represent our best estimate of the cash that we expect to ultimately collect.

5.5 Results of Operation

	Year Ended December 31,		
(in thousands of $)	**2022**	**2021**	**% Change**
Product net sales	400,720	–	100
Collaboration revenue	10,026	497,277	(98)
Other operating income	34,520	42,141	(18)
Total operating income	**445,267**	**539,418**	**(17)**
Cost of sales	(29,431)	–	100
Research and development expenses	(663,366)	(580,520)	14
Selling, general and administrative expenses	(472,132)	(307,644)	53
Loss from investment in joint venture	(677)	–	100
Total operating expenses	**(1,165,607)**	**(888,164)**	**31**
Operating loss	**(720,340)**	**(348,746)**	**107**
Financial income	27,665	3,633	661
Financial expense	(3,906)	(4,578)	(15)
Exchange loss	(32,732)	(50,053)	(35)
Loss for the year before taxes	**(729,314)**	**(399,744)**	**82**
Income tax (expense)/benefit	19,720	(8,522)	(331)
Loss for the year	**(709,593)**	**(408,266)**	**74**
Weighted average number of shares outstanding	54,381,371	51,075,827	
Basic and diluted profit/(loss) per share (in $)	(13.05)	(7.99)	

5.5.1 Product Net Sales

(in thousands of $)	Year Ended December 31, 2022
U.S.	377,659
Japan	15,764
Europe	5,678
Other [1)]	1,619
Total product net sales	**400,720**

1) The product net sales relate to sales made outside of the U.S., Japan and Europe and relate to named patient sales made with the U.S. label.

For the twelve months ended December 31, 2022, the product net sales were related to sales of VYVGART in the U.S. following the approval of VYVGART by the FDA on December 17, 2021, in Japan following the approval of VYVGART by PMDA on January 20, 2022 and the EU following the approval of VYVGART by the EU Commission on August 11, 2022. No product net sales were recognized during the comparable prior periods. Product gross sales for twelve months ended December 31, 2022 was $446.9 million and the gross to net adjustment for twelve months ended December 31, 2022 was $46.2 million, resulting in $400.7 million of product net sales for twelve months ended December 31, 2022.

5.5.2 Collaboration Revenue

	Year Ended December 31,		
(in thousands of $)	**2022**	**2021**	**% Change**
Zai Lab	–	151,903	(100)
Janssen	–	292,279	(100)
AbbVie	–	121	(100)
Upfront payments	**–**	**444,303**	**(100)**
Zai Lab	–	25,634	(100)
Janssen	–	22,865	(100)
AbbVie	–	102	(100)
Other	5,365	1,214	342
Milestone payments	**5,365**	**49,815**	**(89)**
Janssen	–	2,028	(100)
Other	424	298	42
Research and development service fees	**424**	**2,326**	**(82)**
Zai Lab	4,238	833	409
Other revenues	**4,238**	**833**	**409**
Total revenue	**10,026**	**497,277**	**(98)**

Our collaboration revenue decreased by $487.2 million to $10.0 million for the year ended December 31, 2022, compared to $497.3 million for the year ended December 31, 2021. The collaboration revenue recognized in the year ended December 31, 2021 was the result of the recognition of the transaction price from Janssen due to the termination of the collaboration agreement in 2021 and the closing of the strategic collaboration for efgartigimod with Zai Lab during 2021.

There was no revenue recognized from upfront payments during the year ended December 31, 2022. The revenue recognition from upfront payments for the year ended December 31, 2021 was $444.3 million. The revenue recognized during the year ended December 31, 2021 was primarily driven by the recognition of the upfront payment received from Zai Lab upon strategic collaboration for efgartigimod and the recognition of the upfront payment received under the collaboration agreement with Janssen upon termination of the agreement.

The revenue recognition from milestone payments for the year ended December 31, 2022 and December 31, 2021 was $5.4 million and $49.8 million respectively. The revenue recognized during the year ended December 31, 2022, from milestone payments primarily relates to €5.0 million triggered by the option exercised by LEO Pharma to enter into the LEO Pharma Collaboration Agreement for ARGX-112. The revenue recognized during the year ended December 31, 2021, from milestone payments was mainly due to recognition of $25.0 million from Zai Lab upon regulatory approval of efgartigimod by the FDA in the U.S. and recognition of $22.9 million as a result of the termination of the collaboration agreement with Janssen.

The increase in revenue recognition from other revenues of $3.4 million was primarily driven by the clinical and commercial supply of efgartigimod to Zai Lab.

5.5.3 Other Operating Income

	Year Ended December 31,		
(in thousands of $)	**2022**	**2021**	**% Change**
Grants	2,186	4,398	(50)
Research and development incentives	19,502	13,970	40
Payroll tax rebates	8,576	12,621	(32)
Change in fair value on non-current financial assets	4,256	11,152	(62)
Total	**34,520**	**42,141**	**(18)**

Other operating income decreased by $7.6 million to $34.5 million for the year ended December 31, 2022, compared to $42.1 million for the year ended December 31, 2021. The decrease was primarily driven by:

- the change in fair value on our profit share in AgomAb was $4.3 million for the year ended December 31, 2022, as compared to $11.2 million for the year ended December 31, 2021;
- the decrease in payroll tax rebates for the year ended December 31, 2022, as a result of lower research and development personnel expenses eligible for rebates for the year ended December 31, 2022; and

- the decrease was offset by an increase in research and development incentives due to a Belgian research and development tax incentive scheme, as a result of the overall increased research and development costs incurred.

For more information regarding governmental policies that could affect our operations, see section 1.9 "**Regulation**".

5.5.4 Research and Development Expenses

	Year Ended December 31,		
(in thousands of $)	**2022**	**2021**	**% Change**
Personnel expense	162,010	160,464	1
External research and development expenses	366,955	382,902	(4)
Materials and consumables	2,396	2,735	(12)
Depreciation and amortization	102,132	3,742	2,629
Other expenses	29,872	30,677	(3)
Total	**663,366**	**580,520**	**14**

Our research and development expenses totaled $663.4 million and $580.5 million for the years ended December 31, 2022 and 2021, respectively. The increase of $82.8 million for fiscal year 2022 as compared to fiscal year 2021 was primarily from the derecognition of the PRV submitted with the BLA filing for SC efgartigimod for the treatment of gMG, which resulted in a research and development expenses of $99.1 million recorded under depreciation and amortization in the table above.

Personnel expense primarily relates to internal and external personnel. The expense also includes share-based compensation expenses related to the grant of stock options and RSUs to our research and development employees. We employed on average 474.8 full-time equivalents in our research and development functions in the year ended December 31, 2022, compared to 349.7 in the year ended December 31, 2021.

Our external research and development expenses for the year ended December 31, 2022 totaled approximately $367.0 million, compared to approximately $382.9 million for the year ended December 31, 2021. The expense reflects clinical trial costs and manufacturing expenses related to the development of our product candidate portfolio. The table below provides additional detail on our external research and development expenses by program:

	Year Ended December 31,		
(in thousands of $)	**2022**	**2021**	**% Change**
efgartigimod	280,572	311,038	(10)
cusatuzumab	13,554	24,630	(45)
ARGX-117	32,384	22,759	42
Other programs [1)]	40,445	24,475	65
Total	**366,955**	**382,902**	**(4)**

1) Other programs include general expenses not allocated to specific program of $22.7 million in 2022 and $6.6 million in 2021.

External research and development expenses for our lead product candidate efgartigimod totaled $280.6 million for the year ended December 31, 2022, compared to $311.0 million for the year ended December 31, 2021. This decrease corresponds primarily to manufacturing and clinical development activities in relation to:

- the execution of the bridging study for ENHANZE® efgartigimod in MG;
- the execution of two Phase 3 clinical trials in CIDP;
- the execution of two Phase 3 clinical trials in ITP;
- the execution of the Phase 3 clinical trial in PV and PF;
- the execution of Phase 2 clinical trial in BP;
- the execution of Phase 1 clinical trial in Myositis; and
- the execution of pre-clinical and Phase 1 trials in new indications identified.

External research and development expenses for cusatuzumab totaled $13.6 million for the year ended December 31, 2022 compared to $24.6 million for the year ended December 31, 2021. This decrease of $11.1 million is the result of the termination of the collaboration agreement with Janssen.

External research and development expenses for ARGX-117 totaled $32.4 million for the year ended December 31, 2022 compared to $22.8 million for the year ended December 31, 2021. This increase of $9.6 million was due to increased research and development expenses in relation to the advancement of our ARGX-117 program, a complement-targeting antibody against C2.

External research and development expenses on other programs increased by $16.0 million to $40.4 million for the year ended December 31, 2022, compared to $24.5 million for the year ended December 31, 2021. Of the total research and development expense, $22.7 million relates to general allocation of expenses.

5.5.5 Selling, General and Administrative Expenses

	Year Ended December 31,		
(in thousands of $)	**2022**	**2021**	**% Change**
Personnel expenses	234,740	164,646	43
Professional and marketing fees	178,570	102,674	74
Supervisory board	6,912	12,958	(47)
Depreciation and amortization	2,211	2,126	4
IT expenses	17,431	8,977	94
Other expenses	32,268	16,263	98
Total Selling, general and administrative expenses	**472,132**	**307,644**	**53**

Our selling, general and administrative expenses totaled $472.1 million and $307.6 million for the years ended December 31, 2022 and 2021, respectively. The increase in our selling, general and administrative expenses for the year ended December 31, 2022 was principally due to an increase of personnel expense and professional and marketing fees, resulting from:

- increased costs of the salary and wages and benefits to our selling, general and administrative employees due to planned increase in the headcount;
- increased costs associated with additional employees recruited to strengthen our selling, general and administrative activities, for the commercial launch of VYVGART;
- increased professional and marketing fees, including promotional and marketing costs primarily due to the commercial launch of VYVGART; and
- continued investment in our IT infrastructure.

We employed on average 442.4 full-time equivalents in our selling, general and administrative functions in the year ended December 31, 2022, compared to 264.4 in the year ended December 31, 2021.

5.5.6 Financial Income (and Expense)

For the year ended December 31, 2022, financial income amounted to $27.7 million compared to $3.6 million for the year ended December 31, 2021. The increase of $24.0 million in 2022 related primarily to higher interest on term accounts.

For the year ended December 31, 2022, financial expense amounted to $3.9 million compared to $4.6 million for the year ended December 31, 2021.

5.5.7 Exchange Gains (Losses)

Exchange losses totaled $32.7 million for the year ended December 31, 2022, compared to exchange losses of $50.1 million for the year ended December 31, 2021. The decrease was mainly attributable to unrealized exchange rate losses on the cash, cash equivalents and current financial assets position in euro during the year ended December 31, 2022 as compared to unrealized exchange rate losses on the cash, cash equivalents and current financial assets position during the year ended December 31, 2021.

5.6 Liquidity and Capital Resources

5.6.1 Sources of Funds

Since our inception in 2008, we have invested most of our resources in developing our product candidates, building our intellectual property portfolio, developing our supply chain, conducting business planning, raising capital and providing general and administrative support for these operations. We currently have only one approved product and as of the year ended December 31, 2022, net product sales also started to contribute to the funding of our operations. To date, we have funded our operations through public and private placements of equity securities, upfront, milestone and expense reimbursement payments received from our collaborators, funding from governmental bodies and interest income from the investment of our cash, cash equivalents and financial assets. Through December 31, 2022, we have raised gross proceeds of $4,318.5 million from private and public offerings of equity securities. We have made net product sales of $400.7 million during the twelve months ended December 31, 2022.

Our cash flows may fluctuate and are difficult to forecast and will depend on many factors. On December 31, 2022, we had cash, cash equivalents and current financial assets of $2,192.5 million, compared to $2,336.7 million on December 31, 2021.

We have no ongoing material financing commitments, such as lines of credit or guarantees, that are expected to affect our liquidity over the next five years, other than leases and our commitments to Lonza and Fujifilm which are detailed in note 29 "**Commitments**" to our consolidated financial statements in section 6 "**Consolidated Financial Statements**".

For more information as to the risks associated with our future funding needs, see section 2.1 "**Risk Factors Related to argenx's Financial Position and Need for Additional Capital**".

For more information as to our financial instruments, please see note 26 "**Financial Risk Management**" in section 6 "**Consolidated Financial Statements**".

5.6.2 Cash Flows

The table below summarizes our cash flows for the years ended December 31, 2022 and 2021.

	Year Ended December 31,		
(in thousands of $)	**2022**	**2021**	**Variance**
Cash and cash equivalents at beginning of the period	**1,334,676**	**1,216,803**	**117,873**
Net cash flows (used in)/from operating activities	(862,807)	(606,812)	(255,995)
Net cash flows (used in)/from investing activities	(461,184)	(347,070)	(114,114)
Net cash flows (used in)/from financing activities	843,757	1,121,342	(277,585)
Effect of exchange rate differences on cash and cash equivalents	(53,702)	(49,587)	(4,115)
Cash and cash equivalents at end of the period	**800,740**	**1,334,676**	**(533,936)**

Net Cash Used in Operating Activities

Net cash outflow from our operating activities increased by $256.0 million to a net outflow of $862.8 million for the year ended December 31, 2022, compared to a net outflow of $606.8 million for the year ended December 31, 2021. The net cash outflow from operating activities for the year ended December 31, 2022 resulted primarily from (i) the research and development expenses incurred in relation to the manufacturing and clinical development activities of efgartigimod and the advancement of other clinical, preclinical and discovery-stage product candidate, (ii) the personnel expenses and consulting expenses incurred for the commercial launch of efgartigimod in the U.S., Japan, and Europe and (iii) the increase in working capital, primarily due to increase in accounts receivables related to product net sales and the increase in inventory levels. The net cash outflow of $606.8 million for the year ended December 31, 2021 was primarily influenced by (i) the research and development expenses incurred in relation to the manufacturing and clinical development activities of efgartigimod and the

advancement of other clinical, preclinical and discovery-stage product candidate, (ii) the personnel expenses and consulting expenses incurred in preparation of the commercial launch of efgartigimod in the U.S. and Japan, and (iii) the manufacturing of inventory ahead of the commercial launch of efgartigimod in the U.S.

Net Cash Used in/from Investing Activities

Investing activities for the year ended December 31, 2022, consist primarily of the purchases of current financial assets and intangible assets. Cash flow from investing activities represented a net outflow of $461.2 million for the year ended December 31, 2022, compared to a net outflow of $347.1 million for the year ended December 31, 2021.

The net outflow for the year ended December 31, 2022 related primarily to (i) the net investment of $368.5 million in current financial assets, including money market funds and term deposit accounts, compared to a net investment of $228.2 million for the year ended December 31, 2021 and (ii) the cash outflow of $102.0 million during 2022 in relation to the purchase of a PRV compared to a cash outflow of $98.0 million for a PRV which was acquired in 2020, however, paid in 2021.

Net Cash Provided by Financing Activities

Financing activities primarily consist of net proceeds from our private placements and public offerings of our securities and exercise of stock options. The net cash inflow from financing activities was $843.8 million for the year ended December 31, 2022, compared to a net cash inflow of $1,121.3 million for the year ended December 31, 2021. The net cash inflows were attributed to (i) $760.6 million net cash proceeds from our global offering in February 2022, compared to $1,091.7 million net cash proceeds from our global offering and concurrent private placement in February 2021 and (ii) $93.2 million proceeds received from the exercise of stock options in 2022, compared to $33.4 million for the year ended 2021.

Operating and Capital Expenditure Requirements

We have never achieved profitability and, as of December 31, 2022, we had accumulated losses of $2,109.8 million. We expect to continue to incur significant operating losses for the foreseeable future as we continue our research and development efforts, incur higher costs for continued commercialization of VYVGART, and seek to obtain regulatory approval and commercialization of other pipeline candidates.

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

- the progress, timing and completion of preclinical testing and clinical trials for our current or any future product candidates;

- the number of potential new product candidates we identify and decide to develop;
- the time and costs involved in obtaining regulatory approval for our product candidates and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to any of our product candidates;
- selling and marketing activities undertaken in connection with the commercialization of VYVGART or potential commercialization of any of our current or any future product candidates, if approved, and costs involved in the creation of an effective sales and marketing organization;
- manufacturing activities undertaken for VYVGART and potential commercialization of any of our current or any future product candidates, if approved, and costs involved in the creation of an effective supply chain;
- the costs involved in growing our organization to the size needed to allow for the research, development and potential commercialization of our current or any future product candidates;
- the costs involved in filing patent applications and maintaining and enforcing patents or defending against claims or infringements raised by third parties;
- the maintenance of our existing collaboration agreements and entry into new collaboration agreements;
- developments related to COVID-19 and its impact on the costs and timing associated with the conduct of our clinical trials, preclinical programs, manufacturing activities and other related activities; and
- developments related to the global economic uncertainties and political instability resulting from the conflict between Russia and the Ukraine.

For more information as to the risks associated with our future funding needs, see section 2.1 of this Annual Report titled "**Risk Factors Related to argenx's Financial Position and Need for Additional Capital**".

5.6.3 Working Capital Statement

In accordance with item 3.1 of Annex 11 of the Commission Delegated Regulation (EU) 2019/980 we make the following statement:

In our opinion, the working capital of the Company is sufficient for the Company's present requirements, at least for a period of twelve months from the date of this Annual Report.

5.7 Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off balance sheet arrangements, as defined in the applicable rules and regulations, such as relationships with unconsolidated entities or financial partnerships, which are often referred to as structured finance or special purpose entities, established for the purpose of facilitating financing transactions that are not required to be reflected on our balance sheets.

5.8 Contractual Obligations

Below an overview is given of our material contractual obligations at December 31, 2022:

	Payments due by period				
(in thousands of $)	Total	Less than 1 year	1–3 years	3–5 years	More than 5 years
Lease liabilities	12,402	3,408	4,784	3,043	1,167
Lease commitments not commenced	18,038	–	–	–	18,038

We signed lease agreements for laboratory and office space in Zwijnaarde, Belgium, offices in Amsterdam, Netherlands, Boston, U.S., and Tokyo, Japan, as disclosed in note 4 "**Property, Plant and Equipment**" in the consolidated financial statements in section 6 "**Consolidated Financial Statements**".

In January 2021, we entered into a binding lease agreement related to the envisioned relocation of our Zwijnaarde facility to a newly built office in Zwijnaarde, with an annual base rent of $1.8 million, which will be operational in the third quarter of 2028, and with an initial term of 10.5 years. Included in the binding lease commitment is a rent-free period of six months following the completion of the building. The total future cash outflows related to this lease are represented in note 29 "**Commitments**" in our consolidated financial statements which are appended to our Annual Report for the period ended December 31, 2022 as "Lease commitments not commenced".

In August 2022, we terminated our lease in Breda, the Netherlands in relation to office space and replaced this on the same date with an annual lease in Amsterdam, the Netherlands with an initial term of one year. We also lease office space in Boston (U.S.), Tokyo (Japan), Geneva (Switzerland), Munich (Germany), Issy Les Moulineaux (France), Vaughan Ontario (Canada), Gerrards Cross (UK) and Milan (Italy).

In addition, our lease liabilities include a lease plan for company cars with maturity dates up to four years.

For a discussion of contractual obligations, please see note 29 "**Commitments**" in our consolidated financial statements in section 6 "**Consolidated Financial Statements**".

5.9 Information Regarding the Independent Auditor

The audited consolidated financial statements as of and for the fiscal year ended December 31, 2022 and 2021 and 2020 have been audited by our independent auditor, Deloitte Accountants B.V. (Deloitte), who rendered an unqualified audit report on these financial statements. The partner of Deloitte who signed the auditors' reports is a member of the Netherlands Institute of Chartered Accountants (*Koninklijke Nederlandse Beroepsorganisatie van Accountants*). The office of Deloitte is located at Wilhelminakade 1, 3072 AP Rotterdam, the Netherlands.

5.10 Material Contracts and Related Party Transactions

5.10.1 Material Contracts

Our material contracts are described in sections 1.4 "**Collaboration Agreements**", 1.5 "**License Agreements**" and 1.6 "**Distribution Agreements**".

5.10.2 Related Party Transactions

Since January 1, 2022, we have not entered into any transactions with any related parties which are – as a single transaction or in their entirety – material to us.

In addition, since January 1, 2022, there has not been, nor is there currently proposed, any material transaction or series of similar material transactions to which we were or are a party in which any of the members of our Board of Directors or senior management, holders of more than 10% of any class of our voting securities, or any member of the immediate family of any of the foregoing persons, had or will have a direct or indirect material interest, other than the compensation and shareholding arrangements we describe in section 4.3 "**Share Classes and Principal Shareholders**", and the transactions we describe below.

From time to time, in the ordinary course of our business, we may contract for services from companies in which certain of the members of our senior management or directors may serve as director or advisor. The costs of these services are negotiated on an at arm's length basis and none of these arrangements are material to us.

Agreements with our Senior Management

We have entered into a management agreement with Tim Van Hauwermeiren as our CEO, our sole executive director. The key terms of his agreement are as follows:

Tim Van Hauwermeiren	
Fixed-base compensation	$638,901
Short-term variable compensation	A target of 60% of the fixed-base compensation based on previously determined bonus targets established by the non-executive directors
Pension contributions [1)]	$23,384
Duration	Indefinite

1) Amounts shown represent pension contributions paid during the year ended December 31, 2022.

We may terminate Mr. Van Hauwermeiren's services upon 18 months' notice, or payment of 18 months' pro-rated base compensation in lieu of notice. Mr. Van Hauwermeiren would be entitled to the same payment in lieu of notice in the event he terminates his services with us in circumstances in which it cannot reasonably be expected for him to continue providing services to us (and after our failure to remedy such conditions after being provided at least 14 days' notice). Mr. Van Hauwermeiren would also be entitled to payment in lieu of notice in the event he terminated his services with us in certain cases of our failure to comply with obligations under applicable law or his agreement (and after our failure to remedy such non-compliance, if non-deliberate, after being provided at least 14 days' notice). In these cases, there will be a full acceleration of the vesting of any outstanding stock options held by Mr. Van Hauwermeiren. There will be no notice period or payment in lieu of notice in certain cases of Mr. Van Hauwermeiren's failure to comply with obligations under applicable law or his agreement. Mr. Van Hauwermeiren may be dismissed immediately as an executive director.

Karl Gubitz, our chief financial officer, has an employment contract with our subsidiary, argenx US Inc., for an indefinite term.

Keith Woods, our chief operating officer, has an employment contract with our subsidiary, argenx US Inc., for an indefinite term. We may terminate his employment contract at any time, subject to a notice period and a severance payment of at least twelve months.

Karen Massey, our chief operating officer, joined argenx in March 2023 and has an employment contract with our subsidiary, argenx US, Inc..

Prof. Hans de Haard, our chief scientific officer, had an employment contract with our subsidiary, argenx BV, for an indefinite term. The contract was terminated with effect as at December 31, 2022.

Peter Ulrichts, our chief scientific officer, since January 2023, has an employment contract with our subsidiary, argenx BV, for an indefinite term.

Arjen Lemmen, our vice president corporate development and strategy, has an employment contract with our subsidiary, argenx BV, for an indefinite term. We may terminate his employment contract at any time, subject to a notice period and a severance payment of at least twelve months.

Andria Wilk, our global head of quality, has an employment contract with our subsidiary, argenx BV, for an indefinite term.

Malini Moorthy, our general counsel, joined argenx in February 2022 and has an employment contract with our subsidiary, argenx US, for an indefinite term.

Luc Truyen, our head of research and development management operations and, since April 1, 2022, our chief medical officer, has an employment contract with our subsidiary, argenx US, for an indefinite term.

Indemnification Agreements

In connection with our initial U.S. public offering, we entered into indemnification agreements with each of our non-executive directors and each member of our senior management. We have entered into such agreements with each new non-executive director or member of our senior management when they have joined us since our initial U.S. public offering. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to non-executive directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the U.S. Securities Act of 1933, as amended (***Securities Act***) and is therefore unenforceable.

5.11 Employees

As of December 31, 2022, we had 843 employees and 216 consultants, which we refer to as "contingent workers." At each date shown below, we had the following number of employees, broken out by department and geography.

	At December 31,		
	2022	**2021**	**2020**
Function			
Research and development	367	289	193
Selling, general and administrative	476	361	143
Total	**843**	**650**	**336**
Geography			
Belgium	363	296	213
U.S.	340	276	108
Japan	75	57	13
The Netherlands	–	–	–
Switzerland	15	9	2
France	11	3	–
Germany	11	9	–
Canada	5	–	–
Other EU - remote	23	–	–
Total	**843**	**650**	**336**

Collective bargaining agreements (***CBAs***) can be entered into in Belgium at the national, industry, or company levels. These CBAs are binding on both employers and employees. We have no trade union representation or CBAs at the company level, but we are subject to the national and chemical industry CBAs. The CBAs currently applicable to us relate to employment conditions such as wages, working time, job security, innovation and supplementary pensions. We have not had, and do not anticipate having, disputes on any of these subjects. CBAs may, however, change the employment conditions of our employees in the future and hence adversely affect our employment relationships.

5.12 Legal and Arbitration Proceedings

From time to time we may become involved in legal, governmental or arbitration proceedings or be subject to claims arising in the ordinary course of our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors. During the previous twelve months, there have not been any legal, governmental or arbitration proceedings (including any such proceedings which are pending or threatened of which we are aware) which may have, or have had in the recent past, significant effects on argenx and/or the Group's financial position or profitability.

5.13 Insurance

We maintain an insurance portfolio that is common and appropriate for our business. Our main insurances are commercial general liability insurances, including products liability insurance, director and officer liability insurance and our maritime insurance covering the risk of loss of product during transit and storage.

6

Consolidated Financial Statements

Audited consolidated Financial Statements for the Year ended December 31, 2022

Consolidated Statements of Financial Position

Assets		As of December 31,		
(in thousands of $)	Note	2022	2021	2020
Non current assets				
Property, plant and equipment	4	16,234	15,844	11,582
Intangible assets	5	174,901	171,684	167,344
Deferred tax asset	6	79,222	32,191	15,038
Other non-current assets	7	40,894	54,876	7,816
Research and development incentive receivables		47,488	32,707	20,626
Investment in joint venture		1,323	–	–
Total non current assets		**360,064**	**307,303**	**222,406**
Current assets				
Inventories	8	228,353	109,076	25,195
Prepaid expenses		76,022	58,946	27,913
Trade and other receivables	9	275,697	38,221	6,978
Research and development incentive receivables		1,578	–	463
Financial assets	10	1,391,808	1,002,052	779,649
Cash and cash equivalents	11	800,740	1,334,676	1,216,803
Total current assets		**2,774,197**	**2,542,971**	**2,057,001**
Total assets		**3,134,261**	**2,850,274**	**2,279,407**

The accompanying notes form an integral part of these consolidated financial statements.

Equity and liabilities		As of December 31,		
(in thousands of $)	Note	2022	2021	2020
Equity	12			
Equity attributable to owners of the parent				
Share capital		6,640	6,233	5,744
Share premium		4,309,880	3,462,775	2,339,033
Translation differences		129,280	131,684	134,732
Accumulated losses		(2,109,791)	(1,400,197)	(991,932)
Other reserves		477,691	333,729	186,474
Total equity		**2,813,699**	**2,534,224**	**1,674,051**
Non-current liabilities				
Provisions for employee benefits		870	417	156
Lease liabilities	22	9,009	7,956	6,181
Deferred tax liabilities	6	8,406	6,438	1,487
Deferred revenue	16	–	–	269,039
Total non-current liabilities		**18,285**	**14,811**	**276,863**
Current liabilities				
Lease liabilities	22	3,417	3,509	3,476
Trade and other payables	14	295,679	293,415	275,192
Tax liabilities		3,181	4,315	3,497
Deferred revenue	16	–	–	46,328
Total current liabilities		**302,277**	**301,239**	**328,493**
Total liabilities		**320,562**	**316,050**	**605,356**
Total equity and liabilities		**3,134,261**	**2,850,274**	**2,279,407**

The accompanying notes form an integral part of these consolidated financial statements.

Consolidated Statements of Profit or Loss

		Year Ended December 31,		
(in thousands of $ except for shares and EPS)	Note	2022	2021 [1)]	2020 [1)]
Product net sales	15, 18	400,720	–	–
Collaboration revenue	16, 18	10,026	497,277	41,243
Other operating income	17	34,520	42,141	23,668
Total operating income		**445,267**	**539,418**	**64,911**
Cost of sales		(29,431)	–	–
Research and development expenses	19	(663,366)	(580,520)	(370,885)
Selling, general and administrative expenses	20	(472,132)	(307,644)	(171,643)
Loss from investment in joint venture		(677)	–	–
Total operating expenses		**(1,165,607)**	**(888,164)**	**(542,528)**
Operating loss		**(720,341)**	**(348,746)**	**(477,617)**
Financial income	23	27,665	3,633	6,459
Financial expense	23	(3,906)	(4,578)	(7,960)
Exchange losses	23	(32,732)	(50,053)	(126,234)
Loss for the year before taxes		**(729,314)**	**(399,743)**	**(605,352)**
Income tax (expense)/benefit	24	19,720	(8,522)	(3,103)
Loss for the year		**(709,594)**	**(408,265)**	**(608,455)**
Loss for the year attributable to:				
Owners of the parent		(709,594)	(408,265)	(608,455)
Weighted average number of shares outstanding		54,381,371	51,075,827	45,410,442
Basic and diluted loss per share (in $)	25	(13.05)	(7.99)	(13.40)

[1)] The financial income and financial expense for 2021 and 2020 presented in here has been adjusted to present on gross basis.

The accompanying notes form an integral part of these consolidated financial statements.

Consolidated Statements of Comprehensive Income and Loss

		Year Ended December 31,		
(in thousands of $)	Note	2022	2021	2020
Loss for the year		**(709,594)**	**(408,265)**	**(608,455)**
Items that may be reclassified subsequently to profit or loss, net of tax				
Currency translation differences, arisen from translating foreign activities		(2,404)	(3,048)	–
Translation effect		–	–	162,273
Items that will not be reclassified subsequently to profit or loss, net of tax				
Fair value gain/(loss) on investments in equity instruments designated as at FVTOCI	7	(18,267)	(39,290)	–
Other comprehensive loss, net of income tax		**(20,671)**	**(42,338)**	**162,273**
Total comprehensive loss attributable to:				
Owners of the parent		**(730,266)**	**(450,603)**	**(446,182)**

The accompanying notes form an integral part of these consolidated financial statements.

Consolidated Statements of Cash Flows

		Year Ended December 31,		
(in thousands of $)	Note	2022	2021	2020
Operating loss		**(720,341)**	**(348,746)**	**(477,617)**
Adjustments for non-cash items				
Amortization of intangible assets	5	99,766	776	246
Depreciation of property, plant and equipment	4	4,576	5,091	3,671
Provisions for employee benefits		459	260	76
Expense recognized in respect of share-based payments	13	157,026	179,366	96,932
Fair value gains on financial assets at fair value through profit or loss	7	(4,256)	(11,152)	(2,951)
Non-cash revenue	16	–	(75,000)	–
Loss from investment in joint venture		677	–	–
		(462,093)	**(249,405)**	**(379,643)**
Movements in current assets/liabilities				
(Increase)/decrease in trade and other receivables	9	(222,260)	(31,632)	21,961
(Increase)/decrease in inventories	8	(119,277)	(83,880)	(23,852)
(Increase)/decrease in other current assets		(18,294)	(30,990)	(16,189)
Increase/(decrease) in trade and other payables	14	329	134,892	50,537
Increase/(decrease) in deferred revenue – current	16	–	(46,327)	(40,441)
Movements in non-current assets/liabilities				
(Increase)/decrease in other non-current assets	7	(16,220)	(13,975)	(10,299)
Increase/(decrease) in deferred revenue – non-current	16	–	(269,039)	2,655
Net cash flows used in operating activities		**(837,815)**	**(590,356)**	**(395,272)**
Interest paid		(851)	(684)	(401)
Income taxes paid		(24,141)	(15,772)	(2,791)
Net cash flows used in operating activities		**(862,807)**	**(606,812)**	**(398,463)**

		Year Ended December 31,		
(in thousands of $)	Note	2022	2021	2020
Purchase of intangible assets	5	(102,986)	(117,811)	(4,071)
Purchase of property, plant and equipment	4	(837)	(3,623)	(1,068)
(Increase)/decrease in current financial assets	10	–	(228,239)	341,869
Purchase of current financial investments [1)]	10	(1,694,046)	–	–
Sale of current financial investments [1)]	10	1,325,540	–	–
Interest received		13,146	2,603	7,962
Investment in joint venture		(2,000)	–	–
Net cash flows (used in)/from from investing activities		**(461,184)**	**(347,070)**	**344,692**
Principal elements of lease payments	22	(4,165)	(3,855)	(2,550)
Proceeds from issue of new shares, gross amount	12	760,953	1,091,326	813,186
Issue costs paid	12	(781)	(528)	(613)
Exchange gain from currency conversion on proceeds from issue of new shares		410	966	68
Payment of employee withholding taxes relating to restricted stock unit awards		(5,855)	–	–
Proceeds from exercise of stock options	12	93,195	33,433	22,912
Net cash flows from financing activities		**843,757**	**1,121,342**	**833,003**
Net increase/(decrease) in cash and cash equivalents		**(480,234)**	**167,460**	**779,232**
Cash and cash equivalents at the beginning of the period		**1,334,676**	**1,216,803**	**372,162**
Exchange gains/(losses) on cash & cash equivalents		(53,702)	(49,587)	65,409
Cash and cash equivalents at the end of the period		**800,740**	**1,334,676**	**1,216,803**

[1)] Due to the change in the maturity of the current financial assets during current year, the presentation has been changed from net basis to gross basis.

The accompanying notes form an integral part of these consolidated financial statements.

Consolidated Statements of Changes in Equity

Attributable to owners of the parent (in thousands of $)	Share capital	Share premium	Accumulated losses	Translation differences	Share-based payment and income tax deduction on share-based payments	Other comprehensive income	Total equity attributable to owners of the parent	Total equity
Balance at January 1, 2020	**5,209**	**1,505,641**	**(383,477)**	**(27,541)**	**80,577**	**–**	**1,180,409**	**1,180,409**
Loss for the year			(608,455)				(608,455)	**(608,455)**
Other comprehensive income/(loss)				162,273			162,273	**162,273**
Total comprehensive income/(loss) for the year			**(608,455)**	**162,273**			**(446,182)**	**(446,182)**
Income tax benefit from excess tax deductions related to share-based payments					8,965		8,965	**8,965**
Share-based payment					96,932		96,932	**96,932**
Issue of share capital	468	812,718					813,186	**813,186**
Transaction costs for equity issue		(613)					(613)	**(613)**
Exercise of stock options	67	21,287					21,354	**21,354**
Balance year ended December 31, 2020	**5,744**	**2,339,033**	**(991,932)**	**134,732**	**186,474**	**–**	**1,674,051**	**1,674,051**
Loss for the year			(408,265)				(408,265)	**(408,265)**
Other comprehensive income/(loss)				(3,048)		(39,290)	(42,338)	**(42,338)**
Total comprehensive income/(loss) for the year			**(408,265)**	**(3,048)**		**(39,290)**	**(450,603)**	**(450,603)**
Income tax benefit from excess tax deductions related to share-based payments					7,179		7,179	**7,179**
Share-based payment					179,366		179,366	**179,366**
Issue of share capital	430	1,090,896					1,091,326	**1,091,326**
Transaction costs for equity issue		(528)					(528)	**(528)**
Exercise of stock options	59	33,374					33,433	**33,433**
Balance year ended December 31, 2021	**6,233**	**3,462,775**	**(1,400,197)**	**131,684**	**373,019**	**(39,290)**	**2,534,224**	**2,534,224**
Loss for the year			(709,594)				(709,594)	**(709,594)**
Other comprehensive income/(loss)				(2,404)		(18,267)	(20,671)	**(20,671)**
Total comprehensive income/(loss) for the year			**(709,594)**	**(2,404)**		**(18,267)**	**(730,266)**	**(730,266)**
Income tax benefit from excess tax deductions related to share-based payments					3,946		3,946	**3,946**
Share-based payment					158,282		158,282	**158,282**
Issue of share capital	294	760,659					760,953	**760,953**
Transaction costs for equity issue		(781)					(781)	**(781)**
Exercise of stock options	113	93,082					93,195	**93,195**
Ordinary shares withheld for payment of employees' withholding tax liability		(5,855)					(5,855)	**(5,855)**
Balance year ended December 31, 2022	**6,640**	**4,309,880**	**(2,109,791)**	**129,280**	**535,247**	**(57,557)**	**2,813,699**	**2,813,699**

Please refer to **note 12** for more information on the share capital and movement in number of shares. See also **note 13** for more information on the share-based payments.

The accompanying notes form an integral part of these consolidated financial statements.

Notes to the Consolidated Financial Statements

1 General Information about the Company

argenx SE is a Dutch European public company with limited liability incorporated under the laws of the Netherlands. The company (COC 24435214) has its official seat in Rotterdam, the Netherlands, and its registered office is at Laarderhoogtweg 25, 1101 EB Amsterdam, the Netherlands. An overview of the company and its subsidiaries (the Company) are described in **note 31**.

argenx SE is a publicly traded company with ordinary shares listed on Euronext Brussels under the symbol "ARGX" since July 2014 and with American Depositary Shares listed on Nasdaq under the symbol "ARGX" since May 2017.

2 Significant Accounting Policies

The significant Company's accounting policies are summarized below.

2.1 Statement of Compliance and Basis of Preparation

The consolidated financial statements are prepared in accordance with the International Financial Reporting Standards and the interpretations issued by the IASB's International Financial Reporting Interpretation Committee as adopted by the European Union (***EU-IFRS***) and in accordance with the legal requirements of Part 9 of Book 2 of the Dutch Civil Code. The consolidated financial statements provide a general overview of the Company's activities and the results achieved. They provide a true and fair view of the entity's financial position, its financial performance and cash flows, on a going concern basis.

The significant accounting policies applied in the preparation of the above consolidated financial statements are set out below. All amounts are presented in thousands of dollar, unless otherwise indicated, rounded to the nearest $ '000.

The consolidated financial statements have been approved for issue by the Company's Board of Directors (the ***Board***) on March 15, 2023.

2.2 Adoption of New and Revised Standards

New Standards and Interpretations applicable for the Annual Period beginning on January 1, 2022

New standards and interpretations for the annual period beginning on January 1, 2022 did not have any material impact on our consolidated financial statements.

New Standards and Interpretations issued, but not yet applicable for the Annual Period beginning on January 1, 2022

We have not early adopted any other standard, interpretation, or amendment that has been issued but is not yet effective. Of the standards that are not yet effective, we expect no standard to have a material impact on our financial statements in the period of initial application.

2.3 Basis of Consolidation

The consolidated financial statements include the financial statements of the Company and entities controlled by the Company (its subsidiaries). Control is achieved when the Company:

- has power over the investee;
- is exposed, or has rights, to variable returns from its involvement with the investee; and
- has the ability to use its power to affect its returns.

The Company reassesses whether or not it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control listed above.

The results of the subsidiaries are included in the consolidated statements of profit or loss and consolidated statements of other comprehensive income from the effective date of acquisition up to the date when control ceases to exist. When necessary, adjustments are made to the financial statements of subsidiaries to bring their accounting policies into line with those used by other members of the Group.

All intercompany transactions and unrealized gains on transactions between group companies are eliminated. Unrealised losses are also eliminated unless the transaction provides evidence of an impairment of the transferred asset.

2.4 Foreign Currency Transactions

2.4.1 Functional and Presentation Currency

Items included in the consolidated financial statements of each of our entities are valued using the currency of their economic environment in which the entity operates. The consolidated financial statements are presented in USD ($), which is the Company's presentation currency.

2.4.2 Transactions and Balances

Transactions in foreign currencies are translated at the exchange rate ruling at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies are translated at the exchange rate ruling at the reporting date. Foreign exchange differences arising on translation are recognized in the consolidated statements of profit or loss and the consolidated statements of other comprehensive income. Non monetary assets and liabilities denominated in foreign currencies are translated at the foreign exchange rate ruling at the date of the transaction.

2.4.3 Financial Statements of Foreign Entities

For foreign entities using a different functional currency than USD:

- assets and liabilities for each balance sheet presented are translated at the closing rate at the date of the balance sheet.
- income and expenses for each statement presenting profit or loss and statements of other comprehensive income are translated at average exchange rates (unless this average is not a reasonable approximation of the cumulative effect of the rates prevailing on the transaction dates, in which case income and expenses are translated at the rate on the dates of the transactions).
- all resulting exchange differences are recognised in the statements of other comprehensive income.

2.5 Intangible Assets

2.5.1 Internally Generated Intangible Assets

Expenditure on research activities is recognized as an expense in the period in which it is incurred.

An internally generated intangible asset arising from development (or from the development phase of an internal project) is recognized if, and only if, all of the following have been demonstrated:

- the technical feasibility of completing the intangible asset so that it will be available for use or sale;
- the intention to complete the intangible asset and use or sell it;
- the ability to use or sell the intangible asset;
- how the intangible asset will generate probable future economic benefits;
- the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and
- the ability to measure reliably the expenditure attributable to the intangible asset during its development.

The amount initially recognized for internally generated intangible assets is the sum of the expenditure incurred from the date when the intangible asset first meets the recognition criteria listed above. Where no internally generated intangible asset can be recognized, development expenditures are recognized in the consolidated statements of profit or loss and the consolidated statements of other comprehensive income in the period in which they are incurred.

Due to uncertainties inherent to the development and registration with the relevant healthcare authorities of its products, the Company estimates that the conditions for capitalization are not met until the regulatory procedures required by such healthcare authorities have been finalized.

2.5.2 Acquired In-Process R&D, Software and Databases and Other intangible assets

Intangible assets with finite useful lives that are acquired separately related to in-process research and development projects, software and databases and other intangible assets are carried at cost less accumulated amortization and accumulated impairment losses. Intangible assets with indefinite useful lives are carried at cost less accumulated impairment losses.

Payments for acquired in-process research and development projects obtained through in-licensing arrangements are capitalized as intangible assets provided that they are separately identifiable, controlled by the Company and expected to provide future economic benefits. As the probability criterion in IAS 38 is always considered to be satisfied for separately acquired research and development assets and the amount of the payments is determinable, upfront and milestone payments to third parties for pharmaceutical products or compounds for which regulatory marketing approval has not yet been obtained are recognized as intangible assets.

Other intangible assets includes the PRV which the Company can use to obtain the priority review by the FDA for one of its future regulatory submissions or may sell or transfer to a third party. The PRV is initially measured at cost and reviewed for impairment when events or circumstances indicate that the carrying value may not be recoverable.

2.5.3 Amortization of Intangible Assets

Intangible assets, which comprises of acquired in-process research and development, software and databases and other intangible assets, are amortized on a straight-line basis over the estimated useful life as from the time they are available for use, or when the underlying drug candidate is approved, generally on the following basis:

- Acquired In-Process R&D – the longer of the patent protection life and the useful life of the combined product
- Software and Databases: 3 – 5 years

The estimated useful life and amortization method are reviewed at the end of each reporting period, with the effect of any changes in estimate being accounted for on a prospective basis.

During 2022, the Company used the PRV to accelerate the review of drug application of SC efgartigimod for the treatment of generalized mysthania gravis, the intangible asset for $99.1 million was amortized and derecognized upon filing of the related Biologic License Application.

2.5.4 Derecognition of Intangible Assets

An intangible asset is derecognized either on disposal or when no future economic benefits are expected from its use. Gains or losses arising from derecognition of an intangible asset, measured as the difference between the net disposal proceeds, if any, and the carrying amount of the asset, are recognized in the consolidated statements of profit or loss and the consolidated statements of other comprehensive income when the asset is derecognized.

2.6 Property, Plant and Equipment

Items of property, plant and equipment held for use in the production or supply of goods or services, or for administrative purposes, are stated in the consolidated statement of financial position at their cost, less accumulated depreciation and impairment losses.

Depreciation is recognized as from acquisition date onwards (unless asset is not ready for use) so as to write off the cost or valuation of assets (other than freehold land and properties under construction) less their residual values over their useful lives, using the straight line method. The estimated useful lives, residual values and depreciation method are reviewed at the end of each reporting period, with the effect of any changes in estimate accounted for on a prospective basis.

Unless revised due to specific changes in the estimated useful life, annual depreciation rates are as follows:

- Office and lab equipment: 3–5 years
- IT equipment: 3 years

An item of property, plant and equipment is derecognized upon disposal or when no future economic benefits are expected to arise from the continued use of the asset. Any gain or loss arising on the disposal or retirement of an item of property, plant and equipment is determined as the difference between the sales proceeds, if any, and the carrying amount of the asset and is recognized in the consolidated statements of profit or loss and the consolidated statements of other comprehensive income.

2.7 Inventories

Inventories are carried at cost or net realisable value, whichever is lowest. Cost is determined using the first-in, first-out method. Cost comprises of costs of purchase, costs of conversion and other costs incurred in bringing the inventories to their present location and condition.

If the expected sales price less completion costs to execute sales (net realizable value) is lower than the carrying amount, a write-down is recognised for the amount by which the carrying amount exceeds its net realisable value.

Included in inventory are products which could, besides commercial activities, be used in preclinical and clinical programs as well as in non-reimbursed pre-approval access program. These products are charged to research & development expenses or selling, general and administrative expenses, respectively, when dedicated to this channel.

We capitalize inventory costs associated with products prior to the regulatory approval of these products, or for inventory produced in production facilities not yet approved, when it is highly probable that the pre-approval inventories will be saleable. The determination to capitalize is based on the particular facts and circumstances relating to the expected regulatory approval of the product or production facility being considered. The assessment of whether or not the product is considered highly probable to be saleable is made on a quarterly basis and includes, but is not limited to, how far a particular product or facility has progressed along the approval process, any known safety or efficacy concern, potential labelling restrictions and other impediments.

Previously capitalized costs related to pre-launch inventories could be required to be written down upon a change in such judgement or due to a denial or delay of approval by regulatory bodies, a delay in commercialization or other potential factors, which will be recorded to research and development expenses in the consolidated statements of profit or loss and the consolidated statements of other comprehensive income.

2.8 Leases

The Company assesses whether a contract is or contains a lease, at inception of the contract. The Company recognises a right-of-use asset and a corresponding lease liability with respect to all lease arrangements in which it is the lessee, except for short-term leases (defined as leases with a lease term of 12 months or less) and leases of low value assets. For these leases, the Company recognises the lease payments as an operating expense on a straight-line basis over the term of the lease unless another systematic basis is more representative of the time pattern in which economic benefits from the leased assets are consumed.

The lease liability is initially measured at the present value of the lease payments that are not paid at the commencement date, discounted by using the rate implicit in the lease. If this rate cannot be readily determined, the lessee uses its incremental borrowing rate. The lease liability is subsequently measured by increasing the carrying amount to reflect interest on the lease liability (using the effective interest method) and by reducing the carrying amount to reflect the lease payments made. The lease liability is presented as a separate line in the consolidated statements of financial position.

The right-of-use assets comprise the initial measurement of the corresponding lease liability, lease payments made at or before the commencement day, less any lease incentives received and any initial direct costs. They are subsequently measured at cost less accumulated depreciation and impairment losses. Right-of-use assets are depreciated over the shorter period of lease term and useful life of the underlying asset. If a lease transfers ownership of the underlying asset or the cost of the right-of-use asset reflects that the Company expects to exercise a purchase option, the related right-of-use asset is depreciated over the useful life of the underlying asset. The right-of-use assets are presented in the consolidated statements of financial position under the caption "**Property, Plant and Equipment**".

2.9 Impairment of Assets

2.9.1 Financial Assets

The impairment loss of a financial asset measured at amortised cost is calculated based on the expected loss model.

For trade receivables, in the absence of a significant financing component, the allowance is measured at an amount equal to lifetime expected credit losses. Those are the expected credit losses that result from possible default events over the expected life of those trade receivables.

2.9.2 Property, Plant and Equipment and Intangible Assets

At the end of each reporting period, the Company reviews the carrying amounts of its tangible and intangible assets to determine whether there is any indication that those assets have suffered an impairment loss. If any such indication exists, the recoverable amount of the asset is estimated in order to determine the extent of the impairment loss, if any. Where it is not possible to estimate the recoverable amount of an individual asset, the Company estimates the recoverable amount of the cash generating unit to which the asset belongs.

Intangible assets with indefinite useful lives and intangible assets not yet available for use are tested for impairment at least annually, and whenever there is an indication that the asset may be impaired.

If the recoverable amount of an asset or cash generating unit is estimated to be less than its carrying amount, the carrying amount of the asset or cash generating unit is reduced to its recoverable amount. An impairment loss is recognized immediately in the consolidated statements of profit or loss and the consolidated statements of other comprehensive income.

Where an impairment loss subsequently reverses, the carrying amount of the asset is increased to the revised estimate of its recoverable amount, but so that the increased carrying amount does not exceed the carrying amount that would have been determined had no impairment loss been recognized for the asset or cash generating unit in prior years. A reversal of an impairment loss is recognized immediately in the consolidated statements of profit or loss and the consolidated statements of other comprehensive income.

2.10 Financial Instruments

Financial assets and financial liabilities are recognized in the consolidated statements of financial position when the Company becomes party to the contractual provisions of the instrument. The Company does not use currency derivatives to hedge planned future cash flows, nor does it make use of forward foreign exchange contracts. Additionally, the Company does not have financial debt at December 31, 2022.

2.10.1 Financial Assets

Financial assets are initially recognized either at fair value or at transaction price. All recognized financial assets are subsequently measured at either amortized cost or fair value under EU-IFRS 9 on the basis of both the Company's model for managing the financial assets and the contractual cash flow characteristics of the financial asset.

- A financial asset that (i) is held within a business model whose objective is to collect the contractual cash flows and (ii) has contractual cash flows that are solely payments of principal and interest on the principal amount outstanding is measured at amortized cost (net of any write down for impairment), unless the asset is designated at fair value through profit or loss (***FVTPL***) under the fair value option.

- A financial asset that (i) is held within a business model whose objective is achieved both by collecting contractual cash flows and selling financial assets and (ii) has contractual term that give rise on specified dates to cash flows that are solely payments of principal and interest on the principal outstanding, is measured at fair value through other comprehensive income (***FVTOCI***), unless the asset is designated at FVTPL under the fair value option.

- All other financial assets are measured at FVTPL.

A financial asset is classified as current when the cash flows expected to flow from the instrument mature within one year.

The Company derecognizes a financial asset when the contractual rights to the cash flows from the asset expire, or the Company transfers the right to receive the contractual cash flows on the financial asset in a transaction in which substantially all the risks and rewards of ownership of the financial asset are transferred.

The Company classifies non-derivative financial assets into the following categories:
- financial asset at fair value through profit or loss or OCI (non-current financial assets, current financial assets and cash equivalents)
- financial assets at amortized cost (receivables and cash and cash equivalents)

Financial Assets at fair value through profit or loss or loss or OCI

Financial assets are designated at fair value through profit or loss if the Company manages such investments and makes purchases and sales decisions based on their fair value in accordance with the Company's investment strategy. Attributable transaction costs are recognised in the consolidated statements of profit or loss and the consolidated statements of other comprehensive income as incurred. Financial assets at fair value through profit or loss are measured at fair value, and changes therein, which take into account any dividend income, are recognized in the consolidated statements of profit or loss and the consolidated statements of other comprehensive income.

2.10.1.1 Non-Current Financial Assets at fair value through profit or loss or OCI

The Company holds investments in non-current financial assets, which based on EU-IFRS 9, are designated as financial assets at fair value through profit or loss or financial assets

at fair value through OCI. The fair value of listed investments is based upon the closing price of such securities at each reporting date. If there is no active market for an equity instrument, the Company establishes the fair value by using valuation techniques.

Based on EU-IFRS 9, the Company irrevocably elected to designate specific investments as a financial asset at fair value through OCI as the participation is not held for trading purposes nor contingent consideration recognised by an acquirer in a business combination.

2.10.1.2 Current Financial Assets at fair value through profit or loss

Current financial assets measured at fair value through profit or loss comprise of money market funds.

2.10.1.3 Cash Equivalents Measured at fair value through profit or loss

Cash equivalents measured at fair value through profit or loss comprise of money market funds that are readily convertible to cash and are subject to insignificant risk of changes in value. These financial assets are used by the Company in the management of the short-term commitments.

Financial Assets at Amortized Cost

2.10.1.4 Receivables

Trade and other receivables are designated as financial assets measured at amortized cost. They are initially measured either at fair value or at transaction price, in the absence of a significant financing component less adjustments for estimated revenue deductions such as rebates, chargebacks and returns.

All receivables are subsequently measured at amortized cost, which generally corresponds to nominal value less expected credit loss provision.

Receivables mainly comprise trade and other receivables and current and non-current research and development incentive receivables. These research and development incentive receivables relate to refunds resulting from research and development incentives on research and development expenses in Belgium and are credited to the consolidated statements of profit or loss and the consolidated statements of other comprehensive income under the line “Other operating income” when the relevant expenditure has been incurred and there is a reasonable assurance that the research and development incentives are receivable.

Loss allowance for expected credit losses are established using a simplified approach of forward-looking expected credit loss model (ECL), which includes possible default events on the trade receivables over the entire holding period of the trade receivable. These provisions represent the difference between the trade receivable’s carrying amount in the consolidated statements of financial position and the estimated collectible amount. Charges for loss allowance for expected credit losses are recorded as marketing and selling costs recognized in the consolidated statements of profit or loss and consolidated statements of other comprehensive income within “Selling, general and administrative” expenses.

2.10.1.5 Cash

Cash are financial assets measured at amortized cost and comprise of cash balances and savings accounts.

2.10.1.6 Cash Equivalents Measured at Amortized Costs

Cash equivalents measured at amortized cost comprise of term accounts that have an initial maturity of less than 3 months that are subject to an insignificant risk of changes in values. The financial assets are used by the Company in the management of short-term commitments.

Cash and cash equivalents exclude restricted cash, which is presented in the consolidated statements of financial position under the line "Other non-current assets".

2.10.1.7 Current Financial Assets Measured at Amortized Costs

Current financial assets include financial assets measured at amortized costs and comprise of term accounts that have an initial maturity equal or less than 12 months, but exceeding 3 months.

2.10.2 Financial Liabilities

Financial liabilities are initially measured at their transaction price. Subsequent to initial recognition, financial liabilities are measured at amortized cost.

Financial liabilities mainly comprise of trade and other payables and other liabilities.

Trade and other liabilities are comprised of liabilities that are due less than one year from the balance sheet date and are in general not interest bearing and settled on an ongoing basis during the financial year. They also include accrued expense related to the Company's research and development costs and gross-to-net accruals.

2.11 Investment in Joint Venture

The Group has an investment which qualifies as joint ventures under IAS 28 Investment in associates and joint ventures. For joint ventures and associates, the Group recognises its interest in the joint venture or associate as an investment and uses the equity method of accounting. The Group recognises its initial investment at cost and the investors' share of the profits or losses is determined based on the proportionate ownership interest.

Investment in joint ventures on December 31, 2022 was related to the investment in Onco Verity, Inc. In July 2022, the Company entered into a joint venture agreement with the University of Colorado Anschutz Medical Campus and UCHealth and created a separate legal entity, OncoVerity, Inc., which is focused on optimizing and advancing the development of cusatuzumab, a novel anti-CD70 antibody, in acute myeloid leukemia (AML). The Company contributed $2 million and the investment has been designated as investment in joint venture and accounted under IAS 28 Investment in associates and joint ventures. The share of net loss resulting from investment in joint ventures is presented in consolidated statements of profit or loss in line "*Loss from investment in joint ventures*".

2.12 Shareholder's Equity

An equity instrument is any contract that evidences a residual interest in the assets of an entity after deducting all of its liabilities. Equity instruments issued by the Company are recognized at the proceeds received, net of direct issue costs.

The Company has never distributed any dividends to its shareholders. As of December 31, 2022, no profits were available for distribution.

2.13 Short-Term Employee Benefits

Short-term employee benefits include payables and accruals for salaries and bonuses to be paid to the employees of the Company. They are recognized as expenses for the period in which employees perform the corresponding services.

2.14 Share-Based Payments

Equity settled share based payments to employees and others providing similar services are measured at the fair value of the equity instruments at the acceptance date. Equity settled share based payments includes expenses related to stock options and restricted stock units granted by the Company.

The fair value determined at the acceptance date of the equity settled share based payments is expensed on a straight line basis over the vesting period, based on the Company's estimate of equity instruments that will eventually vest, with a corresponding increase in equity. At the end of each reporting period, the Company revises its estimate of the number of equity instruments expected to vest. The impact of the revision of the original estimates, if any, is recognized in the consolidated statements of profit or loss and the consolidated statements of other comprehensive income such that the cumulative expense reflects the revised estimate, with a corresponding adjustment to the equity settled share based payment reserve.

2.15 Deferred Revenue

Current and non-current deferred revenue relates to cash received from collaboration & license agreements prior to completion of the earnings process. These payments are recognized as revenue over the estimated duration of the Company's involvement in the research and development programs provided for under the terms of the agreements.

2.16 Income Taxes

Income tax in the consolidated statements of profit or loss and the consolidated statements of other comprehensive income represents the total of the current tax and deferred tax.

The current tax is based on taxable profit for the year. Taxable profit differs from profit as reported in the consolidated statements of profit or loss and consolidated statements of other comprehensive income as it excludes items of income or expense that are taxable or deductible in other years and items that are never taxable or deductible. The Company's liability for current tax is calculated using tax rates that have been enacted or substantively enacted by the end of the reporting period.

Deferred tax is recognized on temporary differences between the carrying amounts of assets and liabilities in the consolidated financial statements and the corresponding tax basis used in the computation of taxable profit. Deferred tax assets are recognized to the extent that it is probable that future taxable profits will be available against which those deductible temporary differences can be utilized. The carrying amount of deferred tax assets is reviewed at the end of each reporting period and reduced to the extent that it is not probable that sufficient taxable profits will be available to allow all or part of the asset to be recovered. Deferred tax assets and liabilities are offset if there is a legally enforceable right to offset current tax liabilities and assets, and they relate to income taxes levied by the same tax authority on the same taxable entity, or on different taxable entities which intend either to settle current tax liabilities and assets on a net basis, or to realize the assets and settle the liabilities simultaneously.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply in the period in which the liability is settled or the asset realized, based on tax rates (and tax laws) that have been enacted or substantially enacted by the end of the reporting period.

2.17 Revenue and Other Operating Income Recognition

2.17.1 Product Net Sales

Revenue from the sale of goods is recognized at an amount that reflects the consideration that the Company expects to be entitled to receive in exchange for transferring goods to a customer, at the time when the customer obtains control of the goods rendered, this means when the customer has the ability to direct the use of the asset. The consideration that is committed in a contract with a customer can include fixed amounts, variable amounts, or both. The amount of the consideration may vary due to discounts, rebates, returns, chargebacks or other similar items. Contingent consideration is included in the transaction price when it is highly probable that the amount of revenue recognized is not subject to future significant reversals.

Our product net sales consists of sales of VYVGART in U.S., Japan and Europe. Product net sales are recognized once we satisfy the performance obligation at a point in time under the revenue recognition criteria in accordance with EU-IFRS 15 *Revenue from contracts with customers*.

Revenue arising from the commercial sale of VYVGART is presented in the consolidated statements of profit or loss under "Product net sales". In accordance with EU-IFRS 15 *Revenue from contracts with customers*, such revenue is recognized when the product

is physically transferred, in accordance with the delivery and acceptance terms agreed with the customer. Payment of the transaction price is payable at the point the customer obtains the legal title to the goods.

The amount of revenue recognized reflects the various types of price reductions or rights of return offered by the Company to its customers. Such price reductions and rights of return qualify as variable consideration under EU-IFRS 15 *Revenue from contracts with customers*.

Products sold are covered by various Government and State programs (such as Medicare and Medicaid) under which products are sold at a discount. Rebates are granted to healthcare authorities, and under contractual arrangements with certain customers. Some wholesalers are entitled to chargeback incentives based on the selling price to the end customer, under specific contractual arrangements. Rebates, chargebacks and other incentives are recognized in the period in which the underlying sales are recognized as a reduction of product sales.

Our significant components of variable consideration are as follows:

Co-payment assistance: We provide co-payment assistance to patients who have commercial insurance and meet certain eligibility requirements. We use the expected-value method for estimating co-payment assistance based on estimates of program redemption using data provided by third-party administrators. Estimates for the co-payment assistance are adjusted quarterly to reflect actual experience. We record an accrued liability for unredeemed co-payment assistance related to products for which control has been transferred to customers.

Chargebacks: Chargebacks are discounts that occur when contracted parties purchase directly from a specialty distributor. Contracted parties, which currently consist primarily of Public Health Service Institutions and federal government entities purchasing via the Federal Supply Schedule, generally purchase the product at a discounted price. The specialty distributor, in turn, charges back the difference between the price initially paid by the specialty distributor and the discounted price paid to the specialty distributor by the contracted parties to the Company. The reserves for chargeback are based on known sales to contracted parties. We establish the reserves for chargebacks in the same period that the related revenue is recognized, resulting in an accrued liability and reduction of product gross sales.

Rebates: We are subject to government mandated rebates for Medicaid Drug Rebate Program, Medicare Part D Prescription Drug Benefit Program, and other government health care programs in the U.S. Rebate amounts are based upon contractual agreements or legal requirements with public sector benefit providers. We use the expected-value method for estimating these rebates. The expected utilization of rebates is estimated based on third-party data from the specialty pharmacies and specialty distributor. Estimates for these rebates are adjusted quarterly to reflect the most recent information. We record an accrued liability and reduction of product sales for unpaid rebates related to products for which control has been transferred to customers.

Medicare Part D Coverage Gap: The Medicare Part D coverage gap is a federal program to subsidize the costs of prescription drugs for Medicare beneficiaries in the U.S.,

which mandates manufacturers to fund a portion of the Medicare Part D insurance coverage gap for prescription drugs sold to eligible patients. Funding of the coverage gap is generally invoiced and paid in arrears. We estimate the impact of the Medicare Part D coverage gap using the expected-value method based on an amount expected to be incurred for the current quarter's activity, plus an accrual balance for known prior quarters. Estimates for the impact of the Medicare Part D coverage gap are adjusted quarterly to reflect actual experience. We record an accrued liability for unpaid reserves related to the Medicare Part D coverage gap.

Distributor fees: The specialty distributor provides distribution services to the Company for a fee, based on a contractually determined fixed percentage of sales. As the services being provided by the specialty distributor are not distinct, the recurring service fees paid to specialty distributors are treated as variable consideration and a reduction to the transaction price. We estimate these distributor fees and record such estimates in the same period the related revenue is recognized, resulting in a reduction of product gross sales. We record an accrued liability for unpaid distributor fees.

The estimated amounts described above are recognized in the consolidated statement of Profit or Loss within "Product net sales" as a reduction of gross sales, and within "Trade and other payables" in the consolidated statements of financial position. They are subject to regular review and adjustment as appropriate based on the most recent data available to management. Each of the above items require significant estimates, judgement and information obtained from external sources. If management's estimates differ from actual results, we will record adjustments that would affect product sales in the period of adjustment.

2.17.2 Collaborations and License Agreements

Collaboration revenue have consisted principally of milestones, license fees, non-refundable upfront fees and research and development service fees in connection with collaboration and license agreements.

The Company recognizes revenue when the customer obtains control of promised goods or services, in an amount that reflects the consideration that the Company expects to receive in exchange for those goods and services. In order to determine revenue recognition for agreements that the Company determines to be in the scope of IFRS 15, following five steps are performed:

1. Identify the Contracts

In our current collaboration and license agreements, we are mainly licensing our intellectual property and/or providing research and development products/services, which might include a cost-sharing mechanism and/or in the future, selling its products to collaborative partner entities. Revenue is generated through these arrangements via upfront payments, milestone payments based on clinical and regulatory criteria, research and development service fees and future sales-based milestones and sales-based royalties. In some cases, the collaboration and license agreements also include an equity subscription component. If this is the case, the Company analyses if the criteria to combine contracts, as set out by IFRS 15, are met.

2. Identify Performance Obligations

Depending on the type of contract, there can be one or more distinct performance obligations under IFRS 15. This is based on an assessment of whether the promises in an agreement are capable of being distinct and are distinct from the other promises to transfer goods and/or services in the context of the contract.

For our material ongoing collaboration and license agreement (i.e. the Zai Lab Agreement), the Company has assessed that there is more than one distinct performance obligation, being the transfer of a license and supply of clinical and commercial product.

This is because the Company considers the performance obligations is distinct in the context of the contract as the license has stand-alone value without the Company being further involved in the research and development collaboration and that there is no interdependence between the license and the clinical and commercial supply to be provided.

For our material ongoing collaboration and license agreement (i.e., the Zai Lab Agreement), the Company has assessed that there is more than one distinct performance obligation, being the transfer of a license and supply of clinical and commercial product.

3. Determine the Transaction Price

Our material ongoing collaboration and license agreements include non-refundable upfront payments or license fees, milestone payments, the receipt of which is dependent upon the achievement of certain clinical, regulatory or commercial milestones, royalties on sales and research and development service fees.

3.1 Non-refundable Upfront Payments or License Fees

If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable upfront fees allocated to this license at the point in time the license is transferred to the customer and the customer has the right to use the license.

For all our material ongoing collaboration and license agreements, the Company considers the performance obligations related to the transfer of the license as distinct from the other promises to transfer goods and/or services. The Company utilizes judgement to assess the nature of the performance obligation to determine whether the performance obligation is satisfied over time or at a point in time. If over time, revenue is then recognized based on a pattern that best reflects the transfer of control of the service to the customer.

3.2 Milestone Payments Other than Sales Based Milestones

A milestone payment, being a variable consideration, is only included in the transaction price to the extent it is highly probable that a significant reversal in the amount of cumulative revenue recognition will not occur when the uncertainty associated with the variable consideration is subsequently resolved. The Company estimates the amount to be included in the transaction price upon achievement of the milestone event. The transaction price is then allocated to each performance obligation on a stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each reporting period,

the Company re-evaluates the probability of achievement of such milestones and any related constraint, and, if necessary, adjusts the estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue and earnings in the period of adjustment.

3.3 Research and Development Service Fees

Our material ongoing collaboration and license agreements may include reimbursement or cost sharing for research and development services. R&D services are performed and satisfied over time given that the customer simultaneously receives and consumes the benefits provided by us. Such costs reimbursements received are recognized in revenues when costs are incurred and agreed by the parties.

3.4 Sales-Based Milestone Payments and Royalties

Our material ongoing collaboration and license agreements include sales based royalties, including commercial milestone payments based on the level of sales, and the license has been deemed to be the predominant item to which the royalties and commercial milestone payments relate. Related revenue is recognized as the subsequent underlying sales occur.

4. Allocate the Transaction Price

In principle, an entity shall allocate the transaction price to each performance obligation identified in the contract on a relative stand-alone selling price basis. As our ongoing collaboration and license agreement (i.e. the Zai Lab Agreement) contains more than one performance obligation, the Company assesses to allocate the transaction price to all performance obligations identified.

5. Recognize Revenue

Revenue is recognized when the customer obtains control of the goods and/or services as provided in the collaboration and license agreements. The control can be transferred over time or at a point in time – which results in the recognition of revenue over time or at a point in time.

As our ongoing collaboration and license agreement (i.e. the Zai Lab Agreement) contains more than one performance obligation, the Company recognised revenue at point in time for transfer of license and the Company recognises revenue over time for supply of clinical and commercial products as the customer simultaneously receive the benefits provided by the Company's performance, satisfied over time.

Other ongoing collaboration and license agreements only contain one single performance obligation which is, as the customer simultaneously receive the benefits provided by the Company's performance, satisfied over time. As such, the Company recognizes revenue over time. The recognition of revenue over time is based on a pattern that best reflects the satisfaction of the related performance obligation, applying the input method. The input method estimates the satisfaction of the performance obligation as the percentage of total collaboration costs that are completed each period compared to the total estimated collaboration costs.

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

2.17.3 Grants, Research and Development Incentives, Payroll Tax Rebates and Changes in Fair Value on Non-Current Financial Assets

Because it carries out extensive research and development activities, the Company benefits from various grants, research and development incentives and payroll tax rebates from certain governmental agencies. These grants, research and development incentives and payroll tax rebates generally aim to partly reimburse approved expenditures incurred in research and development efforts of the Company and are credited to the consolidated statements of profit or loss, under the line "Other operating income", when the relevant expenditure has been incurred and there is reasonable assurance that the grants or research and development incentives are receivable. Fair value gains resulting from the change in the fair value of non-current financial assets are credited to the consolidated statements of profit or loss, under the line "Other operating income".

2.18 Cost of Sales

Cost of sales are related to the sale of VYVGART and are recognised when the associated revenue is recognised. Cost of sales include material, manufacturing costs and other costs attributable to production, including shipping costs, as well as royalties payable on sales of VYVGART.

2.19 Trade Receivables

Trade receivables are initially recognized at their invoiced amounts less adjustments for estimated revenue deductions such as rebates, chargebacks and returns.

Loss allowance for expected credit losses are established using a simplified approach of forward-looking expected credit loss model (ECL), which includes possible default events on the trade receivables over the entire holding period of the trade receivable. These provisions represent the difference between the trade receivable's carrying amount in the consolidated statements of financial position and the estimated collectible amount. Charges for loss allowance for expected credit losses are recorded as marketing and selling costs recognized in the consolidated statements of profit or loss and the consolidated statements of other comprehensive income within "Selling, general and administrative" expenses.

2.20 Segment Reporting

Segment results include revenue and expenses directly attributable to a segment and the relevant portion of revenue and expenses that can be allocated on a reasonable basis to a segment. Segment assets and liabilities comprise those operating assets and liabilities that are directly attributable to the segment or can be allocated to the segment on a reasonable basis. Segment assets and liabilities do not include income tax items.

The Company manages its activities and operates as one business unit which is reflected in its organizational structure and internal reporting. The Company does not distinguish in its internal reporting different segments, neither business nor geographical segments. The chief operating decision maker is the Board of Directors.

3 Critical Accounting Estimates and Judgments

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

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

Critical Estimates in Applying Accounting Policies

Gross to Net Adjustments

Our product gross sales are subject to various deductions, which are primarily composed of rebates to government agencies, distributors, health insurance companies and managed healthcare organizations. These deductions represent estimates of the related obligations, requiring the use of judgment when estimating the effect of these sales deductions on product gross sales for a reporting period. These adjustments are deducted from product gross sales to arrive at product net sales. The significant components of variable consideration under revenue recognition policy summarizes the nature of these deductions and how the deduction is estimated. After recording these, product net sales represent our best estimate of the cash that we expect to ultimately collect.

4 Property, Plant and Equipment

(in thousands of $)	IT, office and lab equipment	Right-of-use assets Buildings	Right-of-use assets Vehicles	Leasehold improve-ments	Lease equipment	Total
Cost						
On January 1, 2020	**3,906**	**7,741**	**1,098**	**908**	**317**	**13,970**
Additions	733	3,335	1,074	432	–	5,574
Disposals	(110)	–	–	–	–	(110)
Translation differences	360	645	101	84	29	1,219
On December 31, 2020	**4,889**	**11,721**	**2,273**	**1,424**	**346**	**20,653**
Additions	3,163	4,923	802	543	–	9,430
Disposals	(217)	–	–	–	–	(217)
Currency translation adjustment	104	(182)	–	14	–	(64)
On December 31, 2021	**7,938**	**16,462**	**3,075**	**1,981**	**346**	**29,802**
Additions	962	3,353	905	–	–	5,219
Disposals	(105)	–	–	–	–	(105)
Currency translation adjustment	(635)	–	–	–	–	(635)
On December 31, 2022	**8,160**	**19,815**	**3,980**	**1,981**	**346**	**34,282**
Depreciation and impairment						
On January 1, 2020	**(2,909)**	**(1,477)**	**(262)**	**(103)**	**(44)**	**(4,795)**
Depreciation	(535)	(2,262)	(441)	(401)	(32)	(3,671)
Disposals	103	–	–	–	–	103
Translation differences	(301)	(305)	(57)	(39)	(6)	(708)
On December 31, 2020	**(3,642)**	**(4,044)**	**(760)**	**(543)**	**(82)**	**(9,071)**
Depreciation	(1,118)	(2,714)	(651)	(539)	(34)	(5,055)
Disposals	158	–	–	–	–	158
Currency translation adjustment	37	(15)	–	(11)	–	10

(in thousands of $)	IT, office and lab equipment	Right-of-use assets Buildings	Right-of-use assets Vehicles	Leasehold improve-ments	Lease equipment	Total
On December 31, 2021	**(4,565)**	**(6,774)**	**(1,411)**	**(1,093)**	**(116)**	**(13,958)**
Depreciation	(1,388)	(2,179)	(735)	(257)	(35)	(4,593)
Disposals	90	–	–	–	–	90
Currency translation adjustment	408	5	1	1	–	414
On December 31, 2022	**(5,454)**	**(8,948)**	**(2,145)**	**(1,350)**	**(150)**	**(18,047)**
Carrying Amount						
On December 31, 2020	1,247	7,677	1,513	881	264	11,582
On December 31, 2021	3,373	9,688	1,664	888	230	15,844
On December 31, 2022	2,706	10,867	1,835	631	196	16,234

As of December 31, 2022, there are no material commitments to acquire property, plant and equipment, except as set forth in **note 29**. Furthermore, no items of property, plant and equipment are pledged. See **note 22** for information for leases where the Company is a lessee.

5 Intangible Assets

(in thousands of $)	Acquired In-Process R&D	Software & databases	Other Intangibles	Total
Cost				
On January 1, 2020	**44,802**	**473**	**–**	**45,275**
Additions	16,182	2,814	98,000	116,996
Translation differences	4,196	256	1,058	5,510
On December 31, 2020	**65,180**	**3,543**	**99,058**	**167,781**
Additions	5,000	–	–	5,000
Disposals	–	(190)	–	(190)
On December 31, 2021	**70,180**	**3,353**	**99,058**	**172,591**
Additions	992	–	102,000	102,992
Disposals	–	(5)	–	(5)
Derecognition	–	–	(99,058)	(99,058)
On December 31, 2022	**71,171**	**3,348**	**102,000**	**176,519**
Amortization and impairment				
On January 1, 2020	**–**	**(158)**	**–**	**(158)**
Amortization	–	(246)	–	(246)
Translation differences	–	(33)	–	(33)
On December 31, 2020	**–**	**(437)**	**–**	**(437)**
Amortization	–	(470)	–	(470)
On December 31, 2021	**–**	**(907)**	**–**	**(907)**
Amortization	–	(711)	(99,058)	(99,768)
Derecognition	–	–	99,058	99,058
On December 31, 2022	**–**	**(1,618)**	**–**	**(1,618)**
Carrying Amount				
On December 31, 2020	65,180	3,106	99,058	167,344
On December 31, 2021	70,180	2,446	99,058	171,684
On December 31, 2022	71,171	1,730	102,000	174,901

The Company performed an annual impairment review on the intangible assets not yet available for use. This review did not result in the recognition of an impairment charge.

During the third quarter of 2022, the Company utilized the PRV submitted with the BLA filing for SC efgartigimod for the treatment of gMG, which resulted in amortization of $99.1 million of research and development expenses within the consolidated statements

of profit or loss and subsequent derecognition of $99.1 million of intangibles included in other intangibles on the consolidated statements of financial position.

In December 2022, we acquired a PRV for $102 million.

As of December 31, 2022, there are no material commitments to acquire additional intangible assets, except as set forth in **note 29**. No intangible assets are pledged as security for liabilities nor are there any intangible assets whose title is restricted.

6 Deferred Taxes

The available deferred tax assets relates to argenx US, Inc. and argenx Japan KK which are profitable due to the global transfer pricing model of argenx, and the deferred tax liabilities are related to argenx BV. The amount of deferred tax assets and liability by type of temporary difference can be detailed as follow:

	At December 31, 2022		
(in thousands of $)	**Assets**	**Liabilities**	**Net**
Deferred tax assets/(liabilities)			
Accruals and allowances	8,884	–	8,884
Income tax benefit from excess tax deductions related to share-based payments	26,887	–	26,887
Profit in inventory	29,711	–	29,711
R&D capitalized expense	11,316	–	–
Property, plant and equipment	2,569	(549)	2,020
Intangible assets	–	(3,430)	(3,430)
Non-current fixed assets	–	(4,975)	(4,975)
Other	404	–	404
Netting by taxable entity	(549)	549	–
Net deferred tax assets/(liabilities)	**79,222**	**(8,406)**	**70,817**

	At December 31, 2021		
(in thousands of $)	**Assets**	**Liabilities**	**Net**
Deferred tax assets/(liabilities)			
Accruals and allowances	2,858	–	2,858
Income tax benefit from excess tax deductions related to share-based payments	26,026	–	26,026
Profit in inventory	3,305	–	3,305
Property, plant and equipment	532	(740)	(208)
Intangible assets	–	(2,714)	(2,714)
Non-current fixed assets	–	(3,725)	(3,725)
Other	210	–	210
Netting by taxable entity	(740)	740	–
Net deferred tax assets/(liabilities)	**32,191**	**(6,438)**	**25,753**

	At December 31, 2020		
(in thousands of $)	**Assets**	**Liabilities**	**Net**
Deferred tax assets/(liabilities)			
Accruals and allowances	2,147	–	2,147
Income tax benefit from excess tax deductions related to share-based payments	13,362	–	13,362
Property, plant and equipment	–	(167)	(167)
Intangible assets	–	(1,792)	(1,792)
Other	–	–	–
Netting by taxable entity	(471)	471	–
Net deferred tax assets/(liabilities)	**15,038**	**(1,487)**	**13,551**

The change in net deferred taxes recorded in the consolidated statements of financial position can be detailed as follows:

(in thousands of $)	**Deferred tax assets**	**Deferred tax liabilities**
Balance at January 1, 2022	**32,191**	**(6,438)**
Recognized in profit or loss	49,075	(2,180)
Recognized in equity	(1,960)	–
Effects of change in foreign exchange rate	(84)	212
Balance at December 31, 2022	**79,222**	**(8,406)**

(in thousands of $)	Deferred tax assets	Deferred tax liabilities
Balance at January 1, 2021	**15,038**	**(1,487)**
Recognized in profit or loss	11,385	(5,082)
Recognized in equity	5,494	–
Effects of change in foreign exchange rate	274	131
Balance at December 31, 2021	**32,191**	**(6,438)**

(in thousands of $)	Deferred tax assets	Deferred tax liabilities
Balance at January 1, 2020	**–**	**–**
Recognized in profit or loss	8,351	(1,384)
Recognized in equity	6,225	–
Effects of change in foreign exchange rate	462	(103)
Balance at December 31, 2020	**15,038**	**(1,487)**

7 Other Non-Current Assets

Other non-current assets consisted of non-current restricted cash and financial assets held at fair value through profit or loss or through OCI.

	At December 31,		
(in thousands of $)	**2022**	**2021**	**2020**
Non-current restricted cash	1,736	1,707	1,509
Non-current financial assets held at fair value through profit or loss	21,715	17,459	6,307
Non-current financial assets held at fair value through OCI	17,443	35,710	–
Total other non-current assets	**40,894**	**54,876**	**7,816**

Non-current restricted cash on December 31, 2022 was mainly composed of deposit guarantees paid under the lease agreements for the laboratory and offices of the Company.

Non-current financial assets held at fair value through profit or loss is comprised of the profit share in AgomAb Therapeutics NV. In March 2019, the Company entered into a license agreement with AgomAb Therapeutics NV for the use of HGF-mimetic SIMPLE Antibodies™, developed under the Company's Immunology Innovative Program. In exchange for granting this license, the Company received a profit share in AgomAb Therapeutics NV. Since AgomAb Therapeutics NV is a private company, the valuation of the profit share is based on level 3 assumptions.

In June 2022, AgomAb Therapeutics NV secured €38.4 million as a result of the extension of Series B. The Company used the post-money valuation of this Series B financing round and the number of outstanding shares in determining the fair value of the profit-sharing instrument, which results in a change in fair value of non-current financial assets of $4.3 million recorded through profit or loss.

Fair value changes on non-current financial assets with fair value through profit or loss are recognized in the consolidated statements of profit or loss in line "Other operating income".

As part of the license agreement for the development and commercialization for efgartigimod in Greater China, the Company obtained, amongst others, 568,182 newly issued Zai Lab shares calculated at a price of $132 per share. The fair value of the equity instrument at reporting date is determined by reference to the closing price of such securities at each reporting date (classified as level 1 in the fair value hierarchy), resulting in a change in fair value. The Company made the irrevocable election to recognize subsequent changes in fair value through OCI in line "Fair value gain/(loss) on investments in equity instruments designated as at FVTOCI".

The table below illustrates these non-current financials assets at fair value through profit or loss or OCI as of December 31, 2022, 2021 and 2020.

	At December 31,		
(in thousands of $)	**2022**	**2021**	**2020**
Cost at January 1	**76,659**	**1,659**	**1,659**
Additions of the year	–	75,000	–
Cost at December 31	**76,659**	**76,659**	**1,659**
Fair value adjustments at January 1	**(23,490)**	**4,648**	**1,257**
Fair value adjustment of the year through profit or loss	4,256	11,152	2,951
Fair value adjustment of the year through OCI	(18,267)	(39,290)	–
Translation difference	–	–	440
Fair value adjustment at December 31	**(37,501)**	**(23,490)**	**4,648**
Net book value at December 31	**39,158**	**53,169**	**6,307**

8 Inventories

	At December 31,		
(in thousands of $)	**2022**	**2021**	**2020**
Raw materials and consumables	126,046	70,134	18,608
Inventories in process	65,016	37,705	6,587
Finished goods	37,291	1,237	–
Total inventories	**228,353**	**109,076**	**25,195**

The cost of inventories, which is recognized as an expense and included in the "cost of sales" on the consolidated statements of profit or loss, amounted to $29.4 million for the year ended December 31, 2022.

On December 31, 2022, inventories amounted to $99.3 million was related to pre-launch SC efgartigimod inventory. Of the total inventory, $76.5 million relates to inventory which is currently awaiting facility approval. As of December 31, 2022, no inventory write-downs were recorded.

Included in inventory are products which could, besides commercial activities, be used for in-house preclinical and clinical programs, non-reimbursed pre-approval programs and clinical programs carried out by Zai Lab.

9 Trade and Other Receivables

The trade and other receivables are composed of receivables which are detailed below:

	At December 31,		
(in thousands of $)	**2022**	**2021**	**2020**
Trade receivable	241,228	28,058	287
Interest receivable	12,918	1,325	993
Other receivable	21,551	8,838	5,698
Total trade and other receivables	**275,697**	**38,221**	**6,978**

The carrying amounts of trade and other receivables approximate their respective fair values. On December 31, 2022, we did not have any provision for expected credit losses.

Please also refer to **note 26** for more information on the financial risk management.

10 Financial Assets – Current

These current financial assets relate to term accounts with an initial maturity longer than 3 months but less than 12 months and money market funds that do not qualify as cash equivalents.

	At December 31,		
(in thousands of $)	**2022**	**2021**	**2020**
Money market funds	46,162	73,052	130,290
Term accounts	1,345,646	929,000	649,359
Total current financial assets	**1,391,808**	**1,002,052**	**779,649**

On December 31, 2022, the current financial assets included $376.8 million (€353.3 million) held in EUR, which could generate a foreign currency exchange gain or loss in our financial results in accordance with the fluctuations of the USD/EUR exchange rate as the Company's functional currency is USD.

Please also refer to **note 26** for more information on the financial risk management.

11 Cash and Cash Equivalents

Cash and cash equivalents may comprise of cash and bank balances, saving accounts, term accounts with an original maturity not exceeding 3 months and money market funds that are readily convertible to cash and are subject to an insignificant risk of changes in value.

	At December 31,		
(in thousands of $)	**2022**	**2021**	**2020**
Money market funds	669,147	997,092	858,291
Term accounts	54,116	95,090	61,356
Cash and bank balances	77,477	242,494	297,156
Total cash and cash equivalents	**800,740**	**1,334,676**	**1,216,803**

Cash positions are invested with preferred financial partners, which are mostly considered to be high quality financial institutions with sound credit ratings to reduce credit risk.

On December 31, 2022, the cash and cash equivalents included $237.1 million (€222.3 million) held in EUR, and $59.0 million (£49.1 million) held in GBP which could generate a foreign currency exchange gain or loss in our financial results in accordance with the fluctuations of the USD/EUR and USD/GBP exchange rates as the Company's functional currency is USD.

Please also refer to **note 26** for more information on the financial risk management.

12 Share Capital and Share Premium

On December 31, 2022, the Company's share capital was represented by 55,395,856 shares. All shares were issued, fully paid up and of the same class. The table below summarizes our share issuances as a result of offerings, exercise of stock options and the vesting of restricted stock units under the Company's Employee Stock Option Plan.

Roll forward of number of shares outstanding:

Number of shares outstanding on January 1, 2020	**42,761,528**
Exercise of stock options	602,463
Global public offering in Euronext and Nasdaq on May 28, 2020	3,658,515
Over-allotment option exercised by underwriters on May 29, 2020	548,777
Number of shares outstanding on December 31, 2020	**47,571,283**
Exercise of stock options	503,282
Global public offering in Euronext and Nasdaq on February 2, 2021	3,125,000
Over-allotment option exercised by underwriters on February 4, 2021	468,750
Number of shares outstanding on December 31, 2021	**51,668,315**
Exercise of stock options	1,024,626
Vesting of RSUs	19,581
Global public offering in Euronext and Nasdaq on March 23, 2022	2,333,334
Over-allotment option exercised by underwriters on March 29, 2022	350,000
Number of shares outstanding on December 31, 2022	**55,395,856**
Issuance of shares in January 2023 relating to exercise of stock options and vesting of RSU in December 2022	15,076

On March 23, 2022, argenx SE offered 2,333,334 of its ordinary shares through a global offering which consisted of 1,433,701 ADSs in the U.S. at a price of $300.0 per ADS, before underwriting discounts and commissions and offering expenses; and 899,633 ordinary shares in the European Economic Area at a price of €273.10 per share, before underwriting discounts and commissions and offering expenses. On March 29, 2022, the underwriters of the offering exercised their overallotment option to purchase 350,000 additional ADSs in full. As a result, argenx SE received $804.1 million in gross proceeds from this offering, decreased by $44.2 million of underwriter discounts and commissions, and offering expenses, of which $44.0 million has been deducted from equity. The total net cash proceeds from the offering amounted to $761 million.

On May 10, 2022, at the annual general meeting, the shareholders of the Company approved the authorization to the Board to issue up to a maximum of 10% of the then-outstanding share capital, for a period of 18 months.

On December 31, 2022, an amount of €428,954.5, represented by 4,289,545 shares, still remained available under the authorization to issue shares as granted to the Board by the shareholders of the Company.

13 Share-Based Payments

The Company has an equity incentive plan for the employees, key consultants, board members, senior managers and key outside advisors ("key persons") of the Company and its subsidiaries. In accordance with the terms of the plan, as approved by share-holders, employees may be granted stock options and/or restricted stock units.

13.1 Stock Option

The stock options are granted to key persons of the Company and its subsidiaries. The stock options may be granted to purchase ordinary shares at an exercise price. The stock options have been granted free of charge. Each employee's stock option converts into one ordinary share of the Company upon exercise. The stock options carry neither rights to dividends nor voting rights. Stock options may be exercised at any time from the date of vesting to the date of their expiry. As of January 1, 2021, the Company decided to change the vesting period of its sign-on stock options from 4 years to 3 years to make the vesting consistent for all the options granted.

The stock options granted (regular and sign-on) vest, in principle, as follows:

- 1/3rd of the total stock options granted will vest on the first anniversary of the granting of the stock options, and
- 1/36th of the total grant on the first day of each month following the first anniversary of the date of grant of the stock options.

Upon leave of the employee, consultant or director, stock options must be exercised before the later of (i) 90 days after the last working day at argenx, or (ii) March 31 of the 4th year following the date of grant of those stock options, and in any case no later than the expiration date of the option.

In order to prefinance the taxes that are paid upon the grant of stock options, Belgian employees have the ability, in exchange for the taxes due upon the grant of the stock options, to transfer the economic benefits related to part of those stock options to a third party. As of December 31, 2022, the economic benefits of 242,729 stock options, for which accelerated vesting applies, were transferred to a third party.

No other conditions are attached to the stock options.

The following stock option arrangements were in existence during the current and prior years and which are exercisable at the end of each period presented:

		Outstanding stock options on December 31,		
Expiry date	**Exercise price per stock options** (in $) [1]	**2022**	**2021**	**2020**
2022	2.60	–	125,339	–
2023	2.60	–	–	165,693
2024	2.60	19,743	94,088	100,086
2024	4.21	5,127	6,113	6,238
2024	7.65	214,800	276,500	294,167
2025	12.20	2,000	4,500	21,500
2025	11.02	–	–	950
2025	10.10	101,861	105,857	114,232
2026	12.13	30,000	41,000	45,000
2026	12.23	99,772	102,840	127,252
2026	15.08	115,211	117,581	176,426
2027	19.64	42,509	53,143	102,479
2027	22.58	303,867	361,350	460,701
2023	86.20	12,111	85,080	85,077
2028	86.20	19,490	39,515	49,532
2023	92.07	124,338	321,473	325,661
2028	92.07	264,392	350,631	381,317
2024	121.04	110,774	111,174	111,174
2029	121.04	110,756	146,765	163,410
2024	144.79	202,852	203,658	195,452
2029	144.79	537,110	611,122	692,914
2025	127.49	16,712	16,712	19,000
2030	127.49	71,486	102,558	123,700
2025	209.21	127,731	129,711	131,770
2030	209.21	223,812	282,475	325,150
2025	213.55	32,100	32,100	32,100
2030	213.55	117,790	136,601	175,200
2030	264.09	620,014	692,214	728,517
2025	264.09	202,475	203,214	211,045
2026	250.01	23,491	24,366	–
2026	272.09	60,890	61,505	–
2026	276.78	45,862	48,138	–
2031	250.01	35,214	42,282	–
2031	272.09	167,406	207,464	–
2031	276.78	81,311	92,456	–

Expiry date	Exercise price per stock options (in $) [1]	Outstanding stock options on December 31, 2022	2021	2020
2026	329.79	80,833	82,430	–
2031	329.79	286,353	307,158	–
2027	301.31	14,976	–	–
2032	301.31	79,155	–	–
2027	381.31	61,816	–	–
2032	381.31	238,532	–	–
2027	393.04	13,764	–	–
2032	393.04	85,199	–	–
2027/2032 [2]	383.55	508,132	–	–
		5,511,767	**5,619,113**	**5,365,743**

[1] Amounts have been converted to USD at the closing rate as of December 31, 2022.

[2] As of December 2022, the Company granted options for which the beneficiaries had a 60-day period to choose between a contractual term of five or ten years.

	2022		2021		2020	
	Number of stock options	Weighted average exercise price [1] (in $)	Number of stock options	Weighted average exercise price [1] (in $)	Number of stock options	Weighted average exercise price [1] (in $)
Outstanding at January 1	**5,619,113**	**164.33**	**5,365,743**	**142.87**	**4,358,069**	**78.23**
Granted	1,021,642	375.58	882,584	314.99	1,797,652	266.71
Exercised	(1,025,780)	92.62	(503,282)	64.72	(602,463)	38.86
Forfeited	(103,208)	273.93	(125,932)	234.98	(187,515)	170.98
Outstanding at December 31	**5,511,767**	**205.02**	**5,619,113**	**164.33**	**5,365,743**	**142.87**
Exercisable at December 31	**3,983,960**	**148.11**	**3,613,371**	**106.53**	**2,833,680**	**65.24**

[1] Amounts have been converted to USD at the closing rate of the respective period.

The weighted average share price at the date of exercise of options exercised during the year ended December 31, 2022 was $336.5, compared to $305.9 during the year ended December 31, 2021 and $254.54 during the year ended December 31, 2020. The weighted average remaining contractual life of the stock options outstanding amounted to 6.2 years on December 31, 2022 compared to 6.3 years on December 31, 2021 and 7.08 years on December 31, 2020. The table below shows the weighted average remaining contractual life for each range of exercise price:

Exercise price (in $)	**Outstanding on December 31, 2022**	**Weighted average remaining contractual life** (in years)
2.6–4.21	24,870	1.75
7.65–10.1	316,661	2.29
11.03–15.07	246,983	3.66
19.64–22.58	346,376	4.90
86.2–92.07	420,331	4.32
121.05–144.79	1,049,690	5.32
209.21–264.09	1,382,627	6.43
272.09–329.79	816,786	7.60
381.31–393.04	907,443	9.38

The fair market value of the stock options has been determined based on the Black and Scholes model using the following unobservable assumptions:

- The expected volatility, determined on the basis of the implied volatility of the share price over the expected life of the option.
- The expected option life, calculated as the estimated duration until exercise, taking into account the specific features of the plans.

Below is an overview of the parameters used in relation to the determination of the fair value of the grants during 2022:

Stock options granted in	**April 2022**	**July 2022**	**Oct 2022**	**Dec 2022** [1)]
Number of options granted	102,081	311,311	100,118	508,132
Average Fair value of options (in $) [2)]	111.27–140.23	153.45–190.53	136.66–169.96	163.94–168.34
Share price (in $) [2)]	320.84–321.06	378.11–397.92	352.97–376.01	377.61
Exercise price (in $) [2)]	312.22	372.69	359.80	381.97
Expected volatility (in %)	39.18–40.87	41.30–43.10	39.64–45.97	39.70–39.74
Average Expected option life (in years)	4–6.50	4–6.50	4–6.50	6.15–6.50
Risk free interest rate (in %)	1.05–1.62	1.77–2.28	2.57–2.80	3.09–3.10
Expected dividends (in %)	–	–	–	–

1) In December 2022, the Company granted a total of 508,132 stock options. The beneficiary can choose between a contractual term of five or ten years. The expected option life ranges between 6.15 and 6.50 years. This estimate will be reassessed once the acceptance period of 60 days has passed and the beneficiaries will have made a choice between a contractual term of five or ten years. The total fair value of the grant would range from $77.4 million (100% of the stock options with a contractual term of five years) to $84.1 million (100% of the stock options with a contractual term of ten years).

2) Amounts have been converted to USD at the applicable rate prevailing at the grant date.

Below is an overview of the parameters used in relation to the determination of the fair value of grants during 2021:

Stock options granted in	April 2021	July 2021	Oct 2021	Dec 2021
Number of options granted	67,833	280,339	144,824	389,588
Average Fair value of options (in $) [1)]	98.96–154.88	131.65–159.13	101.53–131.80	75.03–145.34
Share price (in $) [1)]	248.9–283.67	300.78–340.95	286.52–304.5	277.72–351.73
Exercise price (in $) [1)]	275.33	303.16	301.02	349.92
Expected volatility (in %)	54.24–60.08	45.58–47.96	46.01–48.46	43.24–43.64
Average Expected option life (in years)	4–6.50	4–6.50	4–6.50	4–6.50
Risk free interest rate (in %)	(0.41)–(0.08)	(0.41)–(0.17)	(0.18)–(0.05)	0.03–0.67
Expected dividends (in %)	–	–	–	–

1) Amounts have been converted to USD at the applicable rate prevailing at the grant date.

Below is an overview of the parameter used in relation to the determination of the fair value of grants during 2020:

Stock options granted in	April 2020	June 2020	Oct 2020	Dec 2020
Number of options granted	142,700	550,090	196,500	908,362
Average Fair value of options (in $) [1)]	76.46–148.03	83.46–129.64	91.10–156.68	101.23–229.20
Share price (in $) [1)]	155.23–252.29	224.80–281.25	256.46–293.52	273.15–383.10
Exercise price (in $) [1)]	146.68	240.70	245.69	303.83
Expected volatility (in %)	44.44–64.77	43.46–52.19	44.17–52.71	46.80–59.94
Average Expected option life (in years)	4–6.68	4–6.68	4–6.68	4–6.68
Risk free interest rate (in %)	(0.32)–(0.18)	(0.43)–(0.28)	(0.51)–(0.34)	(0.51)–(0.28)
Expected dividends (in %)	–	–	–	–

1) Amounts have been converted to USD at the closing rate of the respective period.

The total share-based payment expense related to stock options recognized in the consolidated statements of profit or loss totaled $120.2 million for the year ended December 31, 2022, compared to $171.2 million for the year ended December 31, 2021 and $96.9 million for the year ended December 31, 2020.

13.2 Restricted Stock Units (RSUs)

The RSUs are granted to key persons of the Company and its subsidiaries. The RSUs have been granted free of charge. Each employee's RSUs converts into one ordinary share of the Company upon vesting. The RSUs carry neither rights to dividends nor voting rights. RSUs once converted into ordinary shares, may be sold at any time from the date of vesting, have no expiry date and may be held by the participant without limitation. The fair value of RSUs is based on the closing sale price of our common stock on the day prior to the date of issuance. RSUs vest over a period of 4 years with 1/4th of the total grant vesting at each anniversary of the date of grant.

The following restricted stock units arrangements were in existence during the current and prior years:

	2022		2021	
	Number of RSUs	Weighted average Grant Date Fair Value (in$)	Number of RSUs	Weighted average Grant Date Fair Value (in$)
Non-vested units – at January 1	**213,038**	**314.25**	**–**	**–**
Granted	243,010	375.81	216,522	313.84
Vested	(53,872)	–	–	–
Forfeited	(16,896)	307.11	(3,484)	288.92
Non-vested units – at December 31	**385,280**	**387.20**	**213,038**	**314.25**

The total share-based payment expense related to RSUs recognized in the consolidated statements of profit or loss totaled $36.9 million for the year ended December 31, 2022 compared to $8.1 million for the year ended December 31, 2021. There was no RSUs related expense during the year ended December 31, 2020 as the Company only started granting the RSUs in 2021.

14 Trade and Other Payables

	At December 31,		
(in thousands of $)	2022	2021	2020
Trade payables	188,721	208,850	206,325
Short term employee benefits	84,337	83,737	68,867
Gross-to-net-accruals	19,478	–	–
Other	3,142	828	–
Total trade and other payables	**295,679**	**293,415**	**275,192**

The carrying amounts of trade and other payables approximate their respective fair values.

Trade payables correspond primarily to clinical and manufacturing activities and include accrued expenses related to these activities.

Short-term employee benefits include payables and accruals for salaries and bonuses to be paid to the employees of the Company.

As of December 31, 2022, the movement in the gross-to-net-accruals was as follows:

(in thousands of $)	Rebates and chargebacks	Distribution fees, product returns and other	Total
Balance at January 01, 2022	**–**	**–**	**–**
Current estimate related to the sales made in the current year	35,426	10,740	46,166
(Credits or payments related to sales made during the year)	(20,028)	(6,661)	(26,689)
Balance at December 31, 2022	**15,399**	**4,079**	**19,478**

15 Product Net Sales

For the twelve months ended December 31, 2022, the product net sales was related to sales of VYVGART in the US following the approval of VYVGART by U.S. Food and Drug Administration (FDA) on December 17, 2021, in Japan following the approval of VYVGART by Pharmaceuticals and Medical Devices Agency (***PMDA***) on January 20, 2022 and Europe following the approval of VYVGART by European Commission on August 11, 2022. No product net sales were recognized during the comparable prior periods. Product gross sales for twelve months ended December 31, 2022 was $446.9 million and the gross to net adjustment for twelve months ended December 31, 2022 was $46.2 million, resulting in $400.7 million of product net sales for twelve months ended December 31, 2022. Refer to **note 18** for the breakdown of Product net sales by country of sale for twelve month ended December 31, 2022.

16 Collaboration Revenue

The following table summarizes details of collaboration revenues for the year ended December 31, 2022, 2021 and 2020 by collaboration agreement and by category of revenue: upfront payments, milestone payments, research and development service fees and other revenue.

	Year Ended December 31,		
(in thousands of $)	**2022**	**2021**	**2020**
Zai Lab	–	151,903	–
Janssen	–	292,279	33,759
AbbVie	–	121	565
Other	–	–	38
Upfront payments	**–**	**444,303**	**34,362**
Zai Lab	–	25,634	–
Janssen	–	22,865	2,641
AbbVie	–	102	762
Other	5,365	1,214	19
Milestone payments	**5,365**	**49,815**	**3,422**
Janssen	–	2,028	3,175
Other	424	298	284
Research and development service fees	**424**	**2,326**	**3,459**
Zai Lab	4,238	833	–
Other revenues	**4,238**	**833**	**–**
Total revenue	**10,026**	**497,277**	**41,243**

For the years ended December 31, 2022, 2021 and 2020, the collaboration revenue was generated under the agreements with Zai Lab, Janssen and AbbVie, each as described below.

The table below summarizes the change in deferred revenue – current and non-current for the year ended December 31, 2022, 2021 and 2020.

(in thousands of $)	Janssen	AbbVie	Other	Total
On January 1, 2020	**324,629**	**1,517**	**56**	**326,202**
Received				
Milestone	–	–	–	–
Revenue recognition				
Upfront	(33,759)	(565)	(38)	(34,362)
Milestone	(2,641)	(762)	(19)	(3,422)
Translation difference	26,915	33	1	26,949
On December 31, 2020	**315,144**	**223**	**–**	**315,367**
Received				
Upfront	–	–	–	–
Milestone	–	–	–	–
Revenue recognition				
Upfront	(292,279)	(121)	–	(292,400)
Milestone	(22,865)	(102)	–	(22,967)
On December 31, 2021	**–**	**–**	**–**	**–**
Received				
Upfront	–	–	–	–
Milestone	–	–	–	–
Revenue recognition				
Upfront	–	–	–	–
Milestone	–	–	–	–
On December 31, 2022	**–**	**–**	**–**	**–**

Below are summaries of the key collaborations:

Zai Lab

On January 6, 2021, argenx and Zai Lab announced the License agreement for the development and commercialization of efgartigimod in Greater China, granting Zai Lab the exclusive rights to develop and commercialize efgartigimod in Greater China.

Under the terms of the agreement, the Company received $175 million in collaboration payments, comprised of a $75 million upfront payment in the form of 568,182 newly issued Zai Lab shares calculated at a price of $132 per share, $75 million as guaranteed non-creditable, non-refundable payment, received in the first quarter of 2021, and an additional $25 million milestone payment upon regulatory approval of efgartigimod by FDA in the U.S. The Company is also eligible to receive tiered royalties (mid-teen to low twenties on a percentage basis) based on annual net sales of efgartigimod in Greater China.

With regard to this collaboration with Zai Lab:

- The Company concluded there are two performance obligations under EU-IFRS 15, being the transfer of a license and the at arms-length supply of clinical and commercial product. The Company concluded that these performance obligations are distinct in the context of the contract.

- The Company concluded that the Subscription Shares granted by Zai Lab, as included in the Share Issuance Agreement, entered into on January 6, 2021, was obtained because of the existing obligations under the terms of the Collaboration and License Agreement, and is therefore to be considered to be part of the overall consideration received.

- The transaction price of these two agreements is composed of a fixed part, that being an upfront payment of $75 million in the form of newly issued Zai Lab shares, and a $75 million guaranteed, non-creditable, non-refundable payment and $25 million milestone for approval of efgartigimod in the U.S. and the consideration received in return for the supply of clinical and commercial product. Sales-based milestones and sales-based royalties are a part of the Company's arrangements but are not yet included in its revenue.

- The fixed part of the transaction price, as well as the $25 million milestone for approval of efgartigimod in the U.S. has been allocated to the transfer of a license performance obligation.

- The Company concludes that the license as of the effective date of the contract has standalone value. As such, the Company concluded that the promise in granting the license to Zai is to provide a right to use the entity's intellectual property as it exists at the point in time at which the license is granted and therefore, revenue accrued has been recognized at a point in time. This conclusion was reached, taking into account following aspects:
    - there are no material restrictions included in the contract which would prevent Zai Lab to direct the use of, and obtain substantially all of the remaining benefits, within Greater China and considering the sales-based royalties which become due to the Company upon successful commercialization.

- the current phase of efgartigimod, successfully completed the Phase III trials.

- Under the collaboration agreement, the Company provides clinical and commercial supply to Zai Lab. Company concludes to recognize such sales as revenue given that the Company acts as principal in the transaction as the risk related to inventory is born by the Company until the inventory is transferred to Zai. The revenue related to clinical and commercial supply is recorded under line item "Other revenues" within the collaboration revenue footnote.

AbbVie

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

The Company granted AbbVie an exclusive option, for a specified period following completion of IND enabling studies, to obtain a worldwide, exclusive license to the ARGX 115 (ABBV-151) program to develop and commercialize products. The Company received an upfront, non-refundable, non-creditable payment of $40 million from AbbVie for the exclusive option to license ARGX 115 (ABBV-151). The Company achieved two preclinical milestones, each of which triggered a $10.0 million payment.

In August 2018, AbbVie exercised its option and has assumed certain development obligations, being solely responsible for all research, development and regulatory costs relating to ARGX-115 based products. In March 2019, the Company achieved the first development milestone upon initiation of a first-in-human clinical trial, triggering a $30.0 million payment. Subject to the continuing progress of ARGX-115 (ABBV-151) by AbbVie, the Company is eligible to receive development, regulatory and commercial milestone payments in aggregate amounts of up to $110 million, $190 million and $325 million, respectively, as well as tiered royalties on sales at percentages ranging from the mid single digits to the lower teens, subject to customary reductions.

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

With regard to its collaboration with AbbVie, the Company concluded as follows:

- There is one single performance obligation under EU-IFRS 15, that being the transfer of a license combined with performance of research and development activities. The Company concluded that the license is not distinct in the context of the contract.

- The transaction price of these two agreements is currently composed of a fixed part, that being an upfront license fee, and a variable part, being milestone payments and cost reimbursements of research and development activities delivered. Milestone payments are only included in the transaction price to the extent it is highly probable that a significant reversal in the amount of cumulative revenue recognition will not occur when the uncertainty associate with the variable consideration is subsequently resolved. We estimate the amount to be included in the transaction price upon achievement of the milestone event. Sales-based milestones and sales-based royalties are a part of the Company's arrangements but are not yet included in its revenues.

- The transaction price has been allocated to the single performance obligation and revenues have been recognized over the estimated service period based on a pattern that reflects the transfer of the license and progress to complete satisfaction of the research and development activities. This is because we considered that there is a transformational relationship between the license and the research and development activities to be delivered.

- The Company has chosen an input model to measure the satisfaction of the single performance obligation that considers percentage of costs incurred for these programs that are completed each period (percentage of completion method).

- Cost reimbursements received are recognized in revenues when costs are incurred and agreed by the parties, as the Company is acting as a principal in the scope of its stake of the research and development activities of its ongoing collaboration and license agreements.

Janssen

On June 4, 2021, the Company received a termination notification from Cilag GmbH International, an affiliate of Janssen, which results in the termination of the Collaboration Agreement to jointly develop and commercialize cusatuzumab. As a result, the Company regains the worldwide rights to its anti-CD70 antibody cusatuzumab.

Under the terms of the agreement, Janssen committed to an upfront payment of $500 million consisting of a license payment of $300 million and a $200 million equity investment in the Company by subscribing to 1,766,899 new shares at a price of €100.02 per share, including an issuance premium. In December 2019, the Company achieved the first development milestone, triggering a $25.0 million payment.

With regard to this collaboration with Janssen, the Company concluded as follows:

- There was one single performance obligation under EU-IFRS 15, that being the transfer of a license combined with performance of research and development activities. The Company concluded that the license is not distinct in the context of the contract.

- The Company concluded that the share premium that Janssen paid above the closing price on the day of entering into the investment agreement (being December 2, 2018) was paid because of the existing obligations to deliver development services under the terms of the collaboration agreement and was therefore considered to be part of the overall consideration received.

- The transaction price of these two agreements composed of a fixed part, that being an upfront license fee, and a variable part, being milestone payments and cost reimbursements of research and development activities delivered.

- The transaction price was allocated to the single performance obligation and revenue was previously recognized over the estimated service period based on a pattern that reflects the transfer of the license and progress to complete satisfaction of the research and development activities.

Following the termination, the Company concluded that it has substantially satisfied the performance obligation, and as a consequence, recorded $315.1 million for the 12 months ending December 31, 2021.

17 Other Operating Income

	Year Ended December 31,		
(in thousands of $)	**2022**	**2021**	**2020**
Grants	2,186	4,398	1,365
Research and development incentives	19,502	13,970	10,257
Payroll tax rebates	8,576	12,621	9,095
Change in fair value on non-current financial assets	4,256	11,152	2,951
Total other operating income	**34,520**	**42,141**	**23,668**

17.1 Grants

The grant income is related to grants received from the Flanders Innovation and Entrepreneurship Agency. No conditions related to the above government grants were unfulfilled, nor were there any material contingencies related thereon at the date of the approval of these consolidated financial statements.

17.2 Research and Development Incentives

The Company has accounted for a tax incentive of $19.5 million in the year ended December 31, 2022, compared to $14.0 and $10.3 million in the year ended December 31, 2021 and December 31, 2020, respectively, following a research and development tax incentive scheme in Belgium according to which the incentive will be refunded after a five-year period, if not offset against the current tax payable over the period.

17.3 Payroll Tax Rebates

The Company accounted for $8.6 million payroll tax rebates in the year ended December 31, 2022, compared to $12.6 and $9.1 million in the year ended December 31, 2021 and December 31, 2020, respectively, as a reduction in withholding income taxes for its highly qualified personnel employed in its research and development department.

18 Segment Reporting

The Company operates from the Netherlands, Belgium, the United States of America, Japan, Switzerland, Germany, France, Canada, UK, and Italy.

Following table summarizes our product net sales by country of sales based on the country of the entity that recognizes product net sales:

(in thousands of $)	Year Ended December 31, 2022
United States	377,659
Japan	15,764
Europe	5,678
Other [1)]	1,619
Total product net sales	**400,720**

1) The product net sales relates to sales made outside of the U.S., Japan and Europe and relates to named patient sale made with the U.S. label.

We sell our products through a limited number of distributors and wholesellers. Four US customers represent approximately 91% of our product net sales in United States during twelve months ended December 31, 2022.

Collaboration revenue is generated by external customers with their main registered office geographically located as shown in the table below:

	Year Ended December 31,		
(in thousands of $)	**2022**	**2021**	**2020**
Denmark	5,365	1,389	342
Belgium	–	–	–
United States	–	317,396	40,901
China	4,238	178,370	–
Other	424	123	–
Total collaboration revenue	**10,026**	**497,277**	**41,243**

The non-current assets of the Company, with the exception of the deferred tax assets, are geographically located as shown in the table below:

	At December 31,		
(in thousands of $)	**2022**	**2021**	**2020**
Netherlands	–	–	1
Belgium	275,620	268,733	200,125
United States	2,325	3,138	4,751
Japan	2,763	3,232	2,491
Switzerland	–	8	–
Germany	130	–	–
France	4	–	–
Total	**280,841**	**275,111**	**207,368**

19 Research and Development Expenses

	Year Ended December 31,		
(in thousands of $)	**2022**	**2021**	**2020**
Personnel expenses	162,010	160,464	86,036
External research and development expenses	366,955	382,902	259,943
Materials and consumables	2,396	2,735	3,562
Depreciation and amortization	102,132	3,742	2,835
Other expenses	29,872	30,677	18,509
Total research and development expenses	**663,366**	**580,520**	**370,885**

20 Selling, General and Administrative Expenses

	Year Ended December 31,		
(in thousands of $)	**2022**	**2021**	**2020**
Personnel expenses	234,740	164,646	108,507
Professional and marketing fees	178,570	102,674	48,681
Supervisory board	6,912	12,958	4,838
Depreciation and amortization	2,211	2,126	1,092
IT expenses	17,431	8,977	–
Other expenses	32,268	16,263	8,525
Total Selling, general and administrative expenses	**472,132**	**307,644**	**171,643**

21 Personnel Expenses

The personnel expenses mentioned in **note 19** and **note 20** above are as follows:

	Year Ended December 31,		
(in thousands of $)	**2022**	**2021**	**2020**
Short term employee benefits – Salaries	216,847	135,676	75,437
Short term employee benefits – Social Security	16,274	12,785	9,087
Post-employment benefits	5,406	2,864	1,242
Termination benefits	401	818	1,005
Share based payment	151,912	167,965	92,558
Employer social security contributions stock options	5,910	5,002	15,214
Total personnel expenses	**396,750**	**325,110**	**194,543**

The post employment benefits relate to the pension plans the Company has in place for its employees.

The average number of full-time equivalents (FTE) employees by function is presented below:

	Year Ended December 31,		
(Average Number of FTE)	**2022**	**2021**	**2020**
Research and development	474.8	349.7	213.0
Selling, general and administrative	442.4	264.4	119.5
	917.2	**614.1**	**332.5**

22 Leases

The statement of financial position shows the following amounts relating to leases:

	Year Ended December 31,		
(in thousands of $)	**2022**	**2021**	**2020**
Right-of-use assets			
Buildings	10,867	9,688	7,677
Vehicles	1,835	1,664	1,513
Equipment	196	230	264
	12,897	**11,583**	**9,454**
Lease liabilities			
Current	3,417	3,509	3,476
Non-current	9,009	7,956	6,181
	12,426	**11,465**	**9,657**

Additions to the right-of-use assets amounted to $4.2 million for the year ended December 31, 2022.

The table below shows a maturity analysis of the lease liabilities as on December 31, 2022:

(in thousands of $)	Less than 1 year	1–3 years	3–5 years	More than 5 years	Total contractual cash flows	Carrying amount
Lease liabilities	3,408	4,784	3,043	1,167	12,402	12,426

The consolidated statements of profit or loss and the consolidated statements of other comprehensive income shows the following amounts relating to leases:

	Year Ended December 31,		
(in thousands of $)	2022	2021	2020
Depreciation charges			
Buildings	2,179	2,714	2,262
Vehicles	735	651	441
Equipment	35	34	32
	2,949	**3,399**	**2,735**
Interest expense (included in finance cost)	1,343	412	201
Expense relating to short-term leases	732	212	264
Expense relating to leases of low-value assets that are not shown above as short-term leases	21	7	6

The total cash outflow for leases in 2022, 2021 and 2020 was $4.2 million, $4.5 million and $3.0 million respectively.

The Company did not enter into any lease agreement with variable lease payments or residual value guarantees. The Company has leases that include extension options. These options provide flexibility in managing the leased assets and align with the Company's business needs. The Company exercises judgement in deciding whether it is reasonably certain that the extension options will be exercised.

23 Financial Result and Exchange Gains/(Losses)

	Year Ended December 31,		
(in thousands of $)	**2022**	**2021**	**2020**
Interest income	24,741	3,489	5,119
Net gain on cash equivalents & current financial assets held at fair value through profit or loss and cash equivalents	2,924	144	1,340
Financial income	**27,665**	**3,633**	**6,459**
Net loss on cash equivalents & current financial assets held at fair value through profit or loss and cash equivalents	(1,713)	(3,482)	(7,559)
Other financial expense	(2,193)	(1,096)	(401)
Financial expense	**(3,906)**	**(4,578)**	**(7,960)**
Realized exchange gains/(losses)	(3,743)	15	(443)
Unrealized exchange gains/(losses)	(28,989)	(50,068)	(125,791)
Exchange gains/(losses)	**(32,732)**	**(50,053)**	**(126,234)**

The exchange losses of $32.7 million for the year ended December 31, 2022 were primarily attributable to unrealized exchange rate losses on our cash and cash equivalents and current financial assets position in EUR due to the unfavorable fluctuation of the EUR/USD exchange rate over the period.

24 Income Tax Expense

The income tax expense for the year can be reconciled to the accounting loss as follows:

	Year Ended December 31,		
(in thousands of $)	**2022**	**2021**	**2020**
Loss before taxes	729,314	399,743	605,352
Income tax (expense)/benefit calculated at 25.8% for 2022 & 25% for 2021 & 2020	188,163	99,936	151,338
Effect of intercompany asset deal / transaction	(112,200)	—	—
Effect of expenses not deductible in determining taxable results	(1,570)	(4,441)	868
Effect of share based payment expenses that are not deductible in determining taxable results	(27,043)	(29,925)	(13,681)
Effect of stock issue expenses that are not taxable in determining taxable results	11,412	14,119	14,139
Effect of concessions	18,264	13,413	7,900
Effect of change of (de)recognition of deferred tax assets on tax losses	(194)	(44,232)	(116,711)
Effect of different tax rates in jurisdictions in which the company operates	(5,566)	(2,084)	(195)
Effect of change of (de)recognition of deferred tax assets	(51,321)	(50,389)	(45,601)
Withholding tax paid	—	(5,076)	—
(Underprovided)/overprovided in prior years	(12)	398	1,014
Other	(213)	(241)	(146)
Income tax (expense)/benefit recognized in the consolidated statements of profit or loss	**19,720**	**(8,522)**	**(3,103)**

The tax rate used for the reconciliations above is the corporate income tax rate of 25.8% payable by corporate entities in the Netherlands. The tax rate used for the 2021 and 2020 reconciliations is the corporate income tax rate of 25% payable by corporate entities in the Netherlands.

On December 27, 2022, argenx Benelux BV transferred certain pipeline activities to argenx BV through a transfer of assets, (hereafter referred to as “asset deal”), for a total amount of $449.0 million. As a result of the asset deal, argenx Benelux BV realised a capital gain on this intellectual property. argenx BV has an unrecognized deferred tax asset amounting to $112.2 million on the future amortizations on IP assets, which results in the rate reconciling item categorized as “effect of intercompany asset deal / transaction”.

Deferred tax have been measured using the substantively enacted or enacted tax rate as applicable in the respective jurisdictions.

The unrecognized deferred tax asset on unused tax losses amounts to $189.3 million on December 31, 2022, compared to $203.8 million on December 31, 2021 and $174.2 million on December 31, 2020. The Company has unused tax losses carried forward for an amount of $756.1 million on December 31, 2022, compared to $815.3 million on December 31, 2021, and $696.7 million on December 31, 2020. The available tax losses carried forward in Belgium and the Netherlands do not have an expiration date based upon the applicable enacted tax legislation.

As a company active in research and development in Belgium, we expect to benefit from the innovation income deduction, or IID, in Belgium. The innovation income deduction regime allows net profits attributable to revenue from among others patented products to be taxed at a lower effective tax rate than other revenues. At the end of 2022, 2021 and 2020, we had $428.8 million, $213.6 million and $52.1 million of cumulative carry-forward IID in Belgium. The unrecognized deferred tax asset on IID amounts to $107.2 million on December 31, 2022, compared to $53.4 million on December 31, 2021, and $13.0 million on December 31, 2020.

Due to the uncertainty surrounding the Company's ability to realize taxable profits in the future, the Company did not recognize any deferred tax assets, with the exception of those further detailed in **note 6**.

Income taxes recognized in the income statement can be detailed as follows:

	Year Ended December 31,		
(in thousands of $)	**2022**	**2021**	**2020**
Current year	(27,162)	(15,224)	(7,847)
Income tax prior years	(12)	398	(1,732)
Current tax expense	**(27,174)**	**(14,826)**	**(9,579)**
Originating and reversal of temporary differences	46,894	6,304	6,476
Deferred tax expense/(benefit)	**46,894**	**6,304**	**6,476**
Total tax expense/(benefit)	**19,720**	**(8,522)**	**(3,103)**

25 Loss per Share

	Year Ended December 31,		
(in thousands of $)	**2022**	**2021**	**2020**
Loss for the year	(709,594)	(408,265)	(608,455)
Weighted average number of shares outstanding	54,381,371	51,075,827	45,410,442
Basic and diluted loss per share (in $)	**(13.05)**	**(7.99)**	**(13.40)**

Earnings/losses per ordinary share are calculated by dividing the loss for the period by the weighted average number of ordinary shares during the year.

As the Company reported a net loss in 2022, 2021 and 2020, stock options and RSUs have an anti dilutive effect rather than a dilutive effect. As such, there is no difference between basic and diluted loss per ordinary share.

26 Financial Risk Management

The financial risks are managed centrally. The Company coordinates the access to national and international financial markets and considers and manages continuously the financial risks concerning the Company's activities. These relate to the financial markets risk, credit risk, liquidity risk and currency risk. There are no other important risks, such as interest rate risk on borrowings, as the Company has no financial debt. The Company does not buy or trade financial instruments for speculative purposes.

Categories of financial assets and liabilities:

	Measurement category	Carrying amount at December 31,		
(in thousands of $)		2022	2021	2020
Financial assets – non-current	FVTPL	21,715	17,459	6,307
Financial assets – non-current	FVTOCI	17,443	35,710	–
Research and development incentive receivables – non-current	Amortized cost	47,488	32,707	20,626
Restricted cash – non-current	Amortized cost	1,736	1,707	1,509
Trade and other receivables	Amortized cost	275,697	38,221	6,978
Financial assets – current	FVTPL	46,162	73,052	130,290
Financial assets – current	Amortized cost	1,345,646	929,000	649,359
Research and development incentive receivables – current	Amortized cost	1,578	–	463
Cash and bank balances	Amortized cost	77,477	242,494	297,156
Cash equivalents	FVTPL	669,147	997,092	858,291
Cash equivalents	Amortized cost	54,116	95,090	61,356
Trade and other payables	Amortized cost	295,679	293,415	275,192

The carrying amounts of trade and other payables and trade and other receivables are considered to be the same as their fair values, due to their short-term nature.

Financial Assets held at Fair Value through Profit or Loss or OCI

Financial assets held at fair value through profit or loss or OCI consisted of equity instruments of listed and non-listed companies and money market funds.

The Company has no restrictions on the sale of these equity instruments and the assets are not pledged under any of its liabilities. These instruments are classified as financial assets held at fair value through profit or loss or OCI which qualify for:

- Level 1 fair value measurement with respect to current financial assets and cash equivalents based upon the closing price (net asset value) of such securities at each reporting date.
- Level 3 fair value measurement with respect to non-current financial assets.

The market price of these financial instruments might face fluctuations and might be affected by a variety of factors, such as the global economic situation. Current financial assets and cash equivalents include collective investment funds nominated in € and $ of which the underlying investments include bonds and other international debt securities. Based on the weighted average maturity of the underlying instruments, amongst others, these investments are either classified as current financial assets or cash equivalents.

The maximum exposure to credit risk is the carrying amount at reporting date.

The Company carried the following assets at fair value on December 31, 2022, 2021 and 2020 respectively:

	At December 31, 2022		
(in thousands of $)	**Level 1**	**Level 2**	**Level 3**
Non-current financial assets	17,443	–	21,715
Current financial assets	46,162	–	–
Cash and cash equivalents	669,147	–	–
Assets carried at fair value	**732,752**	**–**	**21,715**

	At December 31, 2021		
(in thousands of $)	**Level 1**	**Level 2**	**Level 3**
Non-current financial assets	35,710	–	17,459
Current financial assets	73,052	–	–
Cash and cash equivalents	997,092	–	–
Assets carried at fair value	**1,105,854**	**–**	**17,459**

	At December 31, 2020 [1)]		
(in thousands of $)	**Level 1**	**Level 2**	**Level 3**
Non-current financial assets	–	–	6,307
Current financial assets	130,290	–	–
Cash and cash equivalents	858,291	–	–
Assets carried at fair value	**988,581**	**–**	**6,307**

1) The historical consolidated financial information for 2020 presented in this disclosure note has been adjusted to correct for the amounts of current financial assets that are measured at fair value.

During the disclosed calendar year, no transfers occurred between the applicable categories.

Non-Current Financial Assets – Level 3

In March 2019, the Company entered into a license agreement with AgomAb Therapeutics NV for the use of HGF-mimetic SIMPLE Antibodies™, developed under the Company's Immunology Innovative Program. In exchange for granting this license, the Company received a profit share in AgomAb Therapeutics NV.

In March 2021, AgomAb Therapeutics NV secured $74 million in Series B financing by issuing 286,705 of Preferred B Shares. The Company used the post-money valuation of Series B financing round and the number of outstanding shares in determining the fair value of the profit-sharing instrument, which results in a change in fair value of non-current financial assets of $11.2 million recorded through profit or loss. Since AgomAb Therapeutics NV is a private company, the valuation of the profit share is based on level 3 assumptions.

In June 2022, AgomAb Therapeutics NV secured €38.4 million as a result of the extension of Series B. The Company used the post-money valuation of this Series B financing round and the number of outstanding shares in determining the fair value of the profit-sharing instrument, which results in a change in fair value of non-current financial assets of $4.3 million recorded through profit or loss.

Non-Current Financial Assets – Level 1

In January 2021, as part of the license agreement for the development and commercialization for efgartigimod in Greater China (see **note 16** for further information), the Company obtained, amongst others, 568,182 newly issued Zai Lab shares calculated at a price of $132 per share. The fair value of the equity instrument at period-end is determined by reference to the closing price of such securities at each reporting date (classified as level 1 in the fair value hierarchy), resulting in a change in fair value. The Company made the irrevocable election to recognize subsequent changes in fair value through OCI.

Capital Risk

The Company manages its capital to ensure that it will be able to continue as a going concern. The capital structure of the Company consists of equity attributed to the holders of equity instruments of the Company, such as capital, reserves and accumulated losses as mentioned in the consolidated statements of changes in equity. The Company makes the necessary adjustments in the light of changes in the economic circumstances, risks associated to the different assets and the projected cash needs of the current and projected research activities. On December 31, 2022, cash and cash equivalents amounted to $800.7 million and total capital amounted to $4,316.5 million. The current cash situation and the anticipated cash generation are the most important parameters in assessing the capital structure. The Company's objective is to maintain the capital structure at a level to be able to finance its activities for at least twelve months. Cash income from existing and new partnerships is taken into account and, if needed and possible, the Company can issue new shares or enter into financing agreements.

Credit Risk

Credit risk refers to the risk that a counterparty will default on its contractual obligations resulting in financial loss to the Company. The Company has adopted a policy of only dealing with creditworthy counterparties and obtaining sufficient collateral, where appropriate, as a means of mitigating the risk of financial loss from defaults. Concentrations in credit risk are determined based on an analysis of counterparties and their importance on the overall outstanding contractual obligations at year-end.

The Company has a limited number of collaboration and license partners and therefore has a significant concentration of credit risk. However, it has policies in place to ensure that credit exposure is kept to a minimum and significant concentrations of credit exposure are only granted for short periods of time to high credit quality collaboration partners.

The Company applied the EU-IFRS 9 simplified approach to measuring expected credit losses which uses a lifetime expected loss allowance for all receivables. To measure the expected credit losses, receivables have been grouped based on credit risk characteristics and the days past due. The provision for expected credit losses was not significant given that there have been no credit losses over the last three years and the high quality nature of our customers.

Cash and cash equivalents and current financial assets are invested with several highly reputable banks and financial institutions. The Company holds its cash and cash equivalents mainly with different banks which are independently rated with a minimum rating of 'A-'. The Company also holds short term investment funds in the form of money market funds with a recommended investment horizon of 6 months or shorter but with a low historical volatility. These money market funds are highly liquid investments, can be readily convertible into a known amount of cash. Since they are a basket of funds there is no individual credit risk involved. The company has adopted a policy whereby money market funds must have an average rating of "BBB" or higher.

Liquidity Risk

The Company manages liquidity risk by maintaining adequate reserves, by continuously monitoring forecast and actual cash flows, and by matching the maturity profiles of financial assets and liabilities.

The Company's main sources of cash inflows are obtained through capital increases and collaboration agreements. This cash is invested in savings accounts, term accounts and short-term investment funds in the form of money market funds. These money market funds represent the majority of the Company's available sources of liquidity however since all of these are immediately tradable and convertible in cash they have a limited impact on the liquidity risk.

Interest Rate Risk

The only variable interest-bearing financial instruments are cash and cash equivalents and current financial investments. Changes in interest rates may cause variations in interest income and expense resulting from short-term interest-bearing assts. Management does not expect the short-term interest rates to decrease significantly in the immediate foreseeable future, which limits the interest exposure on our cash and cash equivalents and current financial assets.

For the year ended December 31, 2022, if applicable interest rates would increase/decrease by 25 basis points, this would have a positive/negative impact of $0.9 million (compared to $6.2 million for the year ended December 31, 2021 and $1.7 million for the year ended December 31, 2020).

Foreign Exchange Risk

The Company undertakes transactions denominated in foreign currencies; consequently, exposures to exchange rate fluctuations arise. The Company is mainly exposed to the Euro, Japanese yen, British pound and Swiss franc. To limit this risk, the Company attempts to align incoming and outgoing cash flows in currencies other than USD.

The net exposure to exchange differences of the monetary assets (being cash, cash equivalents and current financial assets) of the Company at the end of the reporting period are as follows:

	At December 31,		
(in thousands of $)	**2022**	**2021**	**2020**
EUR	613,866	591,887	703,016
JPY	5,613	6,316	264
GBP	59,026	1,237	48
CHF	3,832	727	2
CAD	657	–	–
SEK	7	–	–
DKK	6	–	–

On December 31, 2022, if the EUR/USD exchange rate would have increased/decreased by 10%, this would have had a negative/positive impact of $61.39 million, compared to $53.81 million and $63.91 million on December 31, 2021 and December 31, 2020, respectively. On December 31, 2022, if the exchange rate for other currencies would have increased/decreased by 10%, this would have had no significant impact.

27 Related Party Transactions

27.1 Relationship and Transactions with Joint Venture Entity

In July 2022, the Company entered into a joint venture agreement with the University of Colorado Anschutz Medical Campus and UCHealth and created a separate legal entity, OncoVerity, Inc., which is focused on optimizing and advancing the development of cusatuzumab, a novel anti-CD70 antibody, in acute myeloid leukemia (AML). The Company contributed $2 million and the investment has been designated as investment in joint venture and accounted under IAS 28 Investment in associates and joint ventures.

At December 31, 2022, the Company has commitments towards its joint venture, OncoVerity, Inc. to fund the operations of the joint venture amounting to $13.0 million.

27.2 Relationship and Transactions with Subsidiaries

See **note 31** for an overview of the consolidated companies of the group, which are all wholly-owned subsidiaries of argenx SE.

Balances and transactions between the Company and its subsidiaries, which are related parties of the Company, have been eliminated on consolidation and are not disclosed in this note.

27.3 Relationship and Transactions with Key Personnel

The Company's key management personnel consists of the members of the management team and the members of the board of directors.

Remuneration of Key Management Personnel

On December 31, 2022, the senior management consisted of 8 members: Chief Executive Officer, Chief Operating Officer, Chief Financial Officer, Chief Scientific Officer, General Counsel, Chief Medical Officer, Vice President Corporate Development and Strategy and Global Head of Quality Assurance. They provide their services on a full-time basis.

On December 31, 2022, the board of directors consisted of 9 members: Peter Verhaeghe, Don deBethizy, Pamela M. Klein, Werner Lanthaler, A. A. Rosenberg, James M. Daly, Camilla Sylvest, Ana Cespedes and Tim Van Hauwermeiren.

Only the Chief Executive Officer is a member of both the senior management team and the board of directors. The Chief Executive Officer does not receive any remuneration for his board membership, as this is part of his total remuneration package in his capacity as member of the senior management team.

The remuneration package of the members of key management personnel comprises:

	Year Ended December 31,		
(in thousands of $, except for the number of stock options & RSUs)	**2022**	**2021**	**2020**
Remuneration of key management personnel			
Short-term benefits for senior management members as a group			
Gross salary	4,199	3,465	3,246
Variable pay	3,077	2,020	1,510
Employer social security	1,015	789	753
Other short-term benefits	372	274	156
Termination Benefits	–	382	385
Post-employment benefits for senior management members as a group	104	150	161
Cost of stock options granted in the year for senior management members as a group	18,393	15,060	42,824
Cost of restricted stock units granted in the year for senior management members as a group	9,594	8,025	–
Employer social security cost related to stock options	1,101	4,172	11,206
Total benefits for key management personnel	**37,855**	**34,337**	**60,241**
Numbers of stock options granted in the year			
Senior Management as a group	117,600	101,446	334,900
Numbers of RSUsrestricted stock units granted in the year			
Senior Management as a group	26,500	22,888	–
Remuneration of non-executive directors			
Board fees and other short-term benefits for non-executive directors	437	435	405
Cost of stock options granted in the year for non-executive directors	3,643	3,263	9,576
Cost of restricted stock units granted in the year for non-executive directors	1,850	1,731	–
Total benefits for non-executive board members	**5,929**	**5,429**	**9,981**
Numbers of stock options granted in the year			
Non-executive directors	21,600	22,950	70,000
Numbers of restricted stock units granted in the year			
Non-executive directors	4,800	5,100	–

Other

No loans, quasi-loans or other guarantees were given by the Company or any of its subsidiaries to members of the board of directors or the senior management. We have not entered into transactions with our key management personnel, other than as described above with respect to remuneration arrangements relating to the exercise of their mandates as members of the senior management and the board of directors.

28 Contingencies

The Company is currently not facing any outstanding claims or litigations that may have a significant adverse impact on the Company's consolidated financial position.

29 Commitments

At balance sheet date, there were no commitments signed for the acquisition of property, plant and equipment. In January 2021, the Company entered into a binding lease commitment related to the envisioned relocation to a newly built office in Zwijnaarde, Belgium. Included in the binding lease commitment is a rent free period for 6 months following the completion of the building. The total future cash outflows related to this lease are as follows:

(in thousands of $)	Less than 1 year	1–3 years	3–5 years	More than 5 years	Total contractual cash flows
Lease commitments not commenced	–	–	–	18,038	18,038

In February 2019, and as amended in September 2020, the Company entered into a global collaboration and license agreement with Halozyme Therapeutics, Inc. Under the terms of the agreement, the Company will pay $12.5 million per target for future target nominations and potential future payments of up to $160.0 million per selected target subject to achievement of specified development, regulatory and sales-based milestones and up to $40.0 million subject to the achievement of additional, specified sales-based milestones. This amount represents the maximum amount that would be paid if all milestones would be achieved but excludes variable royalty payments based on unit sales. In 2019, the Company exercised the option to nominate an additional target (triggering a $10.0 million development milestone payment) and initiated a Phase 1 clinical trial using Halozyme's proprietary ENHANZE® drug delivery technology (triggering a $5.0 million development milestone payment). In 2020, the Company initiated a Phase 3 clinical trial using Halozyme's proprietary ENHANZE® drug delivery technology (triggering a $15.0 million development milestone payment). In 2021, the Company initiated a Phase 1 clinical trial using Halozyme's proprietary ENHANZE® drug delivery technology (triggering a $5.0 million development milestone payment).

The Company's manufacturing commitments with Lonza, its drug substance manufacturing contractor, relate to the ongoing execution of the biologic license application (BLA) services for efgartigimod and its manufacturing activities related to the potential future commercialization. In December 2018, the Company signed its first commercial supply agreement with Lonza related to the reservation of commercial drug substance supply capacity for efgartigimod. In the aggregate, the Company has outstanding commitments for efgartigimod under the first commercial supply agreement of $419.0 million.

During 2022, Company signed an agreement with Fujifilm, for activities relating to the large-scale manufacturing of efgartigimod drug substance. In the aggregate, the Company has outstanding commitments for efgartigimod under the commercial supply agreement of $13.3 million.

At December 31, 2022, the Company has commitments towards its joint venture, OncoVerity, Inc. to fund the operations of the joint venture amounting to $13.0 million.

30 Audit Fees

The following auditors' fees were expensed in the consolidated statements of profit or loss:

	Year Ended December 31,		
(in thousands of $)	**2022**	**2021**	**2020**
Audit Fees [1)]	1,394	1,183	923
Audit-related Fees	280	267	188
Tax Fees [2)]	–	79	–
Total	**1,774**	**1,529**	**1,111**

1) Audit services performed by Deloitte Accountants B.V. as the external auditor referred to in Section 1 of the Dutch Accounting Firms Oversight Act (Wta) as well as by the Deloitte network.

2) Tax services performed by the Deloitte network.

31 Overview of Consolidation Scope

The parent company argenx SE is domiciled in the Netherlands. The Company, argenx SE, has two subsidiaries, argenx BV and argenx Benelux BV, based in Belgium. argenx BV has nine subsidiaries. Details of the Company's consolidated entities at the end of the reporting period are as follows:

Name	Country	Participation
argenx SE	The Netherlands	100.00 %
argenx BV	Belgium	100.00 %
argenx Benelux BV	Belgium	100.00 %
argenx US, Inc.	USA	100.00 %
argenx Switzerland, SA	Switzerland	100.00 %
argenx Japan KK	Japan	100.00 %
argenx France SAS	France	100.00 %
argenx Germany GmbH	Germany	100.00 %
argenx Canada, Inc.	Canada	100.00 %
argenx UK Ltd.	United Kingdom	100.00 %
argenx Netherlands Services B.V.	The Netherlands	100.00 %
argenx Italy S.r.l.	Italy	100.00 %

32 Events After the Balance Sheet Date

No events have occurred after the balance sheet date that could have a material impact on the consolidated financial statements.

7

Company Financial Statements

for argenx SE for the Year ended December 31, 2022

Signatures of Executive and Non-Executive Directors

In accordance with article 2:101 of the Dutch Civil Code, the annual accounts were signed by all executive and non-executive directors on March 15, 2023.

Company Financial Statements for argenx SE

For argenx SE

For the year ended December 31, 2022

Company Balance Sheet on December 31, 2022 argenx SE

		At December 31,	
(in thousands of $)	Note	2022	2021 [1]
Assets			
Non current assets			
Financial Fixed Assets	2		
Investments in Group Companies		2,583,759	2,387,237
Other financial assets		1	1
Total financial fixed assets		**2,583,760**	**2,387,238**
Total non current assets		**2,583,760**	**2,387,238**
Current assets			
Receivables	3	140,185	1,993
Financial assets – current	4	–	4,985
Cash and cash equivalents	5	92,096	142,853
Total current assets		**232,281**	**149,831**
Total assets		**2,816,041**	**2,537,069**
Equity and liabilities			
Equity	6		
Share capital		6,640	6,233
Share premium		4,309,880	3,462,775
Accumulated losses		(2,109,791)	(1,400,197)
Share-based payment reserves		515,158	356,875
Other reserves		(37,467)	(23,146)
Translation reserves		129,280	131,684
Total equity		**2,813,699**	**2,534,224**
Current liabilities	7		
Accounts payable		20	70
Intercompany payables		1,130	1,232
Taxes payable		155	95
Accrued expenses		474	620
Other payables		563	827
Total liabilities		**2,342**	**2,845**
Total equity & liabilities		**2,816,041**	**2,537,069**

[1] The comparative figures for December 31, 2021 have been adjusted to reflect changes booked directly in equity at the subsidiaries.

Company Profit and Loss Account for the Year Ended December 31, 2022 argenx SE

		Year ended December 31,	
(in thousands of $)	Note	2022	2021
Intercompany Recharges		–	–
Total operating income		**–**	**–**
G&A Expenses		(15,543)	(21,944)
Total operating expenses		**(15,543)**	**(21,944)**
Operating result		**(15,543)**	**(21,944)**
Financial income and expense	8	344,696	(5,231)
Share in result of subsidiaries	9	(1,038,746)	(381,493)
Result before taxation		**(709,594)**	**(408,668)**
Taxation on result of ordinary activities		–	404
Result after taxation		**(709,594)**	**(408,265)**

Notes to the Company Financial Statements of argenx SE

1 Accounting Information and Policies

1.1 Basis of Preparation

The company financial statements of argenx SE (hereafter: the company) have been prepared in accordance with Part 9, Book 2 of the Dutch Civil Code. In accordance with article 362 sub8, Book 2 of the Dutch Civil Code, the company's financial statements are prepared based on the accounting principles of recognition, measurement and determination of profit, as applied in the consolidated IFRS financial statements.

1.2 Summary of Significant Accounting Policies

In case no other policies are mentioned, refer to the accounting policies as described in the summary of significant accounting policies in the consolidated IFRS financial statements. For an appropriate interpretation, the company financial statements of argenx SE should be read in conjunction with the consolidated IFRS financial statements.

Participating Interests in Group Companies

Participating interests in group companies are valued using the equity method, applying the IFRS accounting policies endorsed by the European Union. Following the adoption of IFRS 9 by the group, and our interpretation of the Dutch Accounting Standard 100.108, the company shall, upon identification of a credit loss on an intercompany loan and/or receivable, eliminate the carrying amount of the intercompany loan and/or receivable for the value of the identified credit loss.

Result of Participating Interests

The share in the result of participating interests consists of the share of the Company in the result of these participating interests. In so far as gains or losses on transactions involving the transfer of assets and liabilities between the Company and its participating interests or between participating interests themselves can be considered unrealized, they have not been recognized.

All amounts are presented in thousands of USD, unless stated otherwise. The balance sheet and income statement references have been included. These refer to the notes.

1.3 Change in Functional and Presentation Currency as of January 1, 2021

As of January 1, 2021, the Company changed its functional and presentation currency from EUR to USD. The change in functional currency was made to reflect that USD has become the predominant currency in the Company, representing a significant part of the Company's cash flows and financing. The change has been implemented with prospective effect.

The change in presentation currency, effective January 1, 2021, from EUR to USD is retroactively applied on comparative figures according to IAS 8 and IAS 21, as if USD had always been the presentation currency of the consolidated financial statements. The change was made to better reflect the economic footprint of the Company's business going forward. The Company believes that the presentation currency change will give investors and other stakeholders a clearer understanding of the Company's performance over time.

2 Financial Fixed Assets

The Company has two Belgian subsidiaries, argenx BV and argenx Benelux BV, which carry out the research and development activities of the Group. Argenx Benelux BV was incorporated through a partial demerger of argenx BV in 2020. On December 27, 2022, argenx Benelux BV transferred certain pipeline activities to argenx BV through a transfer of assets, (hereafter referred to as "asset deal"), for a total amount of $449 million. As a result of the asset deal, argenx Benelux BV realized a capital gain. argenx Benelux BV has distributed an interim dividend of EUR 325 million to argenx SE, which in turn has increased the share capital of argenx BV for $345 million.

Argenx BV has nine subsidiaries, argenx US, Inc., argenx Japan KK, argenx Switzerland SA, argenx Germany GmbH, argenx France SAS, argenx Canada, Inc., argenx Netherlands Services BV, argenx UK Ltd and argenx Italy SRL. The financial fixed assets consist of the 100% participations in argenx BV and argenx Benelux BV, both registered at Industrie-park 7, Zwijnaarde, Belgium.

The movement in financial fixed assets is as follows:

	At December 31,	
(in thousands of $)	**2022**	**2021** [1)]
Investments in Group companies		
Opening Balance	2,386,238	1,544,024
Share of loss of Investments	(1,038,746)	(437,968)
Share-based payment expenses of investments	153,169	167,965
Changes booked directly in equity at subsidiary level	(22,580)	(34,470)
Fair Value gain on Financial Assets at FVTPL	1,105,678	1,146,687
Closing balance	**2,583,759**	**2,386,238**
Receivable/(payable) on Group companies	–	999
Investments in Group companies	**2,583,759**	**2,387,237**
Other financial assets		
Opening Balance	1	1
Balance as at year-end	**1**	**1**
Total financial fixed assets	**2,583,760**	**2,387,238**

[1)] The comparative figures for December 31, 2021 have been adjusted to reflect changes booked directly in equity at the subsidiaries.

3 Receivables

	At December 31,	
(in thousands of $)	**2022**	**2021**
Interest receivable	323	–
Other receivables	138,918	949
Prepaid expenses	943	1,044
Total receivables	**140,185**	**1,993**

Receivables fall due in less than one year. The fair value of the receivables approximates the nominal value, due to their short-term character.

4 Financial Assets

	At December 31,	
(in thousands of $)	**2022**	**2021**
Money market funds	–	4,985
Total financial assets	**–**	**4,985**

5 Cash and Cash Equivalents

	At December 31,	
(in thousands of $)	**2022**	**2021**
Money market funds	91,002	47,365
Current bank accounts	1,094	95,488
Total cash in banks	**92,096**	**142,853**

6 Equity

(in thousands of $)	Share capital	Share premium	Accumulated losses	Share based payment reserves	Other reserves	Translation reserves	Total equity
Equity per 31 December 2021[1)]	**6,233**	**3,462,775**	**(1,400,197)**	**356,875**	**(23,146)**	**131,684**	**2,534,224**
Result of the year	–	–	(709,594)	–	–	–	(709,594)
SBP expense	–	–	–	158,282	–	–	158,282
Capital increase	294	759,878	–	–	–	–	760,172
Exercised stock options	113	93,082	–	–	–	–	93,195
Changes booked directly in equity at subsidiary level	–	(5,855)	–	–	(14,321)	(2,404)	(22,580)
Equity per 31 December 2022	**6,640**	**4,309,880**	**(2,109,791)**	**515,158**	**(37,467)**	**129,280**	**2,813,699**

1) The comparative figures for December 31, 2021 have been adjusted to reflect changes booked directly in equity at the subsidiaries.

For the details on Sharebased payments we refer to **note 13** of the consolidated IFRS financial statements. The company holds no legal reserves as part of the equity.

7 Current Liabilities

	At December 31,	
(in thousands of $)	**2022**	**2021**
Accounts payable	20	70
Intercompany payables	1,130	1,232
Taxes payable	155	95
Accrued expenses	474	620
Other payables	563	827
Total current liabilities	**2,342**	**2,845**

All current liabilities fall due in less than one year. The fair value of the current liabilities approximates the nominal value, due to their short-term character.

8 Financial Result and Exchange Gains/(Losses)

	At December 31,	
(in thousands of $)	**2022**	**2021**
Interest income on bank deposits	2	–
Net gains on investments at FVTPL	1,151	–
Fees collected from ADS holders	466	484
Interest on I/C current account	321	–
Dividend income	345,784	–
Financial income	**347,724**	**484**
Net losses on investments at FVTPL	–	(364)
Interest expense	(199)	(116)
Other financial expenses	(143)	(44)
Financial expenses	**(342)**	**(524)**
Exchange gains/(losses)	**(2,686)**	**(5,191)**
Financial income and expense	**344,696**	**(5,231)**

9 Share in Result of Subsidiaries

The Company has two Belgian subsidiaries, argenx BV and argenx Benelux BV, which jointly carry out the research and development activities of the Group.

	Year ended December 31,	
(in thousands of $)	**2022**	**2021**
argenx BV	(562,594)	(421,774)
argenx Benelux BV	(476,152)	(16,195)
	(1,038,746)	**(437,968)**

10 Other Disclosures

Contingent Liabilities

The contingent liabilities of the Company consist of a rental agreement for office space in Amsterdam for an amount of KEUR 7 per annum. The lease contract has a duration of two years.

Related-Party Transactions

All legal entities that can be controlled, jointly controlled or significantly influenced are considered as a related party. Also, entities which can control the company are considered a related party. In addition, directors, other key management of argenx SE and close relatives are regarded as related parties. Other than the intercompany cross-charges, there were no related party transactions.

Remuneration

Remuneration of executive director for 2022 and 2021 is as follows:

	Compensation	
(in $)	**2022**	**2021**
Base salary	638,901	651,986
Short term incentive	766,682	586,787
Option awards	4,174,684	3,895,370
Restricted stock units	2,159,689	2,084,509
Pension contributions	23,384	26,894
Social security costs	–	3,456
Other	14,958	14,827
Total current liabilities	**7,778,298**	**7,263,829**

Part of the remuneration of the executive director is being paid by subsidiaries of argenx SE.

See **note 27** of the notes to the consolidated IFRS financial statements for the remuneration of non-executive Board of directors.

Information Relating to Employees

During the year 2022, the Company had an average of 0.2 FTE (2021: 0.2 FTE).

Auditor's Fees

See **note 31** of the notes to the consolidated IFRS financial statements.

Proposal for Appropriation of the Result

The Company reported a net loss of $709.6 million for the year ended on December 31, 2022. The Board of Directors proposes to carry forward the net loss of the year 2022 to the accumulated losses. Anticipating the approval of the financial statements by the shareholders at the annual general meeting of shareholders, this proposal has already been reflected in the 2022 financial statements.

Events After the Balance Sheet Date

For the events after balance sheet date, we refer to **note 32** of the consolidated IFRS financial statements.

Amsterdam, March 16, 2023
The Director
Tim Van Hauwermeiren, CEO

Other Information

Provision in the Articles of Association Governing the Appropriation of Results

- The company shall have a policy on reserves and dividends which shall be determined and may be amended by the board of directors. The adoption and thereafter each material change of the policy on reserves and dividends shall be discussed at the general meeting under a separate agenda item.
- From the profits, shown in the annual accounts, as adopted, the board of directors shall determine which part shall be reserved. Any profits remaining thereafter shall be at the disposal of the general meeting. The board of directors shall make a proposal for that purpose. A proposal to pay a dividend shall be dealt with as a separate agenda item at the general meeting.
- Distribution of dividends on the shares shall be made in proportion to the nominal value of each share.
- Distributions may be made only insofar as the company's equity exceeds the amount of the paid in and called up part of the issued capital, increased by the reserves which must be kept by virtue of the law.
- If a loss was suffered during any one year, the board of directors may resolve to offset such loss by writing it off against a reserve which the company is not required to keep by virtue of the law.
- The distribution of profits shall be made after the adoption of the annual accounts, from which it appears that the same is permitted.
- The board of directors may, subject to due observance of the policy of the company on reserves and dividends, resolve to make an interim distribution, provided the requirement of paragraph 4 of this article has been complied with, as shown by interim accounts. Such interim accounts shall show the financial position of the company not earlier than on the first day of the third month before the month in which the resolution to make the interim distribution is announced. Such interim accounts shall be signed by all members of the board of directors. If the signature of one or more of them is missing, this shall be stated and reasons for this omission shall be given. The interim accounts shall be deposited in the offices of the trade register within eight days after the day on which the resolution to make the interim distribution has been announced.
- At the proposal of the board of directors, the general meeting may resolve to make a distribution on shares wholly or partly not in cash but in shares.
- The board of directors may, subject to due observance of the policy of the company on reserves and dividends, resolve that distributions to holders of shares shall be made out of one or more reserves.
- A claim of a shareholder for payment of a distribution shall be barred after five years have elapsed.

Independent Auditor's Report

To: the Shareholders and the Board of Directors of argenx SE

Report on the Audit of the Financial Statements 2022 Included in the Annual Report

Our Opinion

We have audited the financial statements 2022 of argenx SE, based in Amsterdam, the Netherlands. The financial statements comprise the consolidated financial statements and the company financial statements.

In our opinion:

- The accompanying consolidated financial statements give a true and fair view of the financial position of argenx SE as at December 31 2022, and of its result and its cash flows for 2022 in accordance with International Financial Reporting Standards as adopted by the European Union (EU-IFRS) and with Part 9 of Book 2 of the Dutch Civil Code.
- The accompanying company financial statements give a true and fair view of the financial position of argenx SE as at December 31 2022, and of its result for 2022 in accordance with Part 9 of Book 2 of the Dutch Civil Code.

The consolidated financial statements comprise:

1. The consolidated statements of financial position as at December 31 2022.
2. The following statements for 2022: the consolidated statements of profit or loss, the consolidated statements of comprehensive income and loss, the consolidated statements of cash flows and the consolidated statements of changes in equity.
3. The notes comprising a summary of the significant accounting policies and other explanatory information.

The company financial statements comprise:

1. The company balance sheet as at December 31 2022.
2. The company profit and loss account for 2022.
3. The notes comprising a summary of the significant accounting policies and other explanatory information.

Basis for our Opinion

We conducted our audit in accordance with Dutch law, including the Dutch Standards on Auditing. Our responsibilities under those standards are further described in the 'Our responsibilities for the audit of the financial statements' section of our report.

We are independent of argenx SE in accordance with the EU Regulation on specific requirements regarding statutory audit of public-interest entities, the Wet toezicht accountantsorganisaties (Wta, Audit firms supervision act), the Verordening inzake de onafhankelijkheid van accountants bij assurance-opdrachten (ViO, Code of Ethics for Professional Accountants, a regulation with respect to independence) and other relevant

independence regulations in the Netherlands. Furthermore, we have complied with the Verordening gedrags- en beroepsregels accountants (VGBA, Dutch Code of Ethics).

We believe the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Information in Support of our Opinion

We designed our audit procedures in the context of our audit of the financial statements as a whole and in forming our opinion thereon. The following information in support of our opinion was addressed in this context, and we do not provide a separate opinion or conclusion on these matters.

Materiality

Based on our professional judgement we determined the materiality for the financial statements as a whole at USD 39,700,000. The materiality is based on 3.5% of operating expenses excluding cost of sales and excluding the loss in joint venture. We have also taken into account misstatements and/or possible misstatements that in our opinion are material for the users of the financial statements for qualitative reasons.

We agreed with the Board of Directors that misstatements in excess of USD 1,985,000, which are identified during the audit, would be reported to them, as well as smaller misstatements that in our view must be reported on qualitative grounds.

Scope of the Group Audit

argenx SE is at the head of a group of entities. The financial information of this group is included in the consolidated financial statements of argenx SE.

Because we are ultimately responsible for the opinion, we are also responsible for directing, supervising and performing the group audit. In this respect we have determined the nature and extent of the audit procedures to be carried out for group entities. The audit procedures on all group entities have been performed by the group engagement team.

By performing the procedures mentioned above at group entities, together with additional procedures at group level, we have been able to obtain sufficient and appropriate audit evidence about the group's financial information to provide an opinion on the consolidated financial statements.

Audit Approach Fraud Risks

We identified and assessed the risks of material misstatements of the financial statements due to fraud. During our audit we obtained an understanding of the entity and its environment and the components of the system of internal control, including the risk assessment process and management's process for responding to the risks of fraud and monitoring the system of internal control and how the Board of Directors exercises oversight, as well as the outcomes.

We evaluated the design and relevant aspects of the system of internal control and in particular the fraud risk assessment, as well as among others the code of conduct, whistle blower procedures and incident registration. We evaluated the design and the implementation and, where considered appropriate, tested the operating effectiveness, of internal controls designed to mitigate fraud risks.

As part of our process of identifying fraud risks, we evaluated fraud risk factors with respect to financial reporting fraud, misappropriation of assets and bribery and corruption in close co-operation with our forensic specialists. We evaluated whether these factors indicate that a risk of material misstatement due to fraud is present.

We identified the following fraud risk and performed the following specific procedures:

- We identified a risk of material misstatement due to fraud related to management override of controls. Management is in a unique position to perpetrate fraud because of management's ability to manipulate accounting records and prepare fraudulent financial statements by overriding controls that otherwise appear to be operating effectively.

- We incorporated elements of unpredictability in our audit. We also considered the outcome of our other audit procedures and evaluated whether any findings were indicative of fraud or non-compliance.

- We considered available information and made enquiries of relevant management team members (including the Chief Executive Officer, Chief Operating Officer, Chief Financial Officer, General Counsel, Global Head of Quality, Global Head of Compliance, and Chief Medical Officer) and the Board of Directors.

- We tested the appropriateness of journal entries recorded in the general ledger and other adjustments made in the preparation of the financial statements.

- We evaluated whether the selection and application of accounting policies by the group, particularly those related to subjective measurements and complex transactions, may be indicative of fraudulent financial reporting.

- We evaluated whether the judgments and decisions made by management in making the accounting estimates included in the financial statements indicate a possible bias that may represent a risk of material misstatement due to fraud. Management insights, estimates and assumptions that might have a major impact on the financial statements are disclosed in note 3. Critical accounting estimates and judgments of the financial statements. Reference is made to the section 'Our key audit matters'.

- For significant transactions and transactions of interest, for instance regarding donations to patient charities, we evaluated whether the business rationale of the transactions suggests that they may have been entered into to engage in activities in relation to bribery and corruption.

This did not lead to indications for fraud potentially resulting in material misstatements.

Audit Approach Compliance with Laws and Regulations

We assessed the laws and regulations relevant to the Company through discussion with the General Counsel, the Head of Global Quality and the Head of Global Compliance, reading minutes and reports of internal audit.

We involved our forensic specialists in this evaluation.

As a result of our risk assessment procedures, and while realizing that the effects from non-compliance could considerably vary, we considered the following laws and regulations: adherence to (corporate) tax law and financial reporting regulations, the requirements under the International Financial Reporting Standards as adopted by the European Union (EU-IFRS) and Part 9 of Book 2 of the Dutch Civil Code with a direct effect on the financial statements as an integrated part of our audit procedures, to the extent material for the related financial statements.

We obtained sufficient appropriate audit evidence regarding provisions of those laws and regulations generally recognized to have a direct effect on the financial statements.

Apart from these,argenx SE is subject to other laws and regulations where the consequences of non- compliance could have a material effect on amounts and/or disclosures in the financial statements, for instance, through imposing fines or litigation.

Given the nature of argenx SE‘s business and the complexity of FDA regulations and other healthcare authority regulations, there is a risk of non-compliance with the requirements of such laws and regulations. In addition, we considered major laws and regulations applicable to listed companies.

Our procedures are more limited with respect to these laws and regulations that do not have a direct effect on the determination of the amounts and disclosures in the financial statements. Compliance with these laws and regulations may be fundamental to the operating aspects of the business, to argenx SE‘s ability to continue its business, or to avoid material penalties (e.g., compliance with healthcare regulations) and therefore non-compliance with such laws and regulations may have a material effect on the financial statements. Our responsibility is limited to undertaking specified audit procedures to help identify non- compliance with those laws and regulations that may have a material effect on the financial statements. Our procedures are limited to (i) inquiry of management, the Board of Directors and others within argenx SE as to whether argenx SE is in compliance with such laws and regulations and (ii) inspecting correspondence, if any, with the relevant licensing or regulatory authorities to help identify non-compliance with those laws and regulations that may have a material effect on the financial statements.

Naturally, we remained alert to indications of (suspected) non-compliance throughout the audit.

Finally, we obtained written representations that all known instances of (suspected) fraud or non-compliance with laws and regulations have been disclosed to us.

Audit Approach Going Concern

As explained in the note 2.1 "**Statement of Compliance and Basis of Preparation**" and note 26 "**Financial Risk Management**" of the financial statements, management has prepared the financial statements of argenx SE based on the going concern assumption. No events or circumstances have been identified which cause significant doubt about the entity's ability to continue its operations (going concern risks). Our procedures to evaluate the going concern assessment of management include:

- Consider whether management's assessment of going concern contains all relevant information of which we are aware as a result of our audit and review of the other information. In addition, we inquired with management about the key assumptions underlying the going concern assessment.
- Inquiry with management regarding their knowledge of events and/or circumstances beyond the period of management's assessment.
- We reconciled the cash and cash equivalents position as used in the going concern assessment to the audited position at December 31, 2022.
- We evaluated managements' financial forecasts and analysis prepared for a period of at least 12 months from the date of preparation of the financial statements. This included consideration of the reasonableness of key underlying assumptions by evaluating historically realized and future expected operating and capital expenditure as well as evaluating mathematical accuracy of the assessment.
- We evaluated the adequacy of disclosures made in the financial statements in respect of going concern.

Our audit procedures did not produce results that were inconsistent with management's assumptions and judgments in applying the going concern assumption.

Our Key Audit Matters

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the financial statements. We have communicated the key audit matters to the Board of Directors. The key audit matters are not a comprehensive reflection of all matters discussed.

Product Net Sales — Refer to Note 15 & 18 to the Financial Statements

Description

The Company recognizes product net sales of USD 400.7 million, relating to the sale of their product VYVGART, as specified in **note 15** and **18** to the financial statements. These product sales are accounted for in accordance with IFRS 15 Revenue from Contracts with Customers (***IFRS 15***), whereby the sale of VYVGART to customers is recognized for an amount that reflects the consideration to which the Company expects to be entitled in exchange for these goods. The majority of the product gross sales are in the United States of America, which are subject to various deductions which are primarily composed of rebates to government agencies, distributors, health insurance companies and managed healthcare organizations.

Together, these deductions are referred to as gross-to-net (***GtN***) adjustments. The GtN adjustments that are recognized by the Company represent estimates of the related obligations that will be settled in a future period. The estimated amounts are based on contractual arrangements with healthcare authorities, government and state programs, and gross sales and third-party data.

We identified the GtN adjustments for product net sales in the United States of America as a key audit matter, because of the significant effort spent on auditing these adjustments and the judgment required to obtain sufficient appropriate audit evidence that supports the Company's estimate, due to the reporting data being subject to a time lag.

Our response

Our audit procedures related to the gross-to-net included the following, among others:

- We evaluated the key revenue contracts and supply chain contracts, including evaluation of the accounting treatment of the GtN adjustments and the disclosures thereof in accordance with IFRS 15.
- We evaluated the independent service auditor reports for the service providers used by the Company to process rebates on behalf of the Company.
- We evaluated the Company's methodology and assumptions in developing the GtN adjustments, including testing the completeness and accuracy of the underlying data used by management in their estimates.
- We evaluated the Company's ability to estimate the GtN adjustments by evaluating the historical accuracy of estimates made during the year.

Observations

The scope and nature of the audit procedures we performed was sufficient and appropriate to address the risks of material misstatement related to the GtN adjustments.

In comparison with prior year, we have not included the key audit matters around the R&D accruals and the accounting treatment of the Zai collaboration. The complexity of the estimates related to the R&D accruals decreased as a result of a change in internal processes. The accounting treatment of the Zai collaboration was related to the initial accounting treatment and as such was no longer identified as a key audit matter.

Report on the Other Information Included in the Annual Report

The Annual Report contains other information, in addition to the financial statements and our auditor's report thereon.

The other information consists of:

- Management's Report, including, amongst others, the Remuneration Report and Compensation Statement, and Non-Financial Information.
- Other Information as required by Part 9 of Book 2 of the Dutch Civil Code.

Based on the following procedures performed, we conclude that the other information:

- Is consistent with the financial statements and does not contain material misstatements.
- Contains all the information regarding the management report and the other information as required by Part 9 of Book 2 of the Dutch Civil Code.

We have read the other information. Based on our knowledge and understanding obtained through our audit of the financial statements or otherwise, we have considered whether the other information contains material misstatements.

By performing these procedures, we comply with the requirements of Part 9 of Book 2 of the Dutch Civil Code and the Dutch Standard 720. The scope of the procedures performed is substantially less than the scope of those performed in our audit of the financial statements.

Management is responsible for the preparation of the other information, including Management's Report in accordance with Part 9 of Book 2 of the Dutch Civil Code, and the other information as required by Part 9 of Book 2 of the Dutch Civil Code.

Report on Other Legal and Regulatory Requirements and ESEF

Engagement

We were engaged by the Board of Directors as auditor of argenx SE on May 13, 2015, as of the audit for the year 2015 and have operated as statutory auditor ever since that financial year.

No Prohibited Non-Audit Services

We have not provided prohibited non-audit services as referred to in Article 5(1) of the EU Regulation on specific requirements regarding statutory audit of public-interest entities.

European Single Electronic Format (ESEF)

argenx SE has prepared its annual report in ESEF. The requirements for this are set out in the Commission Delegated Regulation (EU) 2019/815 with regard to regulatory technical standards on the specification of a single electronic reporting format (hereinafter: the RTS on ESEF).

In our opinion, the annual report, prepared in XHTML format, including the (partly) marked-up consolidated financial statements, as included in the reporting package by argenx SE complies in all material respects with the RTS on ESEF.

Management is responsible for preparing the annual report including the financial statements in accordance with the RTS on ESEF, whereby management combines the various components into a single reporting package.

Our responsibility is to obtain reasonable assurance for our opinion whether the annual report in this reporting package complies with the RTS on ESEF.

We performed our examination in accordance with Dutch law, including Dutch Standard 3950N 'Assurance- opdrachten inzake het voldoen aan de criteria voor het opstellen van een digitaal verantwoordingsdocument' (assurance engagements relating to compliance with criteria for digital reporting).

Our examination included amongst others:

- Obtaining an understanding of the company's financial reporting process, including the preparation of the reporting package.
- Identifying and assessing the risks that the annual report does not comply in all material respects with the RTS on ESEF and designing and performing further assurance procedures responsive to those risks to provide a basis for our opinion, including:
  - obtaining the reporting package and performing validations to determine whether the reporting package containing the Inline XBRL instance and the XBRL extension taxonomy files has been prepared in accordance with the technical specifications as included in the RTS on ESEF;
  - examining the information related to the consolidated financial statements in the reporting package to determine whether all required mark-ups have been applied and whether these are in accordance with the RTS on ESEF.

Description of Responsibilities Regarding the Financial Statements

Responsibilities of Management and the Board of Directors for the Financial Statements

Management is responsible for the preparation and fair presentation of the financial statements in accordance with EU-IFRS and Part 9 of Book 2 of the Dutch Civil Code. Furthermore, management is responsible for such internal control as management determines is necessary to enable the preparation of the financial statements that are free from material misstatement, whether due to fraud or error.

As part of the preparation of the financial statements, management is responsible for assessing the company's ability to continue as a going concern. Based on the financial reporting frameworks mentioned, management should prepare the financial statements using the going concern basis of accounting unless management either intends to liquidate the company or to cease operations, or has no realistic alternative but to do so.

Management should disclose events and circumstances that may cast significant doubt on the company's ability to continue as a going concern in the financial statements.

The Board of Directors is responsible for overseeing the company's financial reporting process.

Our Responsibilities for the Audit of the Financial Statements

Our objective is to plan and perform the audit assignment in a manner that allows us to obtain sufficient and appropriate audit evidence for our opinion.

Our audit has been performed with a high, but not absolute, level of assurance, which means we may not detect all material errors and fraud during our audit.

Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements. The materiality affects the nature, timing and extent of our audit procedures and the evaluation of the effect of identified misstatements on our opinion.

We have exercised professional judgement and have maintained professional scepticism throughout the audit, in accordance with Dutch Standards on Auditing, ethical requirements and independence requirements. Our audit included among others:

- Identifying and assessing the risks of material misstatement of the financial statements, whether due to fraud or error, designing and performing audit procedures responsive to those risks, and obtaining audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtaining an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.
- Evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.
- Concluding on the appropriateness of management's use of the going concern basis of accounting, and based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the company to cease to continue as a going concern.
- Evaluating the overall presentation, structure and content of the financial statements, including the disclosures.
- Evaluating whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

Because we are ultimately responsible for the opinion, we are also responsible for directing, supervising and performing the group audit. In this respect we have determined the nature and extent of the audit procedures to be carried out for group entities. Decisive were the size and/or the risk profile of the group entities or operations. On this basis, we selected group entities for which an audit or review had to be carried out on the complete set of financial information or specific items.

We communicate with the Board of Directors regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant findings in internal control that we identified during our audit. In this respect we also submit an additional report to the audit committee in accordance with Article 11 of the EU Regulation on specific requirements regarding statutory audit of public- interest entities. The information included in this additional report is consistent with our audit opinion in this auditor‘s report.

We provide the Board of Directors with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated with the Board of Directors, we determine the key audit matters: those matters that were of most significance in the audit of the financial statements. We describe these matters in our auditor‘s report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, not communicating the matter is in the public interest.

Rotterdam, March 16, 2023
Deloitte Accountants B.V.
V. Fruytier

8 Non-Financial Information

8 Non-Financial Information

8.1 Regulations and Compliance

The Company recognizes the importance of non-financial factors in creating long-term financial value, which involves identifying and mitigating aspects of economic activities that undermine non-financial value, as well as identifying and seizing opportunities to create the long-term value. We are dedicated to conducting our business in a safe and environmentally sustainable manner as part of our commitment to not only improve the lives of patients we hope to serve, but also to positively impact our stakeholders.

The Company encourages the recently increased regulation in this area and does its utmost to comply with applicable regulations to the best of its ability. Since last year, we became subject to the Directive 2014/95/EU of the European Parliament and of the Council of 22 October 2014 amending Directive 2013/34/EU as regards disclosure of non-financial and diversity information by certain large undertakings and groups (***NFRD***), as implemented in Dutch law and the Regulation (EU) 2020/852 of the European Parliament and of the Council of 18 June 2020 on the establishment of a framework to facilitate sustainable investment, and amending Regulation (EU) 2019/2088 (***EU Taxonomy Regulation***) and ancillary delegated regulations.

In this section 8, we make all disclosures required for our compliance with NFRD and the EU Taxonomy Regulation, and ancillary legislation and guidelines applicable to us. In addition to the non-financial disclosures made in this Annual Report, we have published a separate and dedicated report on ESG in 2021, of which an updated version will be published in the second quarter of fiscal 2023, in which we give more context as well as additional, voluntary disclosures on ESG and related subjects.

8.2 NFRD

8.2.1 Introduction to the NFRD

The NFRD requirements, applicable to argenx are included in Article 29a of Directive 2013/34/EU (***Accounting Directive***). Article 29a of the Accounting Directive is implemented in Dutch law under Article 391 of Book 2 of the DCC in the Decree on the contents of the management report (*Besluit inhoud bestuursverslag*), in the Decree on the establishment of further provisions on the content of the annual report (*Besluit tot vaststelling van nadere voorschriften omtrent de inhoud van het jaarverslag*) and in the Decree on the publication of non-financial information (*Besluit bekendmaking niet-financiële informatie*).

The NFRD requires 'large companies' to provide information on how they address and manage social and environmental challenges. In particular, companies are required to report on social, employee and environmental matters, human rights, bribery and anti-corruption, as well as board diversity.

8.2.2 Compliance with the NFRD

On the basis of the above-mentioned Decrees, the Company is required to publish non-financial information in (consolidated) non-financial statements. To this end, the table below provides for the required disclosures.

Subtopic	Disclosure
Social and employee matters	
A brief description of the undertaking's business model	At argenx, we are on a journey together to achieve the unthinkable. We are all working hard to build an integrated, immunology company improving the lives of patients. As we continue to scale up the business to achieve this vision, it is critical that we do so with integrity and passion. When each of us acts with honesty and integrity, we gain the trust of our colleagues, patients and communities. We are dedicated to fostering a workplace where all people feel free to share their thoughts and ideas. And we insist on building and maintaining a safe and secure work environment, where no one is subject to unnecessary risk. We commit to developing our people based on their strengths, to the benefit of the broader team. We comply with international labor standards as well as applicable labor and employment laws, wherever we operate. This includes prohibiting child labor and forced labor, upholding the right to freedom of association, and eliminating discrimination at work. When selecting our business associates, we strive to work with third parties who share our commitment to respecting and improving human rights, and we do not conduct business with any individual or company that participates in forced, bonded or indentured labor or involuntary prison labor, the exploitation of children (including child labor), harsh or inhumane treatment or threat of any such treatment or any form of modern slavery or human trafficking. We believe open communication is critical to guaranteeing a positive work environment and our ultimate success. We understand that to make a difference we need to foster a culture of openness, where colleagues are encouraged to share their thoughts and ideas because diversity of thought leads to and empowers innovation. We actively listen to our colleagues and make sure all voices are heard.

Subtopic	Disclosure
Social and employee matters	
A description of the policies pursued, including due diligence processes	Our Code of Conduct reflects our core values: a way of working that celebrates innovation, co-creation, excellence, humility, and empowerment. Our Code of Conduct translates the core values into a set of clear standards to help guide our conduct as we navigate the complexities of the highly regulated and competitive global marketplace in which we operate as we work to become an independent, fully integrated, and global immunology company. Our commitment to the Code of Conduct enables our core business of innovation and our culture of collaboration. We are all dedicated to and responsible for its success. Each of us contributes to our reputation by living our core values every day and making the best choices for argenx and the many people we serve. Our Code of Conduct sets out core principles for the way we commit to important employee and social matters, including our commitment to maintaining the highest scientific and ethical standards in our research and development activities and complying with all internationally accepted standards that apply to our clinical trials, including the ICH Guidelines for Good Clinical Practice and the ethical principles articulated in the Declaration of Helsinki, as well as applicable local laws and regulations. We monitor compliance with these standards through a number of policies which we regularly train relevant employees on. We operate a personal development program in which we encourage all employees to participate. We operate short-term and long-term incentive plans to encourage attraction and retention of qualified personnel. We take a stance against all forms of discrimination and commit to promoting diversity, equity and inclusion as set out in our Code of Conduct and in our diversity, equity and inclusion policy. We encourage respect of the individual, their integrity and their dignity, by ensuring that the working environment and relations between colleagues are free of discrimination and harassment, whether based on race, religion, color, political convictions, sex, language, pregnancy, ethnic or national origin, civil state, social status, sexual orientation, handicap, age or otherwise. We will protect any colleague who in good faith believes they are victims of harassment or discrimination. This includes actions that can reasonably be considered offensive, intimidating or discriminatory, including sexual harassment, power harassment and bullying, whether physical, verbal or visual. We encourage colleagues to speak up against any incident that could be viewed as harassment or discrimination and to support those affected. Once informed, we will take all measures required to stop any such behavior and to deal appropriately with the person or persons involved. The matter will be treated with discretion and diligence. We strictly prohibit retaliation or retribution against anyone who in good faith reports a concern about harassment, discrimination, or other issues, or cooperates with an investigation into alleged harassment and discrimination, even if the initial concern is ultimately determined to be unfounded, as is further set out in our Speak-up Policy.
The outcome of those policies	All employees have accepted and are trained (and retrained annually) on our Code of Conduct, and accepting, and committing to, the contents thereof is expected of all newcomers to argenx. At the date of this Annual Report, for the fiscal year ended December 31, 2022, we have not identified any material breaches of our Code of Conduct in relation to social or employee matters.
Principal risks	Our employees and relevant third parties may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could have a material adverse effect on our business. Our future growth and ability to compete depends in part on our ability to retain key personnel and recruit additional qualified personnel.

Subtopic	Disclosure
Social and employee matters	
How these risks are managed	In order to maintain oversight over compliance with the our Code of Conduct and other company policies including in relation to potential violations in the area of employee and social matters, and to increase compliance and ensure our colleagues know where to go with questions on the Code of Conduct and its application, we have established the argenx COMPASS Helpline, where our employees can raise any concerns they may have regarding potential violations of our policy confidentially or anonymously (to the extent allowed by law). We revised our Whistleblower Policy into our new Speak-up Policy to comply with Directive (EU) 2019/1937 of the European Parliament and of the Council of 23 October 2019 on the protection of persons who report breaches of Union EU law, which policies (jointly our ***Speak Up and Anti-retaliation Policy***) enables and encourages our employees to speak up and report any suspected violation of our Code of Conduct, and to protect employees from retaliation. We have set-up a specific helpline reachable through different channels including by phone, also anonymously, to report any suspected potential violations. Also to mitigate the risks of non-compliance with our Code of Conduct in relation to employee and social matters, we require all new employees to confirm their acceptance and adherence to the Code of Conduct and we train existing and new employees annually on our Code of Conduct and our Speak-up Policy. We offer competitive remuneration packages and share-based incentives in the form of an Equity Incentive Plan in which all employees are offered the opportunity to participate. We perform periodic benchmark analyses with an external service provider to ensure the competitiveness of the compensation offered to our key personnel in comparison to other (reference group) companies. We pay close attention to creating an environment that supports the further development of the talents of our key people, including through our personal development plan program.
Non-financial key performance indicators	At the date of this Annual Report, for the fiscal year ended December 31, 2022, we have not identified any material breaches of our Code of Conduct in relation to social or employee matters. Our voluntary employee turnover rate for the fiscal year 2022 is 4.27% and our involuntary employee turnover rate for the fiscal year 2022 was 2.25%, both numbers we believe to be below industry averages.

Subtopic	Disclosure
Environmental matters	
A brief description of the undertaking's business model	argenx is dedicated to conducting its business in a safe and environmentally sustainable manner as part of our commitment to not only improve the lives of patients we hope to serve, but also to positively impact our colleagues, business partners, and surrounding communities as well. In an effort to do this we: • comply with environmental laws and regulations that are related to our specific work and responsibilities. • encourage colleagues to respect the environment and natural resources available to us by taking sustainability steps like limiting energy use, reducing waste, and recycling. • have awareness and training programs to teach our employees how to deal with different waste systems. We are committed to expanding and developing our sustainability initiatives in the future. Given the present state of scientific knowledge, it is not possible to examine the complex interactions in a living organism solely by the use of modeling or performing experiments in cell cultures and tissue samples. Research using living animals remains essential in the discovery, development and production of new medicines. We cannot replace all animal experiments in the foreseeable future, but we continuously review the welfare and use of animals and develop procedures that reduce or replace animal experiments. If we engage in research using live animals, we follow all applicable laws and regulations, and argenx policies including our Animal Welfare Policy.
A description of the policies pursued, including due diligence processes	We do not currently have an environmental policy. We conduct our activities within the environmental regulatory framework set out by those jurisdictions in which we operate in and have obtained all required environmental licenses and permits. With the goal of mitigating the risk of failure to obtain any required environmental permits or licenses, or of losing granted permits or licenses we may need to operate our business, we regularly evaluate the requirements of such environmental permits and licenses to ensure continued compliance. We commit to treating research animals in a humane and responsible manner, in accordance with Code of Conduct and our Animal Welfare Policy. Our Animal Welfare Policy requires us to perform due diligence on third party collaborators who engage in research activities on our behalf, by reviewing their external certification on this topic (such as Association for Assessment and Accreditation of Laboratory Animal Care International certification) or if they have not (yet) been certified, by performing our own confirmatory due diligence through reviews and/or interviews or written questions and answers to gain comfort that the standards applied are at the same level as our internal standards on this topic. Compliance, audits and certification of all third parties is overseen by a management-level Animal Welfare Committee, who are responsible for organizing regular lab visits in the EU. Where we are unable to perform in-person audits at our U.S.-based academic collaborators, or elsewhere, our audits are performed virtually.
The outcome of those policies	All employees have accepted and are trained (and retrained annually) on our Code of Conduct, and accepting, and committing to, the contents thereof is expected of all newcomers to argenx. At the date of this Annual Report, for the fiscal year ended December 31, 2022, we have not identified any material breaches of our Code of Conduct in relation to environmental matters.

Subtopic	Disclosure
Environmental matters	
Principal risks	We have assessed our activities to date and did not identify specific risks of material environmental violations and as such we have not identified environmental risks as principal risks for argenx. 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. We may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities. Our personnel could breach the animal welfare commitments set out in our Code of Conduct or our Animal Welfare Policy.
How these risks are managed	We comply with environmental laws and regulations that are related to our specific work and responsibilities and offer training to our employees depending on their area of work. In addition, we have a dedicated safety advisor and facility manager supervising compliance with environmental law on our premises. All employees receive health and safety training relevant to their specific job role. We train all personnel involved in research activities with live animals, on our Animal Welfare Policy. The COMPASS Helpline enables us to maintain oversight over compliance with our Code of Conduct and other Company policies including in relation to potential violations in the area of environmental matters, and to increase compliance and ensure our colleagues know where to go with questions on the Code of Conduct and its application. Employees can raise any concerns they may have regarding potential violations of our Code of Conduct confidentially or anonymously (to the extent allowed by law) through our COMPASS Helpline, including in relation to violations of our Code of Conduct on environmental matters or in relation to violations of our Animal Welfare Policy.
Non-financial key performance indicators	At the date of this Annual Report, for the fiscal year ended December 31, 2022, we have not identified any material breaches of our Code of Conduct in relation to environmental matters, and we have not identified any material breaches of our Animal Welfare Policy.
Matters with respect to human rights	
A brief description of the undertaking's business model	At argenx, we are on a journey together to achieve the unthinkable. We are all working hard to build an integrated, immunology company and reach patients. As we continue to scale up the business to achieve this vision, it is critical that we do so with integrity and passion. When each of us acts with honesty and integrity, we gain the trust of our colleagues, patients and communities.
A description of the policies pursued, including due diligence processes	We commit to compliance with international labor standards as well as applicable labor and employment laws, wherever we operate. This includes prohibiting child labor and forced labor, upholding the right to freedom of association, and eliminating discrimination at work. When selecting our business associates, we strive to work with third parties who share our commitment to respecting and improving human rights, and we do not conduct business with any individual or company that participates in forced, bonded or indentured labor or involuntary prison labor, the exploitation of children (including child labor), harsh or inhumane treatment or threat of any such treatment or any form of modern slavery or human trafficking. Our Code of Conduct includes our commitment to respecting the human rights of all people and ensure fairness in the workspace. All our personnel is trained annually on our Code of Conduct including its provisions on respecting human rights. Accepting, and committing to, the contents of the aforementioned Code of Conduct is expected of all newcomers to argenx.

Subtopic	Disclosure
Matters with respect to human rights	
The outcome of those policies	In fiscal year were no alleged breaches of our Code of Conduct on the topics of human rights or alleged forced labor or child labor.
Principal risks	We have assessed our activities to date and did not identify specific risks of violations of human rights in relation to our business activities and as such we have not identified the risk of violations of human rights as principal risk for argenx.
How these risks are managed	In order to maintain oversight over compliance with the our Code of Conduct and other company policies including in relation to potential violations in the area of human rights, and to increase compliance and ensure our colleagues know where to go with questions on the Code of Conduct and its application, we have established the argenx COMPASS Helpline, where our employees can raise any concerns they may have regarding potential violations of our policy confidentially or anonymously (to the extent allowed by law), including in relation to violations of our Code of Conduct on human rights related topics.
Non-financial key performance indicators	In fiscal year 2022 there were no alleged breaches of our Code of Conduct on the topics of human rights or alleged forced labor or child labor.
Matters with respect to anti-corruption and bribery	
A brief description of the undertaking's business model	We work with healthcare professionals for the benefit of all. The spirit of co-creation is one of our core values. To provide better, more effective products for patients, we regularly engage healthcare professionals to provide various services in support of our business. The services provided by healthcare professionals include clinical investigations, advisory services, and speaking engagements at argenx events.
A description of the policies pursued, including due diligence processes	At argenx, we promote our products ethically and honestly, and only for the uses for which they have been approved. We believe that healthcare professionals and patients have the right to decide the most appropriate treatment options available based on truthful, accurate, and balanced product information that is supported by scientific evidence and is consistent with approved product labeling. We only use promotional material and other product information that have been approved through our internal review process. When acting in a promotional capacity, colleagues and agents of argenx are required to always give a balanced presentation of our products, including relevant safety information. Whenever argenx hires a healthcare professional as a consultant, advisor, investigator, speaker, or in any other capacity, we require the following requirements are met: • There must be a documented legitimate business need for the services on the part of argenx. Business relationships must not be created as a disguised means to induce or reward healthcare professionals to prescribe, purchase, or recommend argenx products. • The selection of healthcare professionals must be based on their qualifications, expertise, capabilities, experience and other appropriate criteria directly related to the identified need. • A written contract must be executed prior to the commencement of the services that accurately describes the nature of the services and the basis for remuneration. • All compensation to healthcare professionals must reflect fair market value for the services provided. • Meetings or events organized or sponsored by argenx involving healthcare professionals' services must be held at appropriate venues that are conducive to the purpose of the meeting or event.

Subtopic	Disclosure
Matters with respect to anti-corruption and bribery	
	All arrangements (or reimbursement of expenses) for travel, lodging, and meals that are provided to healthcare professionals relating to their performance of services must be consistent with Company policies. We ensure that that we avoid even the perception of improper influence by refraining from offering gifts or other items of value.
The outcome of those policies	In fiscal year 2022, we did not identify any breaches of our Code of Conduct in relation to anti-corruption or antibribery matters.
Principal risks	We may be subject to healthcare laws, regulation and enforcement. Our failure to comply with these laws could harm our results of operations and financial conditions. Because many of our healthcare professional are also our customers, there is the risk that patients and others might perceive potential conflicts of interest, even when none exist. Failure to comply with applicable healthcare laws and regulations may lead to enforcement including civil and administrative penalties, fines or criminal prosecution and may cause us to incur significant costs and harm to our business and reputation.
How these risks are managed	To avoid even the suggestion of a conflict of interest, we conduct all interactions with healthcare professionals with the utmost integrity, scrupulously adhering to government and industry body regulations, as well as enforcing our own strict internal guidelines. We have designed and implemented a targeted compliance program consisting of a body of codes, policies and procedures, which we actively and regularly train all relevant personnel on. We have recruited a dedicated legal and compliance team to support and monitor compliance with relevant rules and regulations. Furthermore, all employees are trained annually on our Code of Conduct, including its provisions on anti-bribery and anti-corruption. Accepting, and committing to, the contents thereof is expected of all newcomers to argenx. We established the argenx COMPASS Helpline in order to maintain oversight over compliance with our Code of Conduct and other of our company policies including in relation to potential violations in the area of anti-bribery and anti-corruption, and to increase compliance and ensure our colleagues know where to go with questions on the Code of Conduct and its application. Employees can raise any concerns they may have regarding potential violations of our policy confidentially or anonymously (to the extent allowed by law), including in relation to violations of our Code of Conduct on human rights related topics.
Non-financial key performance indicators	In fiscal year 2022, we did not identify any breaches of our Code of Conduct in relation to anti-corruption or antibribery matters.

Subtopic	Disclosure
Insight into our diversity, equity and inclusion policy and practices	
A description of the policies pursued, including due diligence processes	We value diversity among our colleagues as an integral component in building a sustainable growth platform. We believe that a diverse workforce enhances our overall performance and success. We take pride in creating and sustaining a culture and environment where each of us can excel. We bring together people with diverse backgrounds experiences and functional expertise. By doing so, we broaden the scope of ideas and creativity essential to developing and delivering innovative therapies to patients. Acknowledging and benefiting from different perspectives promotes diversity of thought and empowers innovation. It also contributes to our commitment to improve lives of patients, wherefore we need teams with a healthy mix of contrasting perspectives and backgrounds that reflect the diverse communities we serve. We recognize that our people are our greatest strength. Fostering an inclusive work environment where everyone feels safe and encouraged to contribute leads to better work outcomes and supports high levels of employee commitment and retention. We aspire to be a consciously global company. Our success is built on, and dependent on true collaboration in cross-functional and often cross-regional teams in which open communication is encouraged and safeguarded. Everyone has a voice and is encouraged to contribute to the benefit of our common goals, irrespective of race, ethnicity, age, gender or cultural background. Good ideas as well as real concerns are taken seriously, regardless of who brings them forward.
How our diversity, equity and inclusion policy is being implemented.	Our diversity, equity and inclusion policy is implemented in the way we recruit, develop and promote our employees and Board of Directors. We value our fair, inclusive recruitment process, which is standardized across the organization and focuses on pre-identified 'what counts' factors. The process involves a diverse group of colleagues from across the organization, who are provided with training to recognize any existing biases. Recruitment decisions are based on a group evaluation of available candidates, ensuring different perspectives. Our onboarding program is designed to promote inclusion by building a strong social fabric across teams, functions and geographic locations. Furthermore, all employees are encouraged to participate in a personal development program aimed at building on their individuals strengths to benefit the broader team. We offer opportunities for promotion, training and career development solely based on job-related, appropriate criteria such as skills, competencies, experience, aptitude and enthusiasm and giving account to each individual's experience, ambitions and capabilities. We will continue to implement our diversity, equity and inclusion policy by seeking new ways to improve and support diversity, equity and inclusion in our company.
Diversity targets	We aim to foster an inclusive work environment in support of our strategic plan and priorities. We continue to raise the bar in this regard, and to commit to measures and goals designed to support our maturing company culture. We aim to have an equal gender balance in our Board of Directors and in our Company leadership (including functional leaders and project leaders).

Subtopic	Disclosure
Insight into our diversity, equity and inclusion policy and practices	
The outcome of those policies, results of the Diversity, Equity and Inclusion Policy	As of December 31, 2022, our Board of Directors consisted of 9 directors, including 1 executive director and 8 non-executive directors. The full board contained 6 male directors (including 1 executive director) and 3 female directors (non-executive directors), translating into a 66% male / 33% female balance for our full Board of Directors and a 71.4% male / 28.6% female balance for our non-executive directors. As of December 31, 2022, we estimate that our company leadership team consisted of 31 persons of whom 19 identified as male (61%) and 12 identified as female (39%). For the purpose of this statement we defined the leadership team as consisting of our C-level people as well as the leaders of our largest functions and projects. Each of these positions is characterized by a high impact across the organization, leading a global and cross functional team and having a global reach. As of December 31, 2022, 63% of the members of our workforce who disclosed their gender identity, were female, and 37% male.

8.3 EU Taxonomy

8.3.1 Introduction to the EU Taxonomy Regulation

The **EU Taxonomy Regulation** entered into force on July 12, 2020 and establishes the general framework for determining whether an economic activity qualifies as environmentally sustainable for the purposes of establishing the degree to which an investment is environmentally sustainable. The EU taxonomy framework will develop over time.

On April 21, 2021, the EU Commission adopted the Commission Delegated Regulation (EU) 2021/2139 of June 4, 2021 supplementing Regulation (EU) 2020/852 of the European Parliament and of the Council by establishing the technical screening criteria for determining the conditions under which an economic activity qualifies as contributing substantially to climate change mitigation or climate change adaptation and for determining whether that economic activity causes no significant harm to any of the other environmental objectives (the ***Climate Delegated Act***), which became effective in January 2022.

The EU Commission further adopted the Commission Delegated Regulation (EU) 2021/2178 of 6 July 2021 supplementing Regulation (EU) 2020/852 of the European Parliament and of the Council by specifying the content and presentation of information to be disclosed by undertakings subject to Articles 19a or 29a of Directive 2013/34/EU concerning environmentally sustainable economic activities, and specifying the methodology to comply with that disclosure obligation (the ***Article 8 CDR***), which also became effective in January 2022.

On March 9, 2022, the EU Commission adopted a complementary climate delegated act including, under strict conditions, specific nuclear and gas energy activities in the list of economic activities covered by the EU taxonomy. It was published in the Official Journal on July 15, 2022 and became effective in January 2023.

In this section we present our compliance with the EU Taxonomy Regulation, the Climate Delegated Act, the Article 8 CDR and ancillary legislation applicable to us.

8.3.2 Compliance with the EU Taxonomy Regulation

In 2022 we performed a reassessment of all potential taxonomy-eligible economic activities listed in the Climate Delegated Act based on our activities as a biopharmaceutical group for the current year's activity. The Climate Delegated Act focuses on those economic activities and sectors that have the greatest potential to achieve the objective of climate change mitigation or climate change adaption. The sectors covered include energy, selected manufacturing activities, transport and buildings. Our assessment methodology is listed below.

Companies are required to identify if their activities are eligible under the EU Taxonomy Regulation. Our main activity is NACE 72.11 – Research and experimental development on biotechnology. Our assessment of taxonomy-eligibility is focused on economic activities, defined as the provision of goods or services on a market, thus (potentially) generating revenues. In this context, we, as a commercial-stage biopharmaceutical group, define the research and development and marketing of pharmaceutical products as the core of our business activities. We define activities such as the manufacturing or the transport of our pharmaceutical products to our clients as underlying activities necessary to conduct our core business activities.

Turnover Eligibility and Alignment

These activities do not contribute to climate adaptation or climate mitigation, therefore, they are not reported as taxonomy-eligible activities and not included in our turnover key performance indicators (***KPI***). We have concluded that as eligibility is nil, alignment related to turnover is also considered to be nil and totals 0%. Our net turnover KPI denominator totals $400.7 million. Non-financial undertakings related to turnover are included in the consolidated financial statements, under footnote 15, product net sales.

We will continue to monitor any future reporting obligations and their impact, including the addition of four new taxonomy environmental objectives. We acknowledge these additional requirements and will include these calculations in future assessments.

CapEx Eligibility and Alignment

We have reviewed our core and non-core activities related to CapEx as defined by the taxonomy regulations in accordance with the updated requirements relating to the fiscal year 2022. These activities do not contribute to climate adaptation or climate mitigation. We have concluded that as eligibility is nil, alignment related to CapEx is also considered to be nil and totals 0%. We have concluded that our denominator for calculation of CapEx KPIs, covering tangibles and intangible assets during the financial year (as listed in Annex I, point 1.1.2.1 of Article 8 CDR) total $108.2 million. Non-financial undertakings related to CapEx are listed in the consolidated financial statements, included in footnote 4, property, plant and equipment and footnote 5, Intangible assets.

We will continue to monitor any future reporting obligations and their impact, including the addition of four new taxonomy environmental objectives. We acknowledge these additional requirements and will include these calculations in future assessments.

After a thorough review involving all relevant divisions and functions, we concluded that our core and non-core economic activities related to CapEx are not covered by the Climate Delegated Act and consequently are taxonomy-non-eligible and total 0%.

OpEx Eligibility and Alignment

We have reviewed our core and non-core activities related to OpEx as defined by the taxonomy regulations in accordance with the updated requirements relating to the fiscal year 2022. These activities do not contribute to climate adaptation or climate mitigation; therefore, they are not reported as taxonomy-eligible activities

Additionally, we note that our non-core activities are non-taxonomy eligible, as we do not own or independently manage our offices or research sites and therefore any actions to improve energy efficiency are controlled by the building leaseholder, additionally, we do not manufacture or transport our products.

We have concluded that as eligibility is nil, alignment related to OpEx is also considered to be nil and totals 0%. We have concluded that our denominator for calculation of OpEx KPIs, covering non-capitalised costs such as research and development, building renovation, short-term lease, maintenance and repair, and day to day service of plant, property and equipment during the financial year (as listed in Annex I, point 1.1.3.1 of Article 8 CDR), total $663.4 million across research and development only, as the remaining topics defined are not currently part of operational expenditure. We acknowledge the addition of four new environmental objectives for assessment in future Taxonomy eligibility assessments and will continue to monitor, evaluate, and report against these criteria if eligible.

After a thorough review involving all relevant divisions and functions, we concluded that our core and non-core economic activities related to OpEx are not covered by the Climate Delegated Act and consequently are taxonomy-non-eligible and total 0%.

Future EU Taxonomy disclosures

We are committed to the continual and ongoing assessment of our taxonomy eligibility on an annual basis, we recognise the expansion of the taxonomy to include four new environmental objectives, should our economic activity become material in future years we will ensure to disclose our turnover, CapEx and OpEx KPIs in a tabular format in accordance with Annex II of Article 8 CDR. This table is currently not included for the reasons mentioned above, notably due to the fact that we concluded that our activities qualify as taxonomy-non-eligible activities (concurrently resulting in the absence of any taxonomy-eligible activities) and nil alignment with the environmental objectives listed under the EU Taxonomy Regulation, which will be reviewed annually.

9 Glossary

9 Glossary

9.1 Cross Reference table for annual reporting requirement

The following list of cross references identifies where each item required for us to disclose in our yearly financial report can be found in this Annual Report.

Source of Requirement	Topic	Location	
Article 2:391 DCC, RJ 400, RJ 405	Report on the Company's activities		Shareholder Letter
		1	Presentation of the Group
	Corporate structure	4	General description of the Company and its Share Capital
	Board of Directors report	3	Corporate Governance
	Primary risks and uncertainties	2	Risk Factors
	Risk appetite & control	3.5	Risk Appetite & Control
	Analysis of financial condition and results	5	Operating and Financial Review
	Information on research and development activities	1.3	Our Products and Product Candidates
		1.4	Collaboration Agreements
		1.5	License Agreements – General
	Forward looking paragraph		2023 Outlook
	Compensation statements and remuneration report	3.4	Remuneration Report and Compensation Statement
RJ 430	Key figures, ratios etc.	5	Operating and Financial Review
Article 2:392 DCC/RJ 410	Auditor's opinion	7	Attached to the 2022 Annual Report included herein
	Articles of association on the distribution of profits	4.9	Articles of Association on Profits, distributions and losses
	List of subsidiaries	1.1	Company Profile – Group Structure

Source of Requirement	Topic	Location	
Decree on contents of board report (Besluit inhoud bestuursverslag) Article 2:391 sub 5 DCC	Corporate governance code comply-or-explain	3.1	Dutch Corporate Governance Code, "Comply or Explain"
	Main elements of financial management & control systems in connection with the company's financial reporting	3.5.5	Financial Risks and Controls
	Functioning of the general meeting	4.4	General Meeting and Voting Rights
	Composition and functioning of the board of directors and its committees	3.2.3	Board of Directors
		3.2.4	Non-Executive Directors
Article 10 Decree Takeover Directive (Besluit artikel 10 overnamerichtlijn), Article 2:391 sub 5 DCC	Capital structure	4	General description of the Company and its Share Capital
	Principal shareholders	4.3	Share Classes and Principal Shareholders
	Particular shareholder rights and limitations thereof	4.4	General Meetings and Voting Rights
	Procedure for appointment of board members	3.2	Management Structure
	Procedure for amending the articles of association	4.6	Amendment of Articles of Association
	Authority of the board of directors to issue or acquire shares	4.2.5	Issue of Shares
		4.2.7	Acquisition of Shares in our Capital
	Material arrangements, to which the company is a party, in relation to a public offer	4.5	Anti-Takeover Provisions

RJ = Guidelines on Annual Reporting (Richtlijnen voor de Jaarverslaggeving)

9.2 Management Confirmations

With due regard to best practice principle 1.4.3 of the DCGC, we confirm that:

1. This Annual Report provides sufficient insights into any failings in the effectiveness of the internal risk management and control systems, as is further substantiated in section 2 "**Risk Factors**", and section 3.5 "**Risk Appetite & Control**";

2. The risk- and control systems described herein, particularly in paragraph 3.5.5 "**Financial Risks and Controls**" provide reasonable assurance that the financial reporting does not contain any material inaccuracies;

3. We confirm that we expect that our existing cash and cash equivalents and current financial assets will enable us to fund our operating expenses and capital expenditure requirements through at least the next twelve months. On the basis of the current state of affairs, it is justified that the financial reporting is prepared on a going concern basis; and

4. This Annual Report, particularly section 2 "**Risk Factors**" states those material risks and uncertainties that are relevant to the expectation of our continuity for the period of twelve months after the preparation of this Annual Report. The aforementioned statement does not in any way limit the relevance or applicability of the Risk Factors set out in this Annual Report to the aforementioned period of twelve months.

Signed on behalf of argenx SE

9.3 Definitions

The following explanations are intended to assist the general reader to understand certain terms used in this Annual Report. The definitions set out below apply throughout this Annual Report, unless the context requires otherwise.

Term	Definition
AbbVie	AbbVie, Inc.
AbbVie Collaboration Agreement	the collaboration agreement with AbbVie, Inc. to develop and commercialize ARGX-115 (ABBV-151) as a cancer immunotherapy against the novel target GARP
ACA	the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010
AChR	anti-acetylcholine receptor
AChR-AB+	AChR antibody positive
ADCC	antibody-dependent cell-mediated cytotoxicity
ADS	American Depositary Share
AFM	the Dutch Authority for the Financial Markets (Stichting Autoriteit Financiële Markten)
AgomAb	AgomAb Therapeutics NV
AKS	the U.S. federal Anti-Kickback Statute
ALS	amyotrophic lateral sclerosis
Amgen	Amgen, Inc.
AML	acute myeloid leukemia
AMP	average manufacturer price
AMR	antibody-mediated rejection
Annual Report	this annual report
argenx or the Company	argenx SE
Article 8 CDR	Commission Delegated Regulation (EU) 2021/2178 of 6 July 2021 supplementing Regulation (EU) 2020/852 of the European Parliament and of the Council by specifying the content and presentation of information to be disclosed by undertakings subject to Articles 19a or 29a of Directive 2013/34/EU concerning environmentally sustainable economic activities, and specifying the methodology to comply with that disclosure obligation

Term	Definition
Articles of Association	our current articles of association
Asset Development Agreement	the asset development agreement with IQVIA
ASyS	anti-synthetase syndrome
AV	anti-neutrophil cytoplasmic antibody-associated Vasculitis
B-cell	B-lymphocyte producing a specific antibody
BioWa	BioWa, Inc
BioWa Agreement	non-exclusive license agreement
BLA	biologics license application
Board By-Laws	the rules adopted by our Board of Directors that describe the procedure for holding meetings of the Board of Directors, for the decision-making by the Board of Directors and the Board of Directors' operating procedures
Board of Directors	consisting of our executive director(s) and our non-executive directors.
BLA	biologics license application
BP	bullous pemphigoid
BPCIA	the U.S. Biologics Price Competition and Innovation Act
Broteio	Broteio Pharma B.V.
Broteio Agreement	collaboration with Broteio
C2	component 2
CapEx	capital expenditure
CBA	a collective bargaining agreement
CEO	chief executive officer
CDR	complementary determining region
cGMPs	current good manufacturing practices
CHMP	Committee for Medicinal Products for Human Use
Chugai	Chugai Pharmaceutical Co., Ltd.
CIDP	chronic inflammatory demyelinating polyneuropathy
Climate Delegated Act	Commission Delegated Regulation (EU) 2021/2139 of 4 June 2021 supplementing Regulation (EU) 2020/852 of the European Parliament and of the Council by establishing the technical screening criteria for determining the conditions under which an economic activity qualifies as contributing substantially to climate change mitigation or climate change adaptation and for determining whether that economic activity causes no significant harm to any of the other environmental objectives
CMOs	contract manufacturing organizations
CMS	Centers for Medicare & Medicaid
Code of Conduct	our Code of Business Conduct and Ethics
COMP	European Medicines Authority's Committee for Orphan Medicinal Products
Concerned Member States	the competent authorities of all European Union Member States in which an application for authorization of a clinical trial has been submitted

Term	Definition
CRO	contract research organization
CTA	clinical trial application
DCC	Dutch Civil Code (Burgerlijk Wetboek)
DCGC	the Dutch Corporate Governance Code 2016, dated December 8, 2016
Deloitte	Deloitte Accountants B.V.
DFSA	Dutch Financial Supervision Act (Wet op het financieel toezicht)
DGF	delayed graft function
DHS	dehydrated hereditary stomatocytosis
DM	dermatomyositis
e-Privacy Directive	Directive 2002/58/EC of the European Parliament and of the Council of July 12, 2002
ECL	expected credit loss
EEA	European Economic Area
Elektrofi	Elektrofi, Inc.
Elektrofi Agreement	collaboration and license agreement with Elektrofi
EMA	European Medicines Authority
ENHANZE®	ENHANZE technology
ENHANZE License Agreement	in-license agreement with Halozyme, Inc.
Enterprise Chamber	the Dutch Enterprise Chamber of the Amsterdam Court of Appeal (Ondernemingskamer van het Gerechtshof te Amsterdam)
Equity Incentive Plan	the equity incentive plan as adopted by our Board of Directors on December 18, 2014, which was approved by the General Meeting on May 13, 2015, and amended by the General Meeting on April 28, 2016, and November 25, 2019, and the Board of Directors on December 18, 2019, November 5, 2020, December 15, 2021 and on February 27, 2023.
ESG	environmental, social and corporate governance
ETASU	elements to assure safe use
EU	European Union
EU-IFRS	International Financial Reporting Standards and the interpretations issued by the IASB's International Financial Reporting Interpretation Committee as adopted by the European Union
EU Taxonomy Regulation	Regulation (EU) 2020/852 of the European Parliament and of the Council of 18 June 2020 on the establishment of a framework to facilitate sustainable investment, and amending Regulation (EU) 2019/2088
Euronext Brussels	the regulated market operated by Euronext Brussels SA/NV, a regulated market within the meaning of Directive 2014/65/EU of the European Parliament and of the Council of May 15, 2014, on markets in financial instruments amending Council Directives 2004/39/EC, Directive 85/611/EEC, 93/6/EEC and Directive 2000/12/EC of the European Parliament and of the Council and repealing Council Directive 93/22/EEC (MiFID II)

Term	Definition
Exchange Act	the U.S. Securities Exchange Act of 1934, as amended
Fc	antibody region interacting with cell surface Fc receptors
FCP	Federal Ceiling Price
FcRn	neonatal Fc receptor
FDA	U.S. Food and Drug Administration
FDCA	the U.S. Federal Food, Drug, and Cosmetic Act
FDORA	Food and Drug Omnibus Reform Act
FSS	Federal Supply Schedule
Fujifilm	FUJIFILM Diosynth Biotechnologies Denmark ApS
FVTPL	fair value through profit or loss
FVTOCI	fair value through other comprehensive income
GARP	glycoprotein A repetitions predominant
GARP Agreement	a collaboration and exclusive product license agreement with UCL and its technology transfer company Sopartec
GARP License	exclusive, worldwide commercial in-license for use of certain GARP-related intellectual property rights owned by UCL and the Ludwig Institute for Cancer Research
GCC	Gulf Cooperation Council, comprising Saudi Arabia, Kuwait, the United Arab Emirates, Qatar, Bahrain and Oman
GCPs	good clinical practices
GDPR	Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data
General Meeting	any general meeting of shareholders of argenx SE (i.e., any annual general meeting and any extraordinary general meeting)
Genpharm	Genpharm Services FZ-LLC
Genpharm	partnership agreement with Genpharm Services FZ-LLC
GLPs	good laboratory practices
gMG	generalized myasthenia gravis
Greater China	Mainland China, Hong Kong, Taiwan and Macau
Group	argenx SE together with its subsidiaries
GSK	GlaxoSmithKline plc
Halozyme	Halozyme, Inc.
Hatch-Waxman Act	the U.S. Drug Price Competition and Patent Term Restoration Act of 1984
HGF	hepatocyte growth factor
HHS	U.S. Department of Health and Human Services
HIPAA	the U.S. federal Health Insurance Portability and Accountability Act of 1996
HITECH	the Health Information Technology for Economic and Clinical Health Act of 2009

Term	Definition
HRSA	Health Resources and Services Administration
I-RODS	Inflammatory Rasch-built Overall Disability Scale
IAVI	International AIDS Vaccine Initiative
IFRS	International Financial Reporting Standards, as issued by the International Accounting Standards Board, and as adopted by the European Union
IgA	Immunoglobulin A
IgD	Immunoglobulin D
IgG	Immunoglobulin G
IgM	Immunoglobulin M
IIP	Immunology innovation program
IL-22R	interleukin-22 receptor
IMM	irreversible morbidity or mortality
IMNM	immune-mediated necrotizing myopathy
INCAT	Inflammatory Neuropathy Cause and Treatment
IND	investigational new drug
IQVIA	IQVIA LTD
IRA	Inflation Reduction Act
IRB	institutional review board
ISTs	immunosuppressive therapies
ITP	immune thrombocytopenia
IV	intravenous
IVIg	intravenous IgG
IWG	International Working Group
Janssen	Janssen Pharmaceuticals, Inc.
KPI	key performance indicator
LEI	European legal entity identifier number
LEO Pharma	Pharma LEO Pharma A/S
LEO Pharma Collaboration Agreement	collaboration agreement with LEO Pharma A/S
LN	lupus nephritis
Lonza	Lonza Sales AG
LUMC	Leiden University Medical Center
Lundbeck	H Lundbeck A/S
MAA	marketing authorization application
MAD	multiple ascending dose
MAR	Regulation (EU) No 596/2014 of the European Parliament and of the Council of April 2014 on market abuse (market abuse regulation) and repealing Directive 2003/6/EC European Parliament and of the Council and Commission Directives 2003/124/EC, 2003/EC and 2004/72/EC, and the rules and regulations promulgated pursuant thereto

Term	Definition
Medison	Medison Pharma Ltd.
Medison Agreement	exclusive distribution agreement with Medison Pharma Ltd. To commercialize efgartigimod in Israel
Medison Multi-Regional Agreement	multi-regional agreement with Medison Pharma Ltd. to commercialize efgartigimod in 14 countries
MET	mesenchymal-epithelial transition factor
MG	myasthenia gravis
MHLW	Ministry of Health, Labour and Welfare
MHRA	Medicines and Healthcare products Regulatory Agency
MMN	multifocal motor neuropathy
MN	membranous nephropathy
MRC QA	Medical Regulatory and Clinical QA
MSE	minimal symptom expression
Multi-Product License	a non-exclusive multi-product in-license agreement with Lonza
MuSK	muscle-specific kinase
myositis	idiopathic inflammatory myopathies
Nasdaq	the Nasdaq Global Select Market
NDA	new drug application
NHI	National Health Insurance
NHSA	National Healthcare Security Administration
NK	natural killer
Non-FAMP	Non-Federal Average Manufacturer Price
NYU	New York University
NYU and LUMC Agreement	collaboration and exclusive license agreements with NYU Langone Health and LUMC
OCI	other comprehensive income
OIG	the Office of Inspector General
OncoVerity	OncoVerity, Inc.
OpEx	operating expenditure
PAA	pre-approval access program
PBM	pharmacy benefit managers
PC-POTS	Post-COVID-19 Postural Orthostatic Tachycardia Syndrome
PD	pharmacodynamic
PDAI	pemphigus disease area index
PDUFA	Prescription Drug User Fee Act
PF	pemphigus foliaceous
Pharmaceutical and Medical Device Act	the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals and Medical Devices
PHSA	the U.S. Public Health Service Act

Term	Definition
Pillar Two Directive	Directive (EU) 2022/2523 on ensuring a global minimum level of taxation for multinational enterprise groups and large-scale domestic groups in the Union
PIP	pediatric investigation plan
PK	pharmacokinetic
PMDA	Pharmaceuticals and Medical Devices Agency (Japan)
POTELLIGENT License Agreements	non-exclusive license agreements for POTELLIGENT CHOK1SV with BioWa and Lonza
PRC	the People's Republic of China
PREA	Pediatric Research Equity Act of 2003, as amended
PRV	Priority Review Voucher
PV	pemphigus vulgaris
PVAS	pemphigus vulgaris activity score
QA	quality assurance
QMG	quantitative myasthenia gravis
Relevant Regulatory Authorities	the MHRA, EMA, FDA, MHLW
RDL	Reimbursable Drug List
REMS	risk evaluation and mitigation strategy
Roche	F. Hoffman-La Roche AG
RSUs	restricted stock units
SC	subcutaneous
SEC	the U.S. Securities and Exchange Commission
Securities Act	the U.S. Securities Act of 1933, as amended
Shire	Shire AG, now known as Shire International GmbH
Shire Agreement	collaboration agreement with Shire AG, now known as Shire International GmbH
Primary SjS	Sjögren's syndrome
SLE	systemic lupus erythematosus
Sopartec	Sopartec S.A.
System	Lonza Sales AG's proprietary glutamine synthetase gene expression system known as GS Xceed™
TCA	trade and cooperation agreement between the European Union and the United Kingdom formally applicable since May 1, 2021
TEAE	treatment emergent adverse events
TED	Thyroid eye disease
TGF-β	transforming growth factor beta
TIS	total improvement score

Term	Definition
Transparency Directive	Directive 2004/109/EC of the European Parliament and of the Council of December 15, 2004, on the harmonization of transparency requirements in relation to information about issuers whose securities are admitted to trading on a regulated market and amending Directive 2001/34/EC and the rules and regulations promulgated pursuant thereto, as amended by various directives including 2013/50/EU
UCHealth	University of Colorado Health
U.S.	the United States of America
USPTO	the United States Patent and Trademark Office
UCL	Université Catholique de Louvain
UK	the United Kingdom
UK GDPR	Legal framework adopted by the United Kingdom substantially equivalent to the Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data
UT Agreement	an exclusive in-license with the Board of Regents of the University of Texas System
UT BoR	The Board of Regents of the University of Texas System
UT Southwestern	University of Texas Southwestern Medical Center
VIB	VIB vzw
VIB Agreement	collaboration agreement concluded with VIB
V-regions	antibody variable regions
VYVGART	VYVGART®
VYVGART Approved Countries	U.S., Japan, all 27 EU Member States plus Iceland, Norway and Liechtenstein
we, us or our	argenx SE together with its wholly owned subsidiaries and, as applicable, its former wholly owned subsidiaries
Zai Lab	Zai Lab Ltd
Zai Lab Agreement	collaboration agreement with Zai Lab Ltd, relating to an exclusive out-license for the development and commercialization of efgartigimod in Greater China
Zai Lab Payments	$75.0 million upfront payment under the collaboration with Zai Lab Ltd in the form of 568,182 newly issued Zai Lab shares calculated at a price of $132.0 per share, a $75.0 million guaranteed non-creditable, non-refundable development cost-sharing payment and a $25.0 million milestone payment in connection with FDA approval of VYVGART
2021 General Meeting	annual general meeting of shareholders held in 2021